

UNITED STATES OF AMERICA

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DEPARTMENT OF DEFENSE

ARMED FORCES EPIDEMIOLOGICAL BOARD

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1999 MEETING

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TUESDAY,

APRIL 13, 1999

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The Board at the North Island Naval Air Station,
Island Club, Trident Room, San Diego, California, at
7:44 a.m., Dr. Dennis M. Perrotta, presiding.

PRESENT:

DR. DENNIS M. PERROTTA,	President
COL. BENEDICT M. DINIEGA,	Executive Secretary
DR. JAMES R. ALLEN,	
DR. HENRY A. ANDERSON,	
DR. MIKE ASCHER,	
DR. DAVID ATKINS,	
PROFESSOR SUSAN P. BAKER,	
DR. E. BARRETT-CONNOR,	
COL. DANA BRADSHAW,	
DR. JAMES CHIN,	
L.CDR. ANN FALLON,	
MAJ. CAROL A. FISHER	
DR. GERALD F. FLETCHER,	
DR. L. JULIAN HAYWOOD,	
DR. RICHARD J. JACKSON,	
COL. JEROME J. KARWACKI,	
MS. SHELLIE ANN KOLAVIC	
MR. TERRENCE LEE	
DR. F. MARC LA FORCE,	
DR. JUDITH H. LAROSA,	
CDR. MCBRIDE	
DR. STANLEY I. MUSIC,	
LCOL. ROBERTO NANG	

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ALSO PRESENT:

DR. D. STEPHEN NICE,
DR. GREGORY A. POLAND,
DR. ARTHUR L. REINGOLD,
LCOL. JAMES R. RIDDLE,
DR. CAROL W. RUNYAN,
DR. MARGARET A.K. RYAN.
DR. JANE F. SEWARD,
DR. ROSEMARY K. SOKAS,
L.COL. FRANK SOUTER,
DR. CLADDE E. STEVENS,
CDR. MARK TEDESCO
CAPT. DAVID TRUMP,
DR. THEODORE F. TSAI,
DR. RONALD J. WALDMAN,
COL. ANDREW S. WARDE,
DR. NEIL D. WEINSTEIN,

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P-R-O-C-E-E-D-I-N-G-S

(7:44 A.M.)

DR. PERROTTA: Good morning. And with that I'd like to open up the spring, 1999 meeting of the Armed Forces Epidemiological Board.

Welcome, and thank everybody for making the trip, long or short, to this meeting.

The home welcome will be given by Captain Beddard, who is the Officer in Charge of the Environmental Preventive Medicine Unit Number 5 here in San Diego. Captain.

CAPTAIN BEDDARD: Doctor Perrotta, Colonel Diniega, members of the AFEB, welcome to San Diego. We're so glad you can be here. And on behalf of COMNAVBASE, Admiral Froman and Admiral Diaz, the Commander of the Navy Medical Center here in San Diego, welcome.

We call this America's finest city. I thought that was a little pretentious when I first came out here, but I see it's really true. I've been out here three years from Washington, D.C., and hopefully the weather's going to cooperate, and you can take advantage of all the things that we have here.

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This is the 50th anniversary of EPMUs. So it's really a pleasure to have you here to kind of help us celebrate our contributions in preventive medicine. We've been involved in various reviews, outbreak investigations with our friends at NHRC, and many of those things have been presented to this board, things like streptococcal disease and pneumonia outbreaks.

So the work of this board is so important.

We are so pleased that you're going to be here and can help us with some of the questions that are pertinent with force health protection in DoD.

I want to make sure that you take an opportunity to visit the Gaslamp, Coronado here, wonderful, and all the things that San Diego has to offer. It's really a wonderful city, and if we could open up these curtains today if the discussion period allows, you'll get a nice view of the Pacific Ocean.

So, again, welcome to San Diego, and if my staff -- and I want to thank publicly Captain Olson and Lieutenant Commander Thornton of EPMU-5 who have done all the logistics to put this meeting together. Ask any of my staff that you see here or me, and we'll help you in any way that you can. Thank you.

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Welcome.

DR. PERROTTA: Colonel Diniega for announcements and housekeeping.

COLONEL DINIEGA: Good morning, and welcome to San Diego. It was raining Sunday, so the weather has cooperated.

First of all, I'd like to welcome some guests from some major DoD representation organizations. Captain Beddard, of course, and the members of EPMU-5, not only welcome to them, but thank you for all the support, especially Captain Olson and Commander Thornton and also the other members who are providing support for the meeting today and tomorrow.

Commander Hansen, who's here representing Admiral Zimble from the Uniformed Services University, and we welcome you here. We invited as a guest for our meeting Doctor Ascher, who's a previous member of the board, and he will be involved with a discussion on NBC weapons of mass destruction later on.

Ms. Ward could not make it because of medical problems, but she was instrumental in getting all the arrangements made and liaison, doing the liaison work between San Diego and Washington, D.C. Hopefully she'll be able to make it to future

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meetings.

Major Fisher, our thanks ahead of time. She volunteered to provide admin support on site besides being a speaker, and I'm sure she's going to be helping with future meetings too.

A few reminders. Be sure to sign in on the attendance sheets out at the registration table. Lunch is not provided on site here. It is a 10-minute walk to the golf course, the closest eating facility.

We have vehicles. The active duty personnel have vehicles, and some members of the boards have vehicles. We can car pool and take people over to the golf course to eat or the other choice is to go up near the main gate, and they have several eateries there. So if you want to have lunch and want to go to the golf course or some place else, please get in touch with myself or some of the other uniform preventive medicine officers.

Rest rooms out the door, women's on the right, men's around the corner. There's supposed to be a phone that is placed here just outside the door.

We'll get the number later on and announce it. Faxes is 619-545-9015, and that's the front office of this building. You can let me know or Major Fisher know.

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The reminder to the board members, your travel settlements need to be done when you get back to -- when you get home, and be sure to send it in. And also when you do get your payment vouchers, you need to send it in, and we'll remind you again tomorrow, and we'll get in touch with you over E-mail.

If you looked at the agenda, it's like the last meeting. It's rather full. We have a leftover question on chlamydia screening to work on. We also have three new questions, one on the use of lyme disease vaccine in the military, another on the need or -- the need for varicella screening and immunization at the recruit level, and the third one is on the use of IPV at the recruit level.

Tomorrow, although it says subcommittees, the President and I discussed this, along with Doctor Poland, only one subcommittee will meet. You'll all participate, and that will be Disease Control Subcommittee because the nature of the questions are such that the recommendations all have to be done tomorrow.

We have two tours scheduled. We'll get more information later as they gel up a little more. I think we'll be sending out a sign-up sheet for the

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tours, and lunch may be available on the ship, and they're still checking on that and trying to confirm.

There's a large Navy exercise, Navy-Marine exercise going on. That's why a lot of the ships and personnel are out at sea.

Remind the speakers to stay within the allotted time, including myself. Doctor Perrotta can do whatever he wants to do. But we have the room for nine hours, and hopefully we'll be done by 4:30 p.m. The meeting is being recorded and will be fully transcribed. The transcriptionist has put out the mikes. Please state your name when you ask questions -- and for the audience we have some mikes up here that you can speak into so we can record you -- your name and your organization, and then go ahead and ask your question or make your comment.

Also, members of the press are -- this is an open meeting, and members of the press may be in the audience. We also have several drug company representatives here attending the meeting.

For the members of the board, if there is a conflict of interest, I do have disqualification statements that need to be signed, and you need to remove yourself from a voting participation.

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Any questions? We'll have an executive session tomorrow just before noon, and we'll be able to discuss the future meetings and nominations to the board and nominations for President, et cetera. Doctor Perrotta.

DR. PERROTTA: Thank you, Colonel. Any questions from board members about the housekeeping? Again, thanks to our local host for having us in such a lovely place, and having airplanes take off right outside is an awful lot of fun for us anyway.

COLONEL DINIEGA: I do have one more comment. On the handouts for the speakers, if you can make sure that the board members get the handout first before you put it on the handout table down in the corner, and Major Fisher needs a copy also so we can include it with the transcribed minutes, and copying services are -- immediate copying services need to be paid for, and they'll do it here. Otherwise, EPMU-5 has volunteered to do copying, but they'd have to go back to their home base across the bay.

DR. PERROTTA: Okay. Well, looking at the agenda, you'll notice that this is -- one way of looking at this is a very large disease control subcommittee meeting, but each one of these items is

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extraordinarily important, part of the continuing work that's being done by the committee and by the board, and it just seemed to make an awful lot of sense to try to take care of as many of these as possible during this meeting, but to send off the committee to do their work and then come back would probably take too much time. So we are all generalists, epidemiologists, medical scientists, so I'd like for all of us to sort of open up and be willing to work on areas even if they're not of your major interest.

That does not mean that we can't have the informal meetings and arrangements for either subcommittees or people in subcommittees to be working on things, and I've even talked to Professor Baker about maybe we need to sit down and do a little work maybe at lunchtime or something about injuries and some of the other areas perhaps if we want to do that.

So a little unusual agenda setup, but exciting I think, and I appreciate Ben and Greg Poland. Fortunately they didn't put the two of us together, so this should be a pretty productive meeting. And let's go ahead and move on with the Preventive Medicine Officers' Reports, and we'd like

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to go with the order that we have down here. Captain.

CAPTAIN TRUMP: Good morning. I'm Dave Trump. I'm the Preventive Medicine Officer assigned to the Office of the Assistant Secretary of Defense for Health Affairs. Major General Claypool, my boss, sends his greetings this morning.

I'm going to try to keep my update short because there interesting things is those that my colleagues with the services are involved with.

One thing I would like to touch on is the Anthrax Vaccine Program, which does continue. As of 30 March, over 245,000 military members have received at least one dose of the vaccine. Over 187,000 have completed three doses, and actually 200 have completed the six-dose series of the vaccine.

This program is organized or coordinated by an Anthrax Vaccine Immunization Program Office within the Office of the Surgeon General of the Army, and they are continuing to update some of the communication and help briefing materials regarding the Anthrax Vaccine Program which is going to continue and eventually achieve total immunization for the Force.

They are also sponsoring a clinical

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conference in late May of this year. It really has a goal of trying to get physicians and other providers across DoD -- now, we're a big organization as you know -- as well informed as possible about Anthrax, Anthrax Vaccine, the expected side effects, and also get out some information as far as some guidelines, clinical practice guidelines, if you want to call them that, for dealing with the side effects or adverse effects of Anthrax Vaccine that are expected.

On other vaccine issues, we at Health Affairs have asked the services to provide us with an update as far as their progress in meeting a goal of having 100 percent of the Force immunized with Hepatitis A vaccine by this past December. We'll have that report from the services here at the end of April. The initial information is actually pretty encouraging from the services when it comes to the operational forces, but it's, again, one of those infectious disease issues that we want to continue to look at.

And the last thing I'd like to cover is just looking at the health of those who are deployed and deploying. We've heard in the past from Lieutenant Colonel Rubertone from the Center for

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Health Promotion and Preventive Medicine about their look at the preventive medicine experience, the post-deployment health experience of those who deployed to Bosnia.

The services are beginning a similar effort facilitated by Health Affairs, and particularly by Lieutenant Colonel Riddle from the staff who's also here today, to assess the health experience of the forces who were more recently deployed to Southwest Asia. This obviously has some tie-ins to, you know, Gulf War illnesses concerns of the past. Ever since the Gulf War there've been a relatively large number of personnel continually rotating through that area.

We're going to look at the preventive medicine activities in theater as far as how they've been able to achieve some of the goals that have been put out by DoD directive and instruction since the Gulf War, some of the disease, non-battle injury experience in theater, and also look at the health of those who deployed and in the time since they've returned, using in addition to what Doctor Rubertone was able to do with hospitalization experience, we're now getting a little broader coverage with the ambulatory datas to look at that information in

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addition.

And unless there are particular questions, I have nothing else this morning.

DR. PERROTTA: Any questions for Captain Trump? Thank you, Dave. Colonel Bradshaw, Preventive Medicine Officer at the Medical Operations Agency.

(Pause.)

COLONEL KARWACKI: Do you want me to leap ahead here, because I'm not going to show any slides? I can just do mine in two minutes here.

COLONEL BRADSHAW: Go ahead.

DR. PERROTTA: Okay.

COLONEL KARWACKI: Colonel Karwacki from the Medical Command, Army Preventive Medicine. I just have two things. This could very well be my last meeting as the Army representative depending on the timing of the next meeting in September I believe. I will be PCS'ing to Bangkok to the research lab there in the fall to take over the Global Emerging Infectious Disease Coordinating position there. So we need to find ourselves a new Army representative, and we'll be searching high and low for that.

One of the other hats that I wear is the token epidemiologist on the Health Affairs CHCS-2, the

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Composite Health Care System, which is the DoD hospital computerized medical record. We have version one up and running in hospitals now. We're working on version two.

One of my objectives in version two is to try to input more epidemiologic information. I would simply put out a call to anyone and everyone at the table and in the audience today, if you have any thoughts on or knowledge of systems that collect epidemiologic information in the process of medical records, I'd appreciate knowing that, and perhaps we might be able to use that to interject into the system.

Obviously one of the problems we have is knowing how things occurred, particularly, Professor Baker, injuries. I won't go into a long dissertation, but it's certainly difficult to know how to prevent something when you don't know where it came from. Trying to collect that information is part of the clinician's record.

Unfortunately, the CHCS-2 remains a provider-centric record. Everything goes in via the provider, not via the patient necessarily. So we need to try to work around and through that, but I would

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appreciate anyone -- any contributions. My E-mail is on the list here I believe, and if not, we can make sure that's available. You can send it through Ben since most of you have that E-mail. I'll be happy to take that to the committee and try to work more epidemiologic information.

The other thing that they're doing is providing the providers with templates such that when they pick a particular symptom or symptom complex, they will go through a template of yes/no questions, fill-in-the-blanks as to what information is necessary for that. If we can interject epidemiologic information into that as well, there should be some ways to build those templates to do that, although that's probably a bit of a difficult situation for most clinicians, but we can probably do it for some things like ARDs in particular. So I would appreciate anyone's input if you have a contribution with that. And I'll turn it back over then to Colonel Bradshaw if we can get him up and running at this point.

DR. PERROTTA: Any questions for Colonel Karwacki? Congratulations on your new assignment. It's unfortunate that I'm going to rotate off here pretty soon because I'd have lobbied for our next

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meeting to be in Bangkok. Every time I say that, Ben's blood pressure goes up a whole bunch, and the travel dollars for the agency may not be able to cover that, but --

COLONEL KARWACKI: We'll see what we can do in the next coming years. I should be there three to five years. So we'll see what happens.

DR. PERROTTA: Congratulations, and we appreciate all the work. Every -- almost every meeting that I've been to we've talked about the quality of the information that is being collected and ways to improve it, and your computerized medical record system is one of the steps that we've seen happen over the years that we really appreciate. If anybody can support that with new and interesting ideas, please do contact Jerry. Thank you.

COLONEL BRADSHAW: I'm Dana Bradshaw from the Air Force Medical Operations Agency. I think we're going to go without the slides here. If we have an opportunity and you're interested, we can look at them maybe later. I think we've got some technical difficulties adjusting the resolution of the projector to the screen -- to the computer.

Briefly, since we don't have a lot of

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time, I was just going to talk about a few things and had a little bit of detail about one particular thing that Lieutenant Colonel Thompson from the Force Health Protection and Surveillance Branch had put together on the Air Force morbidity and mortality survey.

But basically the things I wanted to just bring you up to date on and do a quick overview on related to the Population Health Plan, an initiative that the Air Force Medical Services is actively engaged on right now. This runs in parallel with the Military Health System Optimization Initiative, what we call the PDM-4 initiative, and we had begun this early in August actually of 1998 and have been working on it for some time now. And we're going to kind of be kicking that off in a sense in the Air Force Prevention '99 Conference in May which will be in San Antonio.

Basically the Population Health Plan has five critical success factors that we've identified. The first of those is being able to identify and characterize the health status of our population, our enrolled population in particular, and that involves a lot of the things that you've seen presented at various and sundry times here before in terms of

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hospitalization data, outpatient data, reportable events, mortality data, and just really looking at what the disease burden is in our population.

The second critical success factor is delivering clinical preventive services in a proactive manner. That's something that involves a paradigm shift away from how we've done business in the past in medicine, which has predominantly been a focus on disease management type things. And we're going to try and move the emphasis much more. We've already done that in a sense in the DoD with the Put Prevention into Practice Program, and we're going to try and reemphasize that even more.

The third critical success factor that we have is in disease and condition management. So that will be focusing more on tertiary type prevention aspects, but that's a very important thing for us to do in terms of improving the health of our population and also doing a lot of cost efficiencies actually in how we do things.

The fourth factor is evaluating all that through metrics, appropriate metrics, looking at how much improvement we've had or lack thereof, looking at best practices and how do we get those best practices

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out to the rest of our military health system.

The last factor is being able to take our prevention programs and our disease management, condition management programs and get them out into a community-based approach to try and develop community resiliency, and this goes very well with the Force Health Protection Mandate that the DoD has. And that's the last factor that we've done, and in a sense we've already done that to a degree with the DoD Prevention Plan which focuses on three of the biggest problems that we have in the military health system and the military in general, which is alcohol problems, tobacco-related illnesses, and injuries, particularly accidental and unintentional injuries.

So that's sort of the brief of what we're doing in terms of the Population Health Plan. The other thing you should be aware of is that the DoD in particular is getting out the Preventive Health Care Application, which is an application that's specifically designed to help improve the delivery of clinical preventive services. It has three modules, one which is basically a reminder system that covers the screening, counseling, and immunization and prophylaxis, tenets of the U.S. Preventive Services

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Task Force Guidelines, and that reminder system can help remind providers and clinic personnel of when individuals need certain preventive screening type activities.

The second module is one on immunizations.

It's being developed currently. It will replace the current legacy systems of the various services but integrate it with the other clinical preventive services package.

And the last one is a computer-based version of the Health and Evaluation Assessment Review, which is a kind of health-risk appraisal and utilization management tool that we're using in the military.

The last information that I had in addition to that is what Colonel Trump already mentioned, which is that we're going to be doing a comprehensive report on Southwest Asia surveillance activities, and that will cover not only DMBI but the pre and post assessment tools, the hospitalization and injury data, outpatient visits, and so on, and it's going to be a tri-service activity and a very detailed report that will help us kind of learn where we are, how well we're doing, and where we're going to go with

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that, and that's hopefully something that we can present maybe later to the AFEB when we get the report together for Health Affairs.

The last thing was the Air Force Morbidity and Mortality Report. I had detail in that on the slides, but what I'd like to say is that in 1996, our Force Health Protection and Surveillance Branch, formerly Epreach (phonetic) Services, had put together a report which according to Colonel Thompson -- and he can tell me a little bit more about this -- but it took the equivalent of three people about nine months to put together that report.

Now that we've automated the systems, integrated many databases, we've also developed an Air Force mortality registry, that's taken about what, two people about two weeks to put together.

So that helps give you just kind of a bellwether of where we've gone and where we are now in being able to assimilate some of the data that we need to assess our population. Thank you.

Any questions?

DR. FLETCHER: Just one comment. Since I've been on the board -- '93, Dennis, I guess we've been on the board since '93 -- I've been very

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impressed with the Air Force's thoughts and processing in prevention. I think this is very important to what we do on the board. We do a lot of disease control, but I really believe that what we are doing and a lot of your activities have been in prevention and health maintenance, and I applaud you on this. Hopefully we can continue this and maybe hear more about it later in this meeting.

COLONEL BRADSHAW: Fortunately, I think we're all heading in the right direction I believe on that. Anything else?

DR. PERROTTA: Thank you, Colonel Bradshaw. Commander McBride, Preventive Medicine Officer at the Navy Bureau of Medicine.

COMMANDER MCBRIDE: Thank you. I appreciate the opportunity to speak just for a few moments about preventive medicine in the Navy and the Marine Corps. As the third speaker here -- or actually fourth, so far much of what I was going to say has already been dealt with, so perhaps my remarks will be even shorter, and you'll benefit from the fact that I don't have any notes. I was going to speak off of my slides. So perhaps this will even be shorter indeed.

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But I did want to make a comment about some of the things that we've been doing in the Navy and the Marine Corps with regard to preventive medicine, and if you'll indulge me for a moment, I wanted to further acknowledge, as Captain Beddard indicated this morning, that we in the Navy are celebrating the 50th anniversary of the Navy Environmental Preventive Medicine Unit, of which we have four. I had a slide that was in my presentation that shows where these were, and I think many of you know this, but I thought that since we're here being hosted by one of the EPMUs, we would just acknowledge that and indicate that we have one as you may know in Sicily, one in Norfolk, Virginia, one here in San Diego, and another one in Pearl Harbor in Hawaii, and they do wonderful work for the Navy and particularly for the Fleet Marine Force.

The other point I wanted to share with you is concerning our efforts with the varicella vaccine.

Though we'll hear quite a bit about it later today, a couple of years ago we went out in a significant way with varicella, and as we'll hear from Commander Ryan later, we've had a very positive experience with varicella vaccine at the Recruit Training Center at

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Great Lakes, and we've been a little less than vigorous with this with the Marine Corps Recruit Depots in Parris Island and in San Diego, but the one in San Diego has recently started this, and we're hoping as Parris Island starts very soon that we'll have a positive experience with that.

We're anxious to hear what the Army experiences, and so this is an issue that's in some flux, but we feel fairly confident that we'll have a good experience with the use of the varicella vaccine with the Marine Corps Recruit Depots as we've had with RTC Great Lakes.

I wanted to just make a comment or two about the Navy Disease Reporting System. I don't believe we've shared this with you, but over the past year or so, we have fielded an automated reporting system that has taken the place of kind of a hard-copy reporting system that has gone from the Navy units to the central Navy Environmental Health Center reporting reportable medical events and diseases, and we have obtained this from the Air Force, so it has many of the features of the program that the Air Force uses, and we're very pleased with this. It's not been out all that long, and we're still learning from it and

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getting it out, but we feel this will be a very helpful tool in allowing trends and analysis both at the local level or at the EPMU level, as well as pushing this data to NEHC, the Navy Environmental Health Center, for further analysis and reporting. NEHC generates a monthly publication that's entitled the -- that we call NMSR, the NMSR, the Navy Medical Surveillance Report, which shows a lot of this information and many people are finding to be a very helpful resource. And of course much of this data is further pushed forward to the Defense Medical Surveillance System for further analysis and reporting.

Just a word about Atsugi. Some of you know of the concerns that have occurred there. We have a naval air facility in Japan that's adjacent to an incinerator which operates almost continuously, and there's a real concern about air quality and a number of ill health effects, and they're in the throes of a comprehensive health and environmental assessment that should be finished probably the first part of 2000 with a comprehensive report, peer review report to be released later.

The Bureau of Medicine, in conjunction

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with the NEHC had proposed at the request of the Chief of Naval Operations a number of things to do about this, and among them were limitations to the terms that people would stay there for the duration of their duty, but these were not accepted, and they wanted to wait until this comprehensive evaluation comes forward.

So this is a continuing issue, a real concern for a lot of the folks that go to Atsugi. There is a vigorous effort to screen people before they take assignment there, and their family members, to determine if they have any acute respiratory disease or chronic illnesses that need to be acknowledged before they go there, and occasionally people are turned away because they don't pass the criteria to be assigned there. But we're anxious to see what that will go, and that might be something that will have real impact on other areas because, as you may know, a number of our other bases and activities, not only in the Navy and the Marine Corps, but the other services that are overseas where some of the air quality standards are not as high as they are in our country, that could be an issue.

Colonel Bradshaw mentioned the

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Preventative Health Care Application. The Navy, as will the other services, we're going out to deploy this to a lot of our hospitals, and we're looking forward to that because this will provide a unified system within all of the DoD to track many of the clinical preventive services as well as immunizations, and we're looking forward to that.

I just wanted to take a moment about two other things. Colonel Bradshaw also commented on the DoD Prevention Plan. I think it's of interest to the board because this started last year as a comprehensive effort from a very high level from DoD.

This is chaired by General Roadman, the Air Force Surgeon General. I believe it's actually called the Prevention, Safety, and Health Promotion Committee where they have representations from each of the services, and the three-pronged effort is the reduction of alcohol consumption, tobacco cessation, and injury prevention. And each service has taken one of those three arms of the effort for action, and this is an effort that we're very involved in, and we're hoping for some very good things to follow.

The last thing I want to comment on is concerning an issue that developed last week. Many of

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us watched in the news with the unfortunate situation in Kosovo and the Balkans there, there were many of the refugees who were targeted to be taken to Guantanamo Bay to be housed there temporarily, and so the Navy was preparing that area there to receive these refugees, and we were asked at the Bureau of Medicine to provide some recommendations on -- with regards to certain immunizations or countermeasures to apply to these populations as they were being prepared to be transported to GTMO, and as we spoke with my colleagues among the preventive medicine officers in the other services, we recognized that it didn't appear to be a standard uniformed template or listing of screening measures and countermeasure recommendations that could be utilized when we screened people for humanitarian movements or refugee situations, and it appeared to be a little of a lack of coordination among some of the commands and what we call combatant commands, the SouthCom, the EuCom, in organizing this, and then as you can appreciate, the UN Commission, High Commission on Refugees and the State Department and a lot of other players were involved, but it appeared to us that perhaps one thing that we could do from the preventive medicine

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community is to provide a kind of a template of screening recommendations and countermeasure recommendations that would be of value to give to these folks as they are faced with these kinds of situations to provide some -- that's consistent and meaningful and they can use.

And so this is what we're going to be trying to do in the near future, and it may be something that we'll want to present to the AFEB for your evaluation and comment at a subsequent meeting. And so hopefully we can do that, and that will be meaningful.

One more thing if I may just -- if you'll permit me, about Anthrax. I just wanted to comment that on the Anthrax vaccination implementation or immunization program, adverse events are tracked very cautiously, very -- as closely as we can. There's a lot of public interest, public scrutiny over these things, and there are voices in the public that feel that the DoD has not been reporting the adverse events as appropriately as we can or perhaps not allowing vaccine recipients to submit adverse reaction reports through the Vaccine Adverse Event Reporting System.

But we have tried everything we can to

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lower the bar, to allow people to make reports. We want to find out what the concerns are. And thankfully, there have been very few serious systemic reactions, and the vast majority of them are the expected ones that we see with local-site reactions and ones associated with that.

There have been -- and this is as of several days ago -- 49 adverse reactions reported to the DMSS that reflect adverse events associated with Anthrax that have been received by VAERS reports from the DoD. And there's 24 additional ones that they have gotten. Some of these come from the FDA that providers and patients submit to the FDA instead of to the service channels, and the FDA -- and we have to get them to change this -- they have been redacting these so comprehensively. They stroke out the name and the social, and we can't really tell what service these people are from. And so it's hard to find out -- to verify these and to analyze these, but the DMSS -- the FDA has been very good about sending them these VAERS, these photocopies of VAERS, but, bless their hearts, they cross out the name and the provider, and I think they're very concerned about Privacy Act issues and whatnot, but they were working

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on doing that because we feel it's important to identify these and that we can validate them and report them, but there's about 24 of those. If you total this up, it's less than 80, but we know that there's probably more adverse reactions, but thankfully, it's unlikely that there's any serious ones, but that's just an issue I share with you.

Are there any questions that I can entertain about preventive medicine in the Navy or the Marine Corps or anything I've shared with you?

DR. PERROTTA: Professor Baker.

PROFESSOR BAKER: Commander, you mentioned that each of the three services sort of with the DoD Prevention Plan has adopted one of the three major focuses of interest. Which service and which problem?

COMMANDER MCBRIDE: Dana, if I get this wrong, help me, but the Navy has taken on the alcohol control. The Air Force has taken on the tobacco cessation, and the Army has taken on the injury prevention effort.

COLONEL BRADSHAW: All three are involved in all three areas. It's very much a cross-service issues. Just the lead for them is the different services.

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DR. PERROTTA: The question is a good one because, in hearing that story, clearly I wanted to remind you and any of the other PMOs or any other of the Armed Forces staff that you have not only -- you have a body of people who are interested and experts you can use on this board, and one of the examples was going to be, gee, we have a few recognized experts on injury, and it would be very nice that you access those people as you do the work rather than waiting until a report's being printed up and then you get a blessing, because I think that would really be helpful.

The Atsugi, if I pronounce it correctly, reminded me that we have environmental health specialists here as well. Doctor Anderson from Wisconsin is well recognized in environmental medicine and environmental public health. So I recommend that as you do your work that you utilize board members directly, not just at the quarterly or the three meetings that we have here, as much as you feel that you can possibly do.

COMMANDER MCBRIDE: I appreciate that comment. If I could say further, I kind of anticipated that, and I was considering this

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discussion. I remember that last year there was quite a bit of effort with one of the subcommittees on alcohol control, and there were some very profound recommendations that came through.

To be honest, I don't know if these have been fully embraced or acknowledged from the effort that I believe the Air Force has kind of been responsible for, but that's something that we've been remiss if we haven't actually acknowledged those and looked at those to see if those can be incorporated into this effort, and subsequent things we do need to recognize the expertise of the board.

There was another question?

DR. REINGOLD: Just in terms of follow-up of that, I would also point out that one board member who's not here today, Ronny Waldman, is actually quite one of the world's leading experts in the area of refugees and the needs of refugees. So in terms of the issues you put forward about potentially drawing up guidelines with templates or things for dealing with these sorts of situations, Doctor Waldman would certainly be an invaluable resource.

COMMANDER MCBRIDE: Thank you very much. That's very good to know.

DR. LA FORCE: Yes, I would also add that those templates have been --

DR. PERROTTA: State your name.

DR. LA FORCE: I'm sorry. Marc La Force.

Those templates have been developed, and just like Art pointed out, Ronny participated in a WHO UNICEF High Commission panel to actually develop the screening of refugee population and what you need to pay attention to first, second, third, fourth.

COMMANDER MCBRIDE: Yes. I can appreciate that, and our intent was not to reinvent the wheel but to identify where these are out there and then bring them into our effort and kind of color them for our purposes for the DoD because there are unique requirements that we have to fulfill and that things -- we may need to tailor those to meet our needs, but this just came to mind last week with the business with the Kosovars and how we came so close to having to receive them at GTMO, and as you know, that's been turned off, but I thought I'd just share that with you.

DR. PERROTTA: Doctor Haywood.

DR. HAYWOOD: On the Anthrax reactions, could you tell us roughly how many -- what's the

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numerical basis for those numbers?

COMMANDER MCBRIDE: Yes, I can. I had a slide for this. Let me share it with you here from the podium. Within the Army, there are 14 adverse reactions that were received from VAERS that were characterized as mild or moderate local reactions and five from the Air Force. There were none from the Navy so far. The Navy's had two severe local reactions. The Army's had four severe local reactions, and the Air Force has had one severe local reaction.

The systemic reactions, which typically are not limited to the local site of vaccine administration, it may be associated with a generalized rash or perhaps even we've had some reports of people fainting or having some lightheadedness or maybe even a low-grade fever.

The Army's had nine systemic reactions, Navy three, and the Air Force 10. The Marine Corps -- you may appreciate this -- their numbers have been very few. The Marine Corps has had one adverse event reported through VAERS that I have record of here.

The most profound reaction that we've seen that I'm aware of was in an individual that after the

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receipt of the second or third vaccine dose experienced a Guillain Barre syndrome and was rather profoundly effected for several days and required medical evacuation from the Persian Gulf area, was taken here to San Diego and was cared for for a period of time and thankfully has done very well. Over a period of time he was on restricted duty but has completely recovered and is back on his ship and is doing well, but it's not -- he won't receive any further Anthrax vaccinations.

DR. HAYWOOD: And this is from a total of approximately how many total?

COMMANDER MCBRIDE: Seven hundred and sixteen thousand doses.

DR. HAYWOOD: Pardon?

COMMANDER MCBRIDE: Seven hundred and sixteen thousand doses as of 30 March. Reports work out -- VAERS reports per doze it was .007 percent.

DR. PERROTTA: Okay. Thank you Commander. Mike.

DR. ASCHER: Mike Ascher. Do you have any numbers of the incipient epidemic of personnel actions for refusal getting a lot of press out here, how many people have refused and are in personnel action for

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this issue?

COLONEL KARWACKI: It's relatively low if you consider it. Dozens at most.

DR. PERROTTA: Commander Tedesco is a medical officer at the Coast Guard.

COMMANDER TEDESCO: Good morning. I'm Mark Tedesco. We'll have the low technology slides that I brought along as a backup.

DR. PERROTTA: The one that works.

COMMANDER TEDESCO: Unless the bulb blows out, which has happened also.

I'm from the Coast Guard. Rear Admiral Johnson, the Director of Health and Safety for the Coast Guard does sends her regards and greetings. Some of you may recall when I briefed you at the last meeting I introduced Sharon Ludwig. She was an Army medical or preventive medicine officer, left the Army last June and came aboard the Coast Guard in December and had been in the Coast Guard for three days at the last meeting.

I can't say that the doubling of our medical work force from one to two has had a remarkable synergistic effect. Some things have moved from the preconception stage to the fetal and even

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infancy stage. I do want to thank her for assistance in making these slides also. Whenever we get a chance, we'll go to the next slide.

I'll just go -- we can go to the third slide, but I'll talk to you today about four different topics, Anthrax program, ARD surveillance, varicella outbreak that we had just about a year ago and the gastroenteritis outbreak that we had about a month ago.

We are nowhere up into the hundreds of thousands of doses in the Coast Guard. Right now with just folks that are deploying -- we only vaccinate those who are deploying with naval task forces, and we're coming up on our second deployment in the near future with about 300 folks getting the vaccine. That prompted our first refusal about a week ago, and the question marks means that I don't know the status of that now, but he enjoyed about six to eight hours of counseling and education from various personnel aboard the ship but is still refusing, and this kind of highlighted very well what we have been hearing.

There's a vast amount of very good disinformation or misinformation out there where a lot of the information out there is true, and then there's

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kernels of incorrect facts or misleading facts that are leading some of these young, impressionable sailors and soldiers I think astray, and we were fortunate enough to be part of the work group recently that met to go over the education and communications plan, trying to update that and counter some of this misinformation that's out there. Next slide please.

We attempted to get an ARD surveillance up and running the past couple of months at Cape May, which is our big basic training center, similar but much smaller than the Great Lakes Naval Training Center, interacting with both GEIS in the Air Force, Project Gargle (phonetic).

What we wanted to do was start with five to 10 specimens a month, realizing that as this got up and running, we would have to develop an MOU with the Air Force. We anticipated starting this in March, but that five-month window where Sharon Ludwig was out of the Army and not yet in the Coast Guard, she was able to avoid her influenza vaccine, and the day she was to travel to Cape May to implement this plan, she came down with a very bad case of influenza. So she has said she will be getting the vaccine from this point forward. So sometime in the next several weeks we

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anticipate getting her back up there and getting this program under way. Next slide please.

DR. PERROTTA: Hands-on preventive medicine.

COMMANDER TEDESCO: Exactly. We thought probably it also wouldn't be good for her to go up there and become the index case amongst a bunch of recruits.

We had a varicella outbreak last June that the CDC went up and ran a case investigation for us. Six varicella cases, four zoster cases, and reading the report it's fairly clear that those zoster cases were unrelated but happened to be in the general area temporally. We lost a number of man days due to a company being confined to quarters as well as the folks who were actually sick each losing about eight to 10 days and probably being recycled into the next recruit company. Next slide please.

Some of the interesting findings we got though is they went through and did a history, fairly extensive questionnaire on everybody at Cape May at the time -- and we had a nice captive population -- and also did IG screening on all these folks to see if they were antibody positive or not. And what we found

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was the folks who did report a positive history, the positive predictive value was about 99.1 percent, which was fairly good. The folks who were negative or uncertain of history, which there were about 12 percent, it turns out that most of them also were positive by serology. However, at the present time, because we don't have the ability to do mass screening, what we have chosen to do as a temporizing measure at least until we can do more with this is go ahead and immunize anyone with an uncertain or negative history at the current time.

What we predict we could probably get down to about four percent of new recruits who truly do need the vaccination, but we are catching most of those by doing the uncertain or negative histories. So we shouldn't have an outbreak like we did. Next slide please.

Also just recently we have an advance training center for our enlisted in Petaluma, California, and just about a month and a half ago, we had a -- 61 cases of acute onset of diarrheal and gastroenteritis illness breakout there, very similar to what you would see in a Norwalk-type virus. About two weeks later, a local high school broke out with a

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similar episode. Next slide please.

What we found was there was no difference between cases and controls. We actually train our food service personnel there, but they live and train separately. For some reason the folks on the base don't eat the food that the food service folks cook. They're in a separate contract facility.

No one in the food service cafeteria there, the mess hall, none of the workers there actually developed this disease. So we have not truly figured out where these -- where the indexed case came from or where the point source was. But -- and the other thing is we only looked at active duty folks. There were a number of family members who we only see the active duty folks at our small clinic there. So the family members went elsewhere. We are expecting cultures back and are very suspicious of a Norwalk-like virus.

And the fact that some of those depictions of a small round structured virus on the bottom look like pepperoni pizzas make no -- no mind of that that pepperoni pizza was the actual true source.

That's the update from the Coast Guard at this point subject to any questions you all may have.

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DR. PERROTTA: Any questions for Commander Tedesco?

COMMANDER TEDESCO: I know we'll get into the varicella issue a lot more in depth later today.

DR. PERROTTA: You bet.

COMMANDER TEDESCO: Thank you.

DR. PERROTTA: Colonel Warde. Colonel Warde is our British Medical Liaison Officer. Appreciate you coming.

COLONEL WARDE: Thank you, Doctor Perrotta. Ladies and gentlemen, I'd just like to report two recent developments which have been initiated by the British Surgeon General. That's our tri-service Surgeon General.

The first is on the subject of health surveillance. As part of his information strategy long-term, the Surgeon General has initiated a three-year program of research into military health surveillance, and existing British military health surveillance systems are being exposed to external academic scrutiny under a contract, and non-military health surveillance systems are also being reviewed. Great emphasis is likely to be placed on the recording of exposure data, and a health surveillance working

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party has been set up by the Surgeon General.

And the second initiative, also starting this month follows the publication in 1998 of a Cochran review of musculoskeletal injuries written by Professor Gerspy (phonetic) I think at the University of Edinburgh, and the working party has been set up by the British Surgeon General to examine and implement evidence-based procedures to prevent musculoskeletal injury, especially in recruits and trainees, and some of you may be attending the Recruit Trainee Health Care Seminar in South Carolina at the end of this month when more information will be provided on this.

Now, both these initiatives, I think even from the presentations we've already had this morning, echo activity here in the U.S., and I would like to offer at appropriate times in the future perhaps to update this board on developments in those initiatives, but also may I appeal to any members of the board or those active in related areas here in the U.S. services please to let me know if you would like me to facilitate contact with the workers in the UK because quite clearly there is scope in both these areas for cooperation and ultimately we hope interoperability.

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Thank you, sir.

DR. PERROTTA: Thank you for coming.
Lieutenant Colonel Souter.

LIEUTENANT COLONEL SOUTER: Souter.

DR. PERROTTA: Souter. I knew I'd get one
of them right. He's the Canadian Medical Liaison
Officer. Thank you, Colonel, for coming.

LIEUTENANT COLONEL SOUTER: Thank you.
I'll mention three things quickly, but, again, two of
them at least relate to a lot of what's been said
already.

First, I've handed out an interesting
little Canadian Forces general message that we
received last week that I thought might be of interest
to the Board on CTD and possible contamination of
Canadian ISG.

The way this came to pass is the Canadian
Red Cross went out with a flyer to all health care
workers in the country alerting them to this possible
contamination and putting on as a requirement to
inform people who might have received this ISG to be
informed of the risk.

As you read through that message, you'll
see it's more or less a tempest in a teapot, but I

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thought the exercise and the identification of this theoretical risk the way we've gone through it would be of interest. It did cause some concern with our people who a lot of them did receive this product in the 1992 to '94 time period. But as the bottom line says in that piece of paper I've given you, their risk of contracting CJD from this ISG is no greater than the risk of the general population of contracting it. So, as I say, tempest in the teapot.

The second thing I would like to mention is the Canadian effort in support of the Kosovar refugees. There's been an awful lot of work done in Canada. Canada's approach to the refugees was not to take them offshore to some base because we don't have bases offshore, but to bring them right into Canada, flying in through airheads in central and eastern Canada and then distributing these people into bases throughout the area.

This was an effort that was to be run by our citizenship and immigration group, but because military bases were the airhead, the initial expectation was that the medical support for the refugees would come from the Canadian Forces Medical Service.

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It quickly became apparent that through our force reductions we've gone through in the last several years, that the Canadian Forces Medical Services were deployed all over the world and didn't have anything left in the country to look after these people. Again, this is a lesson learned I think that you might want to take onboard.

The real critical shortage in-country we had was physicians and X-ray facilities of all things.

We did have some X-ray facilities, and if we were to give them out, it would have prevented deployability of our field hospital which we keep on an immediate standby.

There were some other interesting things that came out of this. The screening thing, we went through it for a week and a half. It's been settled in the last day or so. But, again, it's repeating what's been done before, getting the right people at the table with the information. We do have a screening and a vaccination program set up for when the refugees arrive. We don't expect to see any for at least a week if any at all. We have people on the ground in Macedonia looking at the camps and all the rest of it.

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The other thing that I think might be of interest to this group was over the last week and a half, there was an initial scrambling and confusion as to how the Canadians would respond to this, but we found that over this 10-day period that there's been a coalescing of groups that are responsible from the federal provincial right down to the municipal and NGO level that have developed a very effective program through a series of meetings and conference calls, and they are set to go at this point in time.

The last issue I wanted to mention, and I'll go into it a lot more later on this afternoon, is that we still have concerns in Canada on the Anthrax vaccine issues, and what I'd like to point out to the board is we also have an adverse effects study with an active surveillance program ongoing at this time. I'll present the preliminary results of that this afternoon, but what we would like to do is to get the final results of that out to this group before we actually go to publication. I'm not too sure how -- what mechanism we'll use, possibly this health affairs thing that's coming up in May. We should have the results then, but I'd be prepared either myself or to have some of our people come down and present that

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study at that time.

Any questions?

DR. PERROTTA: Thank you. Any questions?

Appreciate you coming down. Not on the list but has been with us for a while and I understand is moving closer to where we are right now is Lieutenant Commander Fallon with the Marine Corps. Ann, do you have anything to update?

LIEUTENANT COMMANDER FALLON: Yes. I will be transferring this summer to Camp Pendleton to the First Marine Expeditionary Force. I'll be the Preventive Medicine Physician there. And I've enjoyed serving with the board. It's been a short time, but I've really enjoyed it.

Most of the Marine Corps issues have been presented with the Navy presentation. Thank you.

DR. PERROTTA: Thanks again. Good luck.

LIEUTENANT COMMANDER FALLON: Thank you.

DR. PERROTTA: Just to show you that we can be indeed flexible, our host have made some arrangements to see if we can't remedy our electrical and computer problems. And so if you don't mind, if we would move our break up to the beginning, that is, right now, and if we can rejoin exactly at 9:00 a.m.,

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which is about 14 minutes or so, then we'll do that.

(Whereupon, a recess was taken.)

DR. PERROTTA: It appears that our technical difficulties are getting ironed out hopefully. They're better, okay.

Let's go ahead and take up the question to the board. Commander McBride, would you like to start this? Do you have any other notes, Ben?

COMMANDER MCBRIDE: Thank you, Major Fisher and Lieutenant Lee.

COLONEL DINIEGA: Excuse me. Can you read the question?

COMMANDER MCBRIDE: I can. I have it right here.

COLONEL DINIEGA: Okay.

COMMANDER MCBRIDE: Once again, good morning everyone. Let me read with you the question to the board that was submitted regarding Lyme vaccine. I think all of you have it, but for the record I'll read it. This is a memorandum to the Executive Secretary, Armed Forces Epidemiological Board, Subject: Use of Lyme Vaccine among Service Members.

"Request the Board review available data and

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provide a recommendation concerning the use of the recently licensed Lyme vaccine among active duty Service members.

Request the following courses of action be considered:

Establish the vaccine as a routine requirement of all service members.

Require the vaccine be administered as a routine requirement for selected occupational groups.

Require use of the vaccine only to Service members in specific high-risk or geographical regions.

If option (c) is recommended, provide a required period of time for which a member must either be in the high-risk region or must be anticipated to remain in the high-risk region before vaccination administration will occur."

So that was the question to the Board regarding the use of the vaccine. The question did include a couple of likely scenarios. It's not comprehensive, of course. There's other ways to consider this. But what I thought I would do in just the few moments that we have this morning is do a quick review of the presentations that were given to the Board in December.

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I was asked by Colonel Diniega just to highlight some of the presentations and the points and the data that were shared with the group back then, and much of what I will be presenting is just a thumbnail sketch of the data that was given largely by Colonel Sanchez with assistance from the folks at the Army's CHPPM as well as some material I received from SmithKline Beecham.

I'll try to move swiftly through this because I think many of us know some of the basic fundamentals of the vaccine.

The first point was that -- I just wanted to get this thing working if I could. Here we go. Did I go past that?

DR. PERROTTA: Yes, you did.

COMMANDER MCBRIDE: Well, you can forget trying to figure out how to get to the back -- I think we're okay.

Just ever so briefly, Lyme Disease is a multi-system disease that has different stages. An initial stage, and of course it has long-term sequela, typically associated with neurologic or musculoskeletal difficulties, the most commonly diagnosed vector-borne disease in the United States,

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and it has a significant regionalization of its endogenicity. We find that it's mostly concentrated in the northeastern parts of the United States, along the upper midwest, and also in the Pacific coastal region, and it's a -- the data that's been received by the CDC over the last several years, there appears to be a significant trend where the incidence is increasing, and that's been fairly well identified.

There's a bimodal age distribution associated with Lyme Disease. We see a clustering of young children and adolescents as indicated there and in adults over the age of 30. Next slide please.

Well, just a few quick characteristics of the vaccine. It's a genetically-engineered vaccine. It's a recombinant vaccine that contains the surface protein from the *Borrelia burgdorferi*, and it stimulates antibodies against the organism, the bacterial spirochete, but it's specific to the strain that causes most of the infections in the United States.

Though it's recognized that Lyme Disease is seen in other parts of the world, the vaccine that's licensed by SmithKline that we're considering today has not been found to show protection against

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these other strains in other countries.

The hypothesis of how the vaccine works or its mechanism of action is that once an individual is immunized and there is a tick that takes a blood meal from this individual, the tick takes into it's mid-gut the antibodies that actually kill or inactivate the bacterion in the mid-gut of the tick, and this then thwarts the infection, and one presumably does not become infected or fall ill.

It needs to be acknowledged that the vaccine does not prevent the tick from biting the individual, nor does the vaccine prevent the tick from infecting the individual with other types of infectious agents, but it does apparently -- this is the hypothesis of how this achieves its mechanism.

And, as we know, the vaccine is administered intramuscularly on a three-dose series given day zero for example then one month and then at 12 months. Dana, thank you.

Some additional characteristics: It's limited to individuals between the ages of 15 and 70.

It has not been found -- it's not been licensed for the use of individuals under the age of 15 or children, and this is kind of an interesting point

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because many of the people who contract Lyme Disease are in a younger age group.

I'll say that the manufacturer is submitting or is in the process of seeking a recommendation or a licensure from the FDA for administration to individuals under the age of 15.

And also, if I may, about the dosing regimen -- and this is kind of important I think as we consider the use of the vaccine -- currently it's licensed to be given over a period of 12 months, but the manufacturer is seeking from the FDA approval of a shortened vaccine administration from zero, one, and two months. And I'm told that it's likely that this -- a determination will be made on this recommendation later this calendar year, and so that will be very interesting.

Anyway, very quickly, after three doses protection, in the efficacy study, the pivotal efficacy study that was done on the vaccine demonstrated about 78 percent effectiveness against a definitive diagnosis of Lyme Disease. This was characterized by individuals who were found to have the classic symptoms of Lyme Disease, you know, the Erythema migrans, the other manifestations, as well as

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a laboratory determination through Western blot or some other laboratory confirmation. It protected individuals 75 percent from a definitive diagnosis of Lyme Disease.

In individuals that had asymptomatic Lyme Disease -- they had no symptoms, no clinical findings that suggested Lyme Disease, but they did have serologic markers or positive laboratory tests -- it protected 100 percent of the time in this case.

And in individuals that were characterized as possible Lyme Disease -- these were individuals who may have had Erythema migrans diagnosed by a physician provider but did not have any laboratory confirmation or they may have had a flu-like symptom or flu-like illness with some laboratory confirmation, individuals in those categories were classified as possible Lyme Disease -- the protection as you see was 48 percent. And you'll note the confidence limits there are generally rather broad.

With regard to the side effects and local reactions, they do not appear to be striking. Much like any other immunization, local injection site reactions predominate and some mild swelling, swelling and redness and occasionally some flu-like symptoms.

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Dana, please.

Well, what about the incidence of Lyme Disease across the country? Very briefly, we indicated that the rate seems to be increasing over the past several years. I've selected the top 10 states and reflect their numbers of cases and then the cases per 100,000.

As you can appreciate, the state with the highest incidence of Lyme Disease is Connecticut, with over 3,000 cases, with a case per 100,000 rate of 94, and then it goes down through Massachusetts.

If you look at this, we don't have any real significant concentration of military individuals in these states, with perhaps the exception of New York where we have West Point and some activity in New Jersey, but not significant forces in these states. Next slide please.

Well, let's talk about Lyme Disease in the military. There's a few points. With regard to the data that was reported in December to the AFEB -- these data are collected by the Defense Medical Surveillance System, and the reporting bias is in favor of severe, easily recognizable cases that present to the medical treatment facilities, and they

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of course exclude those cases that are reported through civilian hospitals or civilian providers that don't come to the attention of the DoD or the military treatment facilities. And we recognize also because of the rather unique features of our population, an individual may present for care and become diagnosed as having Lyme Disease at one medical treatment facility, but the infection could have occurred a world away, you know, in a far different location, and that's a limitation of the data that we look at with regard to the incidence in the military.

And, of course, the way it's currently coded, there's no distinction between acute and chronic Lyme Disease in our data. And then outpatient data -- I'll comment on this in just a moment. We have data that was not presented to the Board in December from the Ambulatory Data System which over the past two years has provided us data regarding outpatient visits.

This is really unreliable with respect to definitive diagnoses because people present to a clinic, and it's thought that the presumption of diagnosis might be Lyme Disease. This will be applied, and then if it's ruled out, we can't go back

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and take that out of the system. It's already applied there. And so it's interesting to see that data, but it may not be completely reliable. Dana, please.

A few other points. Now, in contradistinction to the incidence of Lyme Disease in the United States, in the military the incidence rate appears to be diminishing over the past several years.

From 1990 to 1998, we see an overall trend of the data -- of the incidence rate diminishing. There's two little spikes at a couple of years, but they're not significant, but the overall trend is for a diminishment in the rate of Lyme Disease. And the overall rate within the DoD is around 1.3 per 100,000 person-years. Next slide please.

This indicates the Lyme Disease incidence by service, and you can see that the army has the predominant number of cases. This was data that Colonel Sanchez presented in December, and we may talk a little bit about what could be causes for this difference in a forthcoming slide. Next one please.

Now, this is data that wasn't shared with you in December, again from the Ambulatory Data System within the DoD. Again, we see that the Army has the predominant number of cases, and the Navy at 79, Air

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Force at 78, Marine Corps even less, and then we've thrown in for Commander Tedesco's benefit a half a dozen cases from the Coast Guard, for a total of 354 cases.

This data is over the past two years. We do not have data beyond 1997 from the Ambulatory Data System. Next slide please.

Well, what are some of the trends we have found in the military with regard to Lyme Disease? The age -- with age, increasing age, the rate increases. So the older individuals seem to have a more likelihood of presenting with Lyme Disease. This is also seen in the civilian data of interest. And also the rate increases with higher rank. Individuals that are more senior in rank appear to have a higher rate of Lyme infections. And the -- as was demonstrated in the data that was given to the Board in December, the highest incidence rates are associated with health care personnel, substantially so, which is kind of interesting, and then the rate in men is almost three times that of the rate in women.

If we take a look at the data per the medical treatment facilities to see if there's some regional trends, the most significant number of cases

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are reported in Walter Reed, and I think it's generally understood that this is -- as a tertiary referral center, they receive a lot of cases from other parts of the country, so I kind of tended to dismiss Walter Reed. Beyond that, the majority of cases are clustered around the Army bases and Marine Corps bases in North Carolina as well as the Army activities in Kentucky and then Hawaii, and then beyond that, there's a long stream of states where there's only three or four cases a year. But, again, the concentration of cases are in these three states, as indicated. Dana, please.

Well, as we conclude the presentation this morning, what are some of the issues to consider? We've found that there are some significant differences in both the outpatient data as well as the inpatient data with regard to services, with the Army having the predominant number of cases.

Could it be that there's some difference in compliance with personal protective measures? That has to be considered. There's certainly differences I think between training and field practices. The Marine Corps, they oftentimes as they transit through areas are on ships for much of the time, and their

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activities may be more associated out of the country.

There's all kinds of things to consider, and the time that people spend in the field conditions, these can contribute to the differences in the rates between the services and are just offered for our consideration.

I think there may be one more slide. This is kind of interesting. This is in some of the promotional material that the manufacturer has given.

And, as we consider applying the vaccine to military population, this is kind of a little quiz, if I may, that's in some of the promotional material that SmithKline Beecham presents, and these are questions that are posed to an individual. If they declare yes to any of these, then they may be at higher risk for Lyme Disease, and you can read this. It says, "Do you live in or plan to travel to an area where Lyme Disease is endemic or found," and "Do you have a dog that you sometimes exercise," and then "Do you live in an area populated by deer, work outdoors, do outdoor recreational activities such as hiking, golfing, camping," and then "I've had Lyme Disease in the past."

That bottom one is significant because even though one has had Lyme Disease in the past, it

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needs to be acknowledged that this does not provide life-long immunity to Lyme Disease, and so individuals who've previously had it are at risk also of developing Lyme Disease again from another infection.

But these are kind of interesting, and it causes I think about -- those individuals in the military, we acknowledge that as they get older, we see the rate increase more. Are these individuals that spend more time outside perhaps or have more accessibility to care? There's a number of issues that were discussed in December regarding that. I think the final slide is the next one, Dana.

If we kind of as a final summary slide look at recommendation for the use of the vaccine in the military. Consider -- these are just some additional thoughts. Consider in high-risk groups personnel training in endemic areas or occupational groups working in forested areas or in field conditions in endemic areas. However, I must acknowledge that in the data that Colonel Sanchez presented in December, they took the inpatient data and cut that by occupational working groups, and there didn't appear to be any significant trends that would suggest one target group. In some of the Army

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artillery units or artillery personnel and ground personnel there, it seemed to be some higher numbers, but it didn't appear that it was significantly striking.

Offer the vaccine to personnel who are at risk through recreational travel activities. We have to acknowledge that perhaps many of the cases that are presented in military individuals were because of recreational exposure and not because they were in field conditions or in a duty status, and then of course not particularly for the Board to determine but for the Services with regard to spouses and children, other beneficiaries, what should the guidelines be for them, and it's thought that perhaps following the recommendations from civilian guidelines would be something to consider for them.

Well, that concludes the brief review of the data and the presentation that was given in December. I just tried to identify some of the high points, review some of these things, and then provide them for our discussion and the Board's deliberation today as we pose this question to the Board with regard to a recommendation for a use of the vaccine.

That concludes my remarks. Are there any

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questions at this point.

DR. PERROTTA: Any questions? Doctor Chin?

DR. CHIN: Do you have any data as to sort of general levels of personal compliance with, you know, the environmental personal protection measures?

COMMANDER MCBRIDE: That varies. The short answer is I don't. I'm sorry, but there are people in the room that might be able to speak to that. Kevin, can I trouble you from your experience with the Marines where you were associating with them closely, do you have any thoughts about the percentage of them using that?

COMMANDER HANSEN: I don't -- I'm not aware of any actual data on that. It is certainly quite variable with an individual unit and how much emphasis a unit puts on it, but I couldn't give you any data.

COMMANDER MCBRIDE: We find that there have been specific activities like in Tandem Thrust, this exercise that occurred a year and a half ago, the rates were variable even within elements in a particular joint activity. I don't think that anybody has made any study where we can characterize the

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compliance within even a service with regard to personal protective measures because it's so dependent on the various activities or exercises that one's working on and the emphasis that this is given by the commander that's on the ground with these personnel.

COLONEL KARWACKI: In response to that, Colonel Gamble at Walter Reed Army Institute of Research a couple of years ago did a study. It was not service-wide. We can probably get you a copy of that. But, as Wayne said, it's sort of snapshot information, sort of targets of opportunity in looking at various commands in various situations, but I don't think any of us in any of the services have a broad view of how the doctrine is applied across the board at various places and at various times under various commands.

DR. CHIN: The reason I ask that is because if you have at least some sense that compliance rates vary tremendously, that's probably your major factor in differential rates of disease, and it would seem to me that, you know, some attention should be made to increase compliance as well as considering vaccine. But, you know, just to go to a magic bullet kind of solution is --

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COMMANDER MCBRIDE: That's a good point.
Captain Cunyon.

DR. PERROTTA: Steve, can you come up and
speak into the --

COMMANDER MCBRIDE: You know the drill,
Steve, and then we'll go with Cladde and Marc after
that.

CAPTAIN CUNYON: Steve Cunyon. There was
talk -- the desert uniforms are now factor
impregnated. I think there was something in effect
that the green uniforms would be impregnated sometime
in the future. I was just wondering if the date had
been set on that.

COMMANDER MCBRIDE: Colonel Driggers, do
you know anything about that?

COLONEL DRIGGERS: I'm sorry. I couldn't
hear the question exactly.

COMMANDER MCBRIDE: He was asking about
the impregnation of the uniforms with primethryn
(phonetic), and I believe that the question concerns
at some point all of the uniforms that were issued to
service personnel would be impregnated, the BDUs or
the field uniforms.

COLONEL DRIGGERS: Let me make a few quick

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comments. This is Colonel Driggers. Let me make a few quick comments about that.

As we know, since the early '90s, we've had what is known as the Individual Dynamic Absorption Kit, which is sometimes called the "old baggie method," in which individuals can impregnate their uniforms. This has been available, has not been greatly availed of, so because of that -- and Doctor Gamble's study indicated that the people were not using this. So the best way to try to do the protection is to actually do the impregnation or the factory-treatment method.

This process was pursued. The manufacturers or the suppliers indicated there were some complications. Studies were done with the Committee on Toxicology to review the situation, and the method in which was put together where they would impregnate the fabric and then they would cut it into uniforms was thought to be unacceptable risk, which was not necessarily agreed with by most of us here in the room.

There has been another impregnation method that has come on line within the last year, year and a half, where it's in an injection method. And, if I'm

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not mistaken, the Germans use this today, and they have a portable laundry that they can impregnate the uniforms.

What is being done, as we speak they are impregnating about 7,000 uniforms in a site in Florida, and it's going to be -- there's going to be a user test conducted at Fort Polk here within the next two months, and the acceptance -- the acceptance of the soldier in the user test will probably bring about the production of the uniforms.

In the last six months, we've had 58 stock numbers assigned for each size because each size of both the BDU pants and the shirt -- or the blouse for both the tropical as well as the desert BDU.

So we are moving on. We've had complications with this. The latest complication was the NEPA challenge. It seems to me -- I don't want to say that we -- there's been quite a few obstructionists in the channel, but in my perception there have been. There's a lot of resistance to doing this because our logistics agency got burnt with fabrics that were impregnated with DDT in the past, and they want to proceed very, very, very slowly.

So, will we have this in the near future?

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We hope so. We have some of the CNCs that are interested in procuring that, and they have a method that the Central Issue Facility say of the Jungle Training Center could have the uniforms that are issued to the people that come down and do the training could be impregnated, and they would be stock.

If we still -- however, we go back to the Committee on Toxicology report, which indicates that we should only put the people in the uniform if they are at risk. So the issuance of it to every single person has been a complication for that reason.

The other issue and one of the NEPA, the environmental issues that was brought up is what happens to the waste water when they are laundered. These are little technicalities that have to be overcome, and we have to knock those down, and I think we're -- within the last couple of weeks I have been with the Office of General Counsel, our environmental lawyers, and apparently have overcome these challenges and are proceeding at this time. Hopefully we'll be able to report at the next meeting that the trial at Fort Polk went well, no adverse effects from the people. And it's kind of interesting because we've

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had these exact same thing with the exact same dosage in the system since the early '90s with no observable adverse effects, but we're being forced to run the gamut again with the factory impregnated or the vendor impregnated uniforms.

Kind of a long answer, but I think I've covered a lot of ground.

DR. PERROTTA: Doctor Stevens.

DR. STEVENS: I had a question about the order of magnitude of the problem of Lyme Disease in the military and how accurate do you think is the data on the cases and how accurate is the diagnosis? Do you think you're missing cases, overdiagnosing?

COMMANDER MCBRIDE: Well --

DR. STEVENS: What's the basis for a diagnosis?

COMMANDER MCBRIDE: Well, the basis for a diagnosis depends on the provider identifying it and recognizing it, applying a diagnosis to it, and then having it reported. So there's a lot of steps that have to occur there.

I guess the short answer would be I think that it's probably fairly accurate. The ADS data may be a little bit overinflated. That would suggest that

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of the cases that have been identified, the number that I've provided may be a little high over the past couple of years, but it's anybody's guess. We're really uncertain beyond that.

There was -- I'll share with you that it was identified some months ago that there would be real value in doing a sero survey of military personnel to determine the presence of antibodies to Lyme Disease, and this was -- we were trying to do this before so that we could have the data to share with you today, but because of some difficulties, that study has not started. Just recently they've secured the funding and laid the groundwork. We have the samples available so that we're anticipating that in a very short period of time we hope that we can on several thousand sera for individuals that have been collected do a sero survey, and on many of these specimens, there is a specimen that was drawn at the time the individual came into the military, and then there's a specimen that was done some years later so that we can then determine -- if these are sera that are positive, we can then determine were they positive before they came onto active duty or not, and that will be very interesting to identify both presumably

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cases that have come to attention as well as asymptomatic cases.

That's I think kind of an important piece of information that we'll have hopefully by the next time the Board meets I think would be reasonable anticipation. And, again, that's going to be over several thousand personnel.

DR. PERROTTA: Let's take one more from Doctor La Force. Then we need to move on.

DR. LA FORCE: I'm going to pursue what Doctor Stevens brought out, and it's an issue that was discussed last time. It is my great suspicion that these cases are really cases of Lyme Disease based on the fact that you've described 354 cases with a rather unusual epidemiology that's not consistent with anybody else's epidemiology, particularly in terms of the highest rates in health care personnel. That's a new one. Unless we're talking about chronic Lyme Disease, where -- and I would just ask you a couple of questions. One, the last time, we asked whether it would be possible to distinguish acute versus chronic Lyme Disease within your surveillance system, and apparently that's still not possible.

So a lot of the cases could simply reflect

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this entity called chronic Lyme Disease where the surest -- you can be assured with a great degree of precision that somebody doesn't have Lyme Disease when they say they have chronic Lyme Disease. I think study after study after study has proven that. So that would be point one.

Point two, I'm delighted to hear that you're going to continue with the serological survey because we discussed this last time as a gold standard that might be able to sort of put a box around this problem and answer the question either yes or no.

The other suggestion that we had is was it possible to go back to the Tripler database, because as I recall, there were many cases that were reported out of Tripler, and there was a sense that that might be a group of cases that one could simply retrospectively go back through the case documentation on those to get some sort of idea as to whether they really look like cases or they weren't cases, and it was something that could be certainly doable.

COMMANDER MCBRIDE: I recall that. Your points are all excellent. With regard to the acute versus chronic, that's a limitation of our reporting system. We can't really tease that out accurately.

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However, with regard to cases at a specific MTF, it's not unreasonable to think that we could perhaps go back and, having identified those, perhaps do a limited review of the medical records and identify what the characteristics of the disease was to help understand, you know, were the diagnoses confirmed, was it acute or chronic. We could perhaps do that in cases that were seen at Tripler or perhaps Walter Reed.

The challenge in our population, as you know, these folks typically rotate and move. It would be challenging to track them down, but we don't know if we don't try, and maybe this is something that we can go back to the services and look at that and then provide that to you in the future, perhaps at the next meeting. I think that that does have merit.

DR. PERROTTA: Let's go ahead and move on then. Dave.

CAPTAIN TRUMP: My objective this morning is to give you an overview of what the ACIP recommendations will be for Lyme Disease. As for my job at Health Affairs, I'm the DoD representative to the ACIP, the Advisory Committee on Immunization Practices, as one of the ex officio members.

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And the ACIP approved the Lyme Disease recommendations at the February meeting. Just a reminder, though, that until those are published in the Morbidity and Mortality Weekly Report, they are not the official recommendations, and I just would like to give you a sense of what those recommendations are going to say although the document essentially is finished pending just the approval and publishing through CDC.

It focuses on use of the vaccine as an adjunct for preventing Lyme Disease, and it really makes recommendations regarding vaccine use that are based on assessment of individual risk, taking into account both geographical risk and the person's activities and behaviors relating to tick exposure.

The populations they look at as far as being at risk of Lyme Disease, strong focus of this is -- biggest risk is acquiring it as periresidential, for individuals who live or work in residential areas surrounded by woods, overgrown by brush, and infested with the vectors of Lyme Disease, also those who have recreational activities that place them at risk such as hiking, camping, and also those who engage in some outdoor occupations may be at risk, and the list

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there.

Prevention and control of Lyme Disease, it's some of the things we've talked about as far as avoidance of tick habitat, certainly the use of personal protection, things like doing tick checks and removals, prophylaxis and -- appropriate prophylaxis and/or treatment after a tick bite, and really stressing that the goal there is that prophylaxis is not -- should not be routine or treatment of suspected Lyme Disease. With Erythema Migrans and the like it is most appropriate.

There should be strategies at the community or the facility-type level to reduce tick abundance, that early diagnosis and treatment is important, and that Lyme Disease vaccine really is one of the last things to consider.

The decisions to administer Lyme Disease vaccine, again, are based on an assessment of individual risk and the likelihood of being bitten by *B. burgdorferi*-infected ticks. That's based on the density of the ticks in the environment, and it's going to vary by place and by season, prevalence of infection in that population of ticks, and then the extent with which people and ticks come into contact,

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by the type and frequency of duration of the activities in that environment.

We really focus on two steps. One is to consider the geographical distribution of Lyme Disease, and I think as we know, it's highest in the northeast and north central states. Really stress that the risk varies greatly between regions, between states, between counties within states, between townships within counties, and that really the best information on distribution of Lyme Disease risk is going to come from the state and local public health authorities.

The second step then is to assess the individual's activities, the things that put them at high risk such as the frequent or prolonged exposure to tick-infested habitats at times of years when the nymphs are seeking hosts, usually starting in April in most areas, the types of activities they are involved in, whether it be recreational, property maintenance, occupational, or leisure pursuits that may put them at high risk, and how good they are, how compliant they are with using measures such as avoidance of the tick habitats and using personal protective measures to minimize their risk.

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What I have not provided but I'll describe is -- and will be in the final report is a national Lyme Disease risk map that really tries to show by counties how they have put some assessment of geographic risk.

The high-risk areas actually combines two things. One is that the vectors there, *I. scapularis* and *pacificus*, are established, and they have a high prevalence of infection in the tick populations and that those counties have had a significant, in this case top 10th percentile, of Lyme Disease cases reported to CDC during that period of time.

The rest of the risk areas, moderate risk, are basically determined by the presence of the vector. Moderate, that the vectors are established, and in the vectors is a high prevalence of infection.

Low risk, that the vectors are there but the infection prevalence is low. And no risk, neither tick species has been established or reported.

The recommendations for the use of Lyme Disease vaccine will be for persons who reside, work, or recreate in areas of high or moderate risk that Lyme Disease vaccines should be considered for persons 15 to 70 who engage in activities that result in

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frequent or prolonged exposure to tick-infested habitats.

For those who are familiar with the ACIP recommendations, a "should be considered" is not an "is recommended." It's sort of a qualification of how strongly the vaccine should be considered in making a decision here.

That it may be considered for those who are exposed to tick-infested habitats, but whose exposure is neither frequent nor prolonged, and it's not recommended for those who are at minimal or no exposure to tick-infested habitats, even if they reside, work, or recreate in areas of high or moderate risk. And if there's low or no risk, the vaccine is not recommended.

Some of the other recommendations that they cover -- and I'll go over these quickly -- have to do with travelers to areas of high or moderate risk. There was a good bit of discussion about what sort of recommendation you should make with some of those issues like Doctor McBride had raised about how long -- how long is prolonged or how often is frequent. But the vaccination should be considered if frequent or prolonged exposure to tick habitats are

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anticipated, but also stressing the use of personal protective measures, again, stating that it's really unknown whether this vaccine will have any protection against the Eur-Asian strains of the vaccine -- of the B. burgdorferi.

For those -- for children, as we noted, certainly at high risk, it's not recommended right now until safety and immunogenicity of the vaccines in children have been established and that the studies did not include persons over the age of 70. So really all they say is that safety and efficacy has not been established.

It's not recommended for women who are know to be pregnant. And SmithKline Beecham has established a vaccine pregnancy registry.

On spacing and timing of administration, as we noted, it's three doses, really stressing that at least two of those doses should be -- the first two doses should be given prior to the transmission season and that the third dose should also be given in that time just before the transmission season in the spring of the year in most places and that further data really is needed to make decisions about booster doses, although based on the mechanism of this vaccine

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of really having the antibodies circulating that have to be taken up by the tick, the impression is that repeat boosters are going to be required.

And for some of the other categories, in particular with persons with musculoskeletal diseases, those who had diseases with joint swelling, including Rheumatoid Arthritis and diffused musculoskeletal pain were excluded from the phase three trial. As we had noted, previous uncomplicated Lyme Disease, Arthritis is -- or Lyme Disease of any type is an indication for vaccine except if they have treatment-resistant Lyme Disease, and that, again, the studies excluded people with chronic joint or neurologic illness related to Lyme Disease and also atrioventricular blocks from the phase three trials.

And that's it. I think most of the details are here. Again, I want to give you a sense of what the ACIP recommendation will be saying regarding recommendations for the use of this vaccine in the general population. Any questions?

DR. PERROTTA: Thank you, Captain. For the Board members, on your agenda there's also LYMERix information pointed out, and there are handouts in the pile of stuff that you have there, and

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if you have any questions, I'd ask that you direct them to the SKB representative who's here. Are there any questions for Captain Trump? Colonel Karwacki?

COLONEL KARWACKI: Are we moving to discussion?

DR. PERROTTA: Yes.

COLONEL KARWACKI: I have a comment rather than the question.

DR. PERROTTA: Okay.

COLONEL KARWACKI: Colonel Karwacki from Medical Command, Army. I'd like to expand the -- to complicate the Board's work by suggesting that we need to expand the question as proposed in the current Admiral Engel document that Wayne presented.

In the first sentence it discusses active duty members, and the data that was shown in terms of geographical distribution does suggest that we don't have large concentrations of active duty members in those high-incident areas. However, I would also suggest that for the reserve members, our reserve forces tend to follow the population centers. So the I-95 corridor from Boston on down through Pennsylvania, New York, Washington, Baltimore, has a large concentration of reserve members who train and

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work in those areas.

So, although it's almost impossible for us to get reliable data, much less any data, with regard to infections in reserve members, I would postulate that there probably are some who are suffering from this problem based on their residence and training in the areas of highest incidence.

I'd also like to clarify the fact that the -- we're not asking for I should say permission to use the vaccine given the ACIP recommendation. Certainly the vaccine will be available and is available from SmithKline Beecham in the DoD in terms of individual patient provider encounters. If the patient and provider determine that there are requirements or indications for the use of this vaccine, that can and does take place.

The question to the Board is a matter of policy. Are there identified risk groups that we would give this to on a mandatory basis. If you are here, there, or elsewhere for a certain amount of time, you will get this vaccine. So it's not a question of availability. It's not a question of patient provider determinations on a one-to-one basis, yes, I do this, that or the other thing that puts me

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at risk. It's every soldier at, every sailor at will get this regardless of his actual exposure based on some premise that he would potentially be exposed.

So, just to clarify the situation in terms of policy versus clinical encounter, we don't need necessarily a clinical encounter. That is available.

That is not a problem. It's a matter of policy in terms of who should get this on a mandatory basis.

DR. PERROTTA: We can probably work an answer in. I suspect we'll have to answer the question as written, but I think that we can include additional information that would address the reserve and how that is likely to have more exposure going on.

Is that a reasonable thing?

DR. ASCHER: I'd just speak very briefly to the reserve risk issue. I'm a reservist and have a conflict of interest. But Fort Chaffey is world famous for tick-borne disease in reservists, and it was the basis for the discovery of Erlackichaffensis (phonetic) and Spotted Fever transmission of that base, and it is a very hot spot. I don't know about Lyme.

DR. PERROTTA: Doctor Sokas.

DR. SOKAS: I just had a question whether

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the seroprevalent study that's going to be implemented could include some reserve units if that's a possibility.

DR. PERROTTA: They've done it at Chaffey for reservists, yes.

COLONEL BRADSHAW: This is Colonel Bradshaw, Air Force Medical Operations Agency. We just concluded a seroprevalent study with Hepatitis C, and they did include reservists in that. So that can be done. We'll have to talk with the folks doing the protocol, but I believe they probably allowed for that.

DR. SOKAS: Good.

COLONEL BRADSHAW: Also, I'd just comment that I just know that our folks at Fort Dix in New Jersey have already said they're going to purchase and use about 60 -- I guess get 60 individuals immunized up at Fort Dix just based on the current availability.

COLONEL DINIEGA: Reservists sera is available in the repository because I think they also -- the HIV serum is stored there.

But I think Doctor La Force's point about acute versus chronic distinction is a very good one to remember. And on the reserve issue, there probably is

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a place that you can find out how many line-of-duty determinations were submitted to the Reserve Command and also National Guard Bureau of Command to -- for line-of-duty determinations for Lyme because if it's service-connected, they do get care, and if it's not service-connected, they can't receive care from the military system. So that data might available.

DR. ASCHER: Annual training related presumably.

COLONEL DINIEGA: Possibly.

DR. ASCHER: Annual training?

COLONEL DINIEGA: Right.

DR. ASCHER: Where they go somewhere else at risk and come back?

COLONEL DINIEGA: Right, rather than acquired via their own recreational province. And New Jersey had one of the earlier places to, I think the Early Gray Installation up in New Jersey was also another place where they had a Lyme problem and Erlickiosis (phonetic), and I'm not so sure if they use that for chaplain's training still yet. That's what used to occur up there, but I think the -- looking at human cases, looking at infected tick population areas, endemic areas identified in the

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military are keys to making a determination of who should get the vaccine or not on a policy.

DR. PERROTTA: Doctor Reingold.

DR. REINGOLD: Well, unfortunately, I wasn't here in December. So I'm not familiar with the discussion that took place around the seroprevalence study. I actually have to say I'm quite skeptical that it's going to answer any important questions about risk groups or who should be vaccinated, both my concerns about the specificity of most of the tests and exactly what seropositivity is going to tell us about risk of disease and lack of readiness and other things that are important to the military.

So I'm not persuaded that once we have those data they're going to be very useful in terms of making a decision. It seems to me, frankly, if the basic question is should this vaccine be mandatory, my answer is no. I can't think of anyone in the military for whom this should be a mandatory vaccine. This is an imminently treatable disease with a very inexpensive, safe course of antibiotics. The morbidity is relatively low, and it looks like the incidence is fairly small. I think it should be optional for people who are in the risk situations

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that are put forward in the ACIP guidelines, but I can't imagine making this a mandatory vaccine. I just don't see the justification.

COLONEL DINIEGA: Can you go up to use one of the mikes?

CAPTAIN OLSEN: I can talk loud.

COLONEL DINIEGA: No.

DR. PERROTTA: We're taping it.

COLONEL DINIEGA: They're recording it. That's the main reason.

DR. PERROTTA: Appreciate it, Captain.

DR. REINGOLD: I'm not sure the mikes are on.

COLONEL DINIEGA: No, those aren't microphones. Those are recording.

DR. PERROTTA: Those are recording.

DR. REINGOLD: I see. Thank you.

CAPTAIN OLSEN: Captain Olsen at EPMU-5, Epidemiology. Just a sequitur to what was just said as a comment for the Board, the March 26th medical letter, which expresses extreme reservations about the vaccine, notably also including question about very limited duration of protection, probably protective antibodies lasting eight months or less after three

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doses.

DR. ASCHER: Dennis, when we looked at the Bosnia deployment issues, this was on the chart, and we also had TBE, Congocrimean, and all the rest of the issues, and one of the decisions about TBE was based on the fact of risk exposure and the effectiveness of these personal protective measures, and we wrote at that time a recommendation that was pretty soft about TBE, and it appeared to be successful, and the data that came back said there was not a lot of disease, but there was also not a lot of exposure.

So I'm concerned about two things. One is that the personal protective stuff seems to be stuck in the bureaucracy at some level, and I'd like to get a little more data like what happened in the troops coming out of Bosnia. I think the numbers are again small for Lyme. But if we put people on the ground in Kosovo, that's going to be the first question, what do we do with TBE again, what do we do with Lyme. And I think that's a concrete example. But I completely agree. For general use, I can't imagine that this would be recommended.

DR. PERROTTA: Again, these are points for discussion, not for a final decision right now, but

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tomorrow as a very large committee, and Greg will be in charge tomorrow, and he'll wrangle all of this, and I'll give you the gavel. Any other questions or comments on this topic?

DR. ATKINS: Can I ask a procedural question?

DR. PERROTTA: Sure.

DR. ATKINS: There's -- one level question is should there be a policy of routine administration. Is another question about should there be specific guidance or endorsement of ACIP-like guidance about -- for individual clinician patient encounters?

COMMANDER MCBRIDE: No to the second. I think it's just the first question you asked, David. We're not seeking anything regarding the other issue about individual doctor provider determinations. That would be independent of whatever the AFEB recommends.

DR. PERROTTA: We've often tried to stay out of that very -- most of the time very personal doctor patient interaction. This is a policy of you're in a unit, here are the things you have to get, and is Lyme Disease part of that or is it not and do we want to say those things or not. Does that make sense?

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COMMANDER MCBRIDE: Yes.

DR. PERROTTA: Okay. Thanks, Wayne. I've got 10:00 o'clock, and we need to move to varicella. So I appreciate everybody's willingness to continue. Colonel Karwacki.

COLONEL KARWACKI: I'm going to do this in a low-tech method if I could have somebody assist me with the overheads.

DR. PERROTTA: Jerry, while they're doing that, can you read the questions please?

COLONEL KARWACKI: Yes. What I want to do today is present you with the introduction to what's going to be a rather extensive discussion of the incidence and prevalence and experience of the services with Varicella Disease, and we want to pose that in the form of a formal question.

You have a document signed by Brigadier General Kiley on Army letterhead, Army Surgeon General letterhead entitled, the subject is "Varicella Infections Among Service Members."

The question to the Board is a request to consider the following courses of action: The timing of this vaccine in recruits -- or rather pose the original question: Review the available data and

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provide a recommendation concerning the use of Varicella vaccine among Service members.

We ask you to consider the following courses of action:

The timing of this vaccine in recruits versus later in military service.

The universal use of this vaccine versus serologic screening to identify susceptible members and immunization of only that subject population.

And other issues we would like you to consider in making any recommendations are the timing of the testing, whether that should be at the Military Entrance Processing Stations while the individual -- prior to the time the individuals enter the military service, or after their arrival at the service points of entry, the impact that any kind of a serologic testing system may have on laboratory resources, and then consideration as a way to offset some of the costs, the concurrent screening for measles, mumps, and rubella immunity to reduce that information -- or reduce that impact.

Let me just tell you a bit because you'll hear great detail from the Service members how we got to this original question. I took over my current

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position at the Army's Medical Command about three years ago, and one of the first things I did at that time was to ask the inpatient records folks known as PASBA, the statistical folks for the DoD, to give me a readout -- if you'll go on to the next slide please -- a readout of the incidence of infectious diseases, particularly vaccine-preventable diseases. I'll have to step away here so I can actually read it myself.

Let's just concentrate down here. We looked at vaccine-preventable diseases, and in terms of those that the -- the number of cases, the number of days lost in the inpatient environment and some statistics related to that in terms of average number of cases, and I really want to concentrate for the varicella perspective all the way down at the bottom if we can somehow get that in focus.

These were the vaccine-related -- or vaccine -- the current vaccines in use, and we drop down here to other infectious diseases, and if you could raise that up so we can get to this cell right there.

Varicella infections provided almost 4200 infections. This is through the 1990s. This data was 1990 through 1995, the cumulative data experience for

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active duty Army members 1990 to 1995. So there almost 4,200 cases of varicella, accounting for nearly 30,000 hospital inpatient days, at a cost of about seven inpatient days per case.

You can't obviously read these very well because of this focus problem we're having, but that just jumps off the page at me as being the number one problem. The total for this other infectious diseases category is only 33,000 total hospital days, of which 30,000 were accounted for by varicella itself.

So this said to me I think we have a problem. We need to pursue this and determine whether or not there's something we can do, because by this time the Merck vaccine had already been -- actually I think we had both vaccines available to us. So we had -- we had vaccine -- I'm sorry. We had the Merck vaccine -- there was only vaccine -- available to us for use should we decide to use that. So you can move on to the next slide.

The next issue was well, is this something cost effective, can we do this, and should we be screening, how could we determine this.

One of our preventive medicine officers had done his doctoral thesis on this topic, and he was

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able to determine some of the prevalence and incidence rates. Let's move on to the next slide.

What I did in my office was a flash analysis, and you're going to see a much more detailed analysis. Boy, this is going to be tough to read. Basically I looked at the fact that we bring on about 100,000 recruits, and this is Army only, in an annual cycle. Sixty thousand of those come to active duty. The remaining of the 40,000 are basically equally split between reservists and National Guard members who go through the same active duty eight-week basic training phase but then return home. They may or may not go on directly to an individual training at that.

They may return up to a year or so later to individual training.

So the common experience for those 100,000 is the first eight weeks of training. Sixty thousand of them go on then to remain on active duty. Forty thousand go back to other units as reservists and National Guardsmen.

We do universal measles and rubella in the Army -- we've since added mumps because of the unavailability of the MR vaccine. That's been taken off the market -- but at a cost of about \$18 per dose for

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\$1,800,000 direct cost for that vaccine. Just to simply add varicella, it was about \$33 a dose at the time I did this analysis. Two doses would be another \$6,600,000 for those 100,000 troops, for a total of about \$8,400,000 if we just simply did this as a matter of policy with no retraction or no change in policy, if we just added this on.

The data that came out of Doctor Kelly's thesis showed us that about 25 percent of the recruits were susceptible or 75 percent were immune to measles, rubella, and about eight percent were susceptible to chicken pox. So if we were able to screen at about \$10 per person, we could determine those percentages who were susceptible and only immunize that group of people for the particular diseases that they were susceptible to.

And then the indirect cost, we figure that it would be about 600 hospital days -- this is looking at recruit populations only, that first eight to 10 weeks of incidence -- we could save about 600 days of hospitalization at about \$1100 a day, and we would save another 700 days of recruit training, those 600 plus a day added onto that for getting in and out of the hospital, at about \$150 a day.

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So my flash analysis -- again, and I say this because I didn't do much with trying to refine these populations. This was put together over a period of a couple of days -- said that we would perhaps actually find some savings if we were able to, one, screen for those -- serologically screen for those entities, provide the vaccine in such a time that it would protect the troops during the time when they were most susceptible as recruits.

Now, this does not account for those incidents of disease after the recruit population, and you'll see in the analysis they become a very important factor. The CHPPM folks are going to provide you with a much more detailed analysis.

I basically handed them this data and said we need to pursue this on a much greater detail and determine whether or not this is a cost-effective basis. Move on to the next slide please.

Something you'll see I believe in the CHPPM report as well, if you look at this one slide of rates, our rate from 1990 to 1995 was basically steadily declining. So that became another factor. If we did nothing, as it simply -- we were doing nothing here, what was the cause of this decline? Why

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were we seeing fewer cases in these 100,000 recruits as they came across the threshold into the Army? But, indeed, over the years, that rate had gone down from -- if we could find it up here, I think it was -- just about two to .71 was the final year. This was the aggregate I believe, the average across the board.

So it went from two to .71, again, with no interaction and no overt action to do anything about the disease. And I believe the last slide.

UNIDENTIFIED SPEAKER: That was it.

COLONEL KARWACKI: That's it, okay.

So having said that then, I'll present the question to the Board, and we'll move on then to the service presentations, their experiences with how they are approaching the use of this disease in various populations.

DR. PERROTTA: Thank you, Jerry.
Commander Ryan.

DR. REINGOLD: Could I just ask one quick question?

DR. PERROTTA: Okay.

DR. REINGOLD: Can you just comment on how -- what the practical issues are around screening and selective vaccination? When we've occasionally

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visited various facilities and watched vaccination, it appears to be a fairly group process where large numbers of people march into a room, all get the same vaccine, and march out of the room, and I'm just not clear how easy it is to identify eight percent and vaccinate those eight percent.

COLONEL KARWACKI: Well, that's precisely the problem, and I'll defer that question until after the presentation because I think that will come up during the CHPPM analysis, and if not -- if it's not sufficiently answered, we can come back to that.

DR. PERROTTA: Doctor Chin.

DR. CHIN: I don't question your arithmetic, but I just wonder whether it's fair to say that each hospital day will cost \$1,100. If you didn't hospitalize those recruits, do you think that the Service would save \$1,100?

COLONEL KARWACKI: Actually, a slide I didn't show you, we looked, again, briefly at the rank distribution and the age distribution of those cases, and they were concentrated in the lower three ranks, the E-1, E-2, E-3.

I don't think that's a reflection of the incidence so much as the living arrangements of those

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soldiers. Remember, these are hospitalized data. This is inpatient data, such that the folks who live in the barracks are much more likely to get hospitalized for this disease than someone who doesn't. They can just be sent home and segregated in that way.

DR. CHIN: No. I'm questioning whether each --

COLONEL KARWACKI: Let me come back to that. What I did do was there is a database under the TRICARE system that tries to identify the cost of a hospital day at a hospital for a particular DRG, and although the DRGs are fairly generous, there is a respiratory disease DRG, and we went back and looked at those six hospitals that hospitalized recruits, and that \$1100 was the average cost at that time when I did this three years ago of a hospital day at that hospital for that DRG. So that number came out of a database that purports to try to put a price on the various costs of hospitalization by the diagnosis group.

I think that CHPPM has a much more refined number. This was very much of a what I call flash analysis. I took the best available data over a

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period of about a week, threw it all together and said I think we have a problem. We need to pursue this with greater detail to determine whether or not there's something we can do about it. And I believe they'll address that in their presentation.

DR. SOKAS: I have a question. Commander Tedesco seemed to suggest that just asking people whether they've had the disease was almost as good as doing serology. Will that be addressed in some of the presentations?

COLONEL KARWACKI: Yes.

DR. SOKAS: Okay.

DR. PERROTTA: Okay. Dana, we probably need you to sit there.

LIEUTENANT COMMANDER RYAN: Thank you for letting me come to discuss this again. I talked about the Varicella Prevention Program in the Navy about a year ago, and now I'm going to update you on some more data that we've got after doing this with recruits for now two years.

So, of course, chicken pox is a concern to the military, and forgive me for just reviewing, but we care about it because it causes lost time from training. Also it can cause outbreaks in critical

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settings. We have had outbreaks on ships which have been very problematic for the Navy, and certainly sometimes severe morbidity and mortality, especially from the complications of secondary strep infections.

So the program at Great Lakes, which is the only Navy boot camp, currently about 45,000 recruits come through there every year, and we began the program in December, '96. So it's been going just two years, and I can give you two years worth of that experience.

What happens at Great Lakes is all recruits get a rapid serologic test. It happens very quickly. It's on the first processing day, and it's done right there at accessioning. And those that are sero-negative to the rapid test get the vaccine on the next processing day which is also the day that they will receive their other live-virus vaccines, which include MMR and Yellow Fever and oral polio, and recruits get their second vaccine -- actually it's more at the end of boot camp than it is 30 days later.

So it's closer to 60 days later. It's at the time of record review when they're sort of out-processing from boot camp. So the ones that we find sero-negative get their second dose at the end of boot camp.

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So what have we found in two years of doing this? A very consistent approximately seven percent, 7.2 percent of recruits have tested sero-negative, and that's been really robust through time.

That is, in the first three months, we found seven percent, and in the next year we found seven percent, and really you can see the denominator there -- I'm sorry it's tiny -- but pretty big sample over those two years.

And demographic analysis it's always interesting to look at. There's been demographic analysis of varicella cases in the military, but we can do it on just the sero-negatives. So these are our susceptible young people who come into the military. We did a logistic regression on this looking at demographic variables that I had which included age, gender, home of record, and race. And the only thing that falls out significant in the multivariable model is a couple of the racial groups.

Actually home of record does not fall out as significant in the multivariable model which is interesting because you can see little clusters in certain homes of record or places that people come from of varicella susceptibility, but it doesn't sort

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of pan out in our multivariable model.

Now, a big question that has come up before and continues is in terms of screening, we do the serologic test on all recruits. How well does history predict susceptibility to varicella because certainly history is a lot simpler than drawing blood or so it would appear.

And I apologize that this is tiny. Hopefully you can read it. The top line is our data from Great Lakes, and this is what I've shown before, and it has also been consistent, although I don't have this data on 80,000 recruits but on just a sample of 1500 where we've asked history of chicken pox before doing the serology, and basically the history question is not good in this population.

About half of the sero-negative recruits will report a certain history of chicken pox. That is, if we'd asked the question first, we would have only screened half of the people who should have been screened. We'll actually screen 16 percent of recruits, but among those 16 percent, we'll only find half of the sero-negatives, half of that seven percent that are sero-negative, which is really unfortunate in that population, and that's why we've chosen not to do

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history as a pre-screen.

We'll often see history -- the question about history reported as -- and I saw Commander Tedesco did it -- positive predictive value of history. The positive predictive value is actually still good because among those with a positive history, most of them are immune. But what I'd rather look at is what I prefer to call sensitivity, though it gets a little muddled when you talk about negative and positives here, but the sensitivity of history picking up a sero-negative could be called 49 percent the way I'm looking at it here, and then I've reviewed for you what I found published on sensitivity, that same question, how good is history at picking up sero-negatives from other literature.

A lot of these actually are done in military populations, although I didn't review just military. Jerant published something fairly recently, and although he reported it out as positive predictive value, when you look through his article, you get that his sensitivity was actually rather low for that question, 60-something percent.

Struewing and Kelley, Colonel Kelley and Doctor Struewing back in the samples in 1989 looked at

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Army, Navy, Marine recruits and actually got sensitivities of the history question ranging to the 60 to 80 percent level, and the last reference there is on a civilian -- small sample of civilian data where, again, history was not that good at predicting sero-negativity.

Some other supporting data that would kind of support the idea that history is problematic -- the Air Force is going to talk about this, so I'm referencing their cost-benefit analysis that they recently published. They made an assumption about history -- it's probably a pretty good assumption without hard data from the Air Force -- but used 70 percent as the sensitivity of history, and also Doctor Wallace who's at our own Naval Hospital here in San Diego published another interesting subgroup which is people who have chicken pox. He found actually 11 percent of people with verified varicella have a history of it being more than one episode, that is, that they've had varicella before, and their serology does not support that. So it sort of implies that history is not good even in people who have chicken pox. So we have not included it in Great Lakes screening program. However, we can continue to

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reassess it. That is, we can take subsets of recruits -- and that's what I've done three times now to get to the total of 1500 -- subsets of recruits where we ask history before we screen with serology.

Okay. So what happened since we began doing the vaccination. We've had -- since the program started -- that was December, '96 -- we had 16 cases with chicken pox at the boot camp in '97 and only 14 in '98. Now, you can compare this to previous Great Lakes data where it was not unusual to see about 100 cases a year.

Now, the incidence of varicella is a little bit hard, and there's my small print again at the bottom, but the incidence has not been constant. It increased through the 1980s in the military to a peak in about 1987, '88, which was a very high incidence of chicken pox that year throughout the military, 250 cases per 100,000 person year, but then dropped through the 1980s, and Captain Gray published work on that that showed that the cases really dropped off in the early '90s and got to about where we are now, 50 cases per 100,000 person year throughout the military.

It's interesting that sero-negativity

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rates have not been steady throughout, but in 1989, Doctor Kelley and Doctor Struewing in their work had about seven percent sero-negative in recruit surveys.

We just saw Colonel Karwacki present some of that information, eight percent for an Army subset, but it was about seven percent overall, which is consistent with what we're seeing now at Great Lakes. So it doesn't appear that susceptibility changed through the years, although the incidence climbed way up into the late '80s and then has fallen down throughout the '90s.

If you review the 30 chicken pox cases we had just at Great Lakes in the past two years, it's interesting to talk about them because they were privy to the vaccine program. The vast majority -- not the vast majority -- 16 out of those 30 actually came on board likely incubating chicken pox. So they arrived and got their varicella -- acute varicella manifestation less than three weeks after arrival.

I've broken it down there. We had a couple where we assumed that there were lab errors and a couple that were in-processing errors, that is, that they were sero-positive but then later presented with real chicken pox, not a lot in that almost 90,000

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sample of recruits through the years, through those two years, but certainly we do see that breakthrough, and I think we should expect that breakthrough, that it's going to be an imperfect vaccine program when you put it in.

We've seen no cases in anybody who's received both doses of vaccine, which is pretty nice.

And we have no reported adverse events. Again, we just talked about VAERS systems. There's certainly no severe events. I would expect that there are probably some -- that doesn't mean that there aren't any sore arms out there from getting their vaccines, but there have been no VAERS reports and no adverse events at Great Lakes.

Now, here's the incidence again, and this is all the services, Army, Navy, Marines, and Air Force. Hospitalization data for varicella -- and this is what I was describing before -- throughout the '90s, the incidence has been falling off, and the -- the bright blue line there is Navy, and we had been falling off in incidence before the vaccine program. When the vaccine program got put in at Great Lakes, the incidence fell off further.

Now, this slide represents E-1. That's

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the lowest rank enlisted personnel. So I cut hospitalization data just for E-1s. It's not perfect for recruits, but it's a surrogate for recruits, for people at the earliest stage of enlistment.

You can see that in '97, actually about half of that little bar in '97 represents the cases that I saw at Great Lakes, the breakthrough cases, and then there were the E-1 cases who were not privy to the vaccine program because they were already out of Great Lakes before the vaccine program got put in the beginning of '97.

What's nice about this graph to me is that in 1998 all those cases in E-1s I can account for at Great Lakes, there were no more E-1 cases outside of Great Lakes. Those were all the breakthrough cases that happened that I described, either came onboard incubating chicken pox or were just errors at in-processing. So just a little handful there.

I kind of like this graph, although you could debate since the denominators are a little smaller here, but these are E-2s, people who are just past -- they've just been promoted one rank, not a surrogate perfectly for recruits or people just past boot camp, but it's people who've just been promoted

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one rank, and you can see E-2 rates have been much lower than E-1 rates throughout the years. It's interesting that the Air Force no longer looks quite as immune if you will to problems. When you get to the E-2 level, the Air Force actually has a pretty interesting incidence back there in '93, but there's no Navy cases in E-2s after '97. So that's nice to me, and I'd like to see that in '98 there's no more E-2s or E-3 cases and hopefully even E-4 cases. That would be what we would hope for through the years, but we would have to see a little bit longer out if we really see breakthrough cases in enlisted members a few years out.

Okay. I'll just touch on this because the Army's going to do -- I've already seen a little preview -- a very nice sophisticated cost analysis of vaccine program, but this is my simple cost analysis of what's happened at Great Lakes, and it doesn't include all the variables, but it's what we think basically we've put into the program and what we have gotten out of the program just in Navy enlisted personnel.

We do serology on everybody. That costs us two dollars a person. You're going to see that's a

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difference between what the Army estimates and what we use, but that's what we've spent, and actually my lab tells me we spend a dollar a person. I put in the extra dollar for lab contact time just for drawing the specimen, although that specimen is being drawn anyway for in-processing lab work. People are getting their blood drawn for their blood typing and they're actually getting a lipid screen at in-processing. So there's not a lot of contact time that that adds at in-processing for enlisted members.

We have to vaccinate the 7.2 percent that are sero-negative. Costs us about \$60 for a vaccine.

I put in five dollars more for contact time. Again, the medical contact time and the lost time from training almost negligible in this population because they're coming in to get their vaccines at in-processing, and at their second dose the seven percent are also getting a record review and getting set to graduate.

So, again, if you put that all in, it costs us \$668 per person to do the vaccine program, to invest in the vaccine program.

The cost prevention, what we save in varicella incidence -- and, again, I just heard the

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question about how much does a case cost you. Well, we think it actually does cost a fair amount. And put in \$5,000 a case because that's lost time from training, five days lost time from training and hospitalization costs. So it's medical contact time, the medication time, and the person's lost-time cost.

There's some sort of standard data that DMDC uses, and they actually put in about \$1300 a day for one hospitalization day. So I think that's actually a conservative estimate. When you think about a complicated case, that would be a very low estimate. Think about a fatality, and the last fatality at Great Lakes was in 1989, that would be extremely low estimate for the cost of a case. So we have to spread out complications there in the average cost of the case.

Again, we're going to talk about the incidence. Now, I put in here modeling incidence. It's a little bit tough because the incidence was dropping off. So I used a very conservative -- what I thought was a very low estimate of incidence, 75 cases per 100,000 person year for enlisted personnel. I showed you that all the military has dropped to about 50 cases per 100,000 person-years, but that's not for

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recruits or enlisted people where they -- still the incidence is well over 100 per 100,000 person-years even at the low levels we're at now.

So I'm going to say that it's 75 cases per 100,000 person-years and that we're going to protect them for three years. That's the cohort for three years, which would be their average enlistment.

And I'm also going to put in a conservative estimate that I can only prevent 80 percent of the expected cases. So hopefully that's not too promoting of the program. I hopefully will prevent more than 80 percent of the expected cases, but if we put that kind of stuff in -- I'm sorry, I'm going to talk to you just briefly about an alternative, and then I'll show you a graph of what that looks like. I just skipped ahead.

On that graph the bottom line there was that -- yeah, can you go back -- was that we would -- the cost savings is nine dollars a head, and so we actually saved two fifty or so, two and a quarter per person. When you multiply that times 45,000 in a recruit cohort, it's a substantial savings, about \$200,000 a year that we save by doing the vaccine program.

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An alternative that's frequently been brought up is this question about doing history as a pre-screen since that's obviously cheaper than doing serology on everybody.

Just modeling it in a simple sense, if we do varicella history on every recruit, I've put in a nominal cost of 50 cents a head to do that on everybody, and then we'll only have to do serology on 16 percent at two dollars a cost per serology. We'll only vaccinate half of the ones we wanted to vaccinate. So we'll only vaccinate 3.6 percent, and it will cost a lot less per person.

Then again, if you put in this assumptions on what varicella costs, you could argue with this too, but I would -- I made an assumption that we'd only prevent 40 percent of the cases instead of 80 percent since we're vaccinating half as many people. So we're not going to save quite as much, but it's still cost saving to do this by this rather simple model.

And then if you do kind of map it out, this is the how much you save per person, and what I varied here on the X axis is the cost per case. I actually think the \$5,000 per case is a conservative

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estimate. So I wanted to map out what happens when the cost per case goes up, which is possible it does when you talk about complicated cases or outbreaks on ships where you have to Medevac people, can be very costly per case.

And so, as the cost per case goes up, the program that we have in the brighter yellow line becomes more cost saving than the one where you would vaccinate less people by using history first as a screen.

Only at the -- it's about \$4,000 or so per case does it kind of break even by the simple model, so that, you know, when cases become real cheap, it doesn't pay to do the prevention program, but I honestly think that \$5,000 a case is still pretty conservative in that they're not cheap.

The other thing I wanted to map out here is just to show you what happens when the incidence goes up. It's actually the same curve because it's a simple linear model, but as the incidence goes up from 75 per 100,000 person a year to as high as 225, which has been seen in enlisted personnel and E-1 personnel, you really save quite a bit more person if the incidence goes up.

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I'm concerned that incidence could go up in the next decade the way it did in the late 1980s. Since the serology, seroprevalence test doesn't seem to have changed, I'm not sure why we've enjoyed sort of a decrease in chicken pox. We may be set up for an increase again. I think it's hard to predict, and as long as we have susceptible or sero-negative recruits or enlisted personnel, we have the potential to have high incidence again, and then the program becomes much more cost saving.

So that the summary of our experience is that the current program has been cost saving for the Navy and that the serology-directed program as opposed to a history pre-screen program has been more beneficial to us because of the potential for higher-cost cases or even higher incidence of varicella.

That's all I've got. Any questions?

DR. PERROTTA: Any questions for Commander Ryan?

COLONEL DINIEGA: I have one.

DR. PERROTTA: Okay.

COLONEL DINIEGA: Meg, do you know what the level of protection is after one shot or Doctor Seward?

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DR. SEWARD: Seventy-five percent.

COLONEL DINIEGA: After one shot.

LIEUTENANT COMMANDER RYAN: And we -- I kind of skipped through that quickly, but we had breakthrough cases who appeared to have been exposed at Great Lakes and had only one dose of vaccine. Yes, ma'am.

DR. STEVENS: I think I recall at previous presentations you've made there were questions about the accuracy of your serologic test, but it looks like from your data, at least the practical data on the outcome, as if it's pretty good. I mean, if you're not having cases in E-2s and you're really preventing through the screening --

LIEUTENANT COMMANDER RYAN: It appears that in practice it has been very good. I think I showed three breakthrough cases where we assume lab error, where somebody screened sero-positive but then developed clinical chicken pox later. So not a perfect test. I believe the manufacturer puts on this sero test something like 98 to 99 percent specificity or accuracy of the test. It's -- they're all in the 90s sensitivity and specificity for the test.

It's problematic when you can't tolerate

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one case, and we did talk about that with measles in the past. If you really cannot tolerate a single case of disease, it's more problematic to use a less than 100 percent perfect screen. But in the case of varicella, it's been beneficial to us because we've dropped from a fairly high caseload to a low caseload.

DR. PERROTTA: Doctor Ascher.

DR. ASCHER: How many of the people who developed disease after vaccination in basic had a history of exposure prior to coming on basic?

LIEUTENANT COMMANDER RYAN: It's a little hard to tease out because we get -- you know, we usually get the report after the person's moving through, and it's hard to sometimes get individual histories. But I do have for my 30 cases at Great Lakes a knowledge of their histories, and just about all of them had exposure to each other if you will, those 30 cases.

So the ones I have who are breakthrough cases -- I think there's about six or seven -- who had one dose of vaccine but got chicken pox more than three weeks after arrival had arrived --

DR. ASCHER: I'm talking about less than three weeks. I'm talking about --

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LIEUTENANT COMMANDER RYAN: Ones who arrived less than three weeks?

DR. ASCHER: -- the ones who were incubating.

LIEUTENANT COMMANDER RYAN: I can't say exactly that I know all their histories of exposure, but a lot of them were in divisions together. That is --

DR. ASCHER: You take the point if a recruit at the time of bringing -- coming into basic knew that they had been exposed to chicken pox in the preceding two weeks, you could defer basic.

LIEUTENANT COMMANDER RYAN: That's true. I think that history is probably really hard to get from recruits. That would just be my instinct, although we haven't asked that question to all recruits as a routine as they come in.

DR. PERROTTA: Doctor Seward.

DR. SEWARD: Jane Seward, CDC. I had the same question about your lab test. I mean, no lab test is perfect, so you're going to misclassify some people both ways with any lab test you use.

On the susceptibility issue, the more recent data from Jerant -- I don't know if I'm

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pronouncing his name correctly -- susceptibility was lower in that study, four percent compared to the eight percent in Struewing and Kelley in the '80s. And so he actually acknowledged -- wondered in that paper if the lower susceptibility was paralleling the declining rate.

National serological data that hasn't been published yet but I know in detail shows that there is -- there are substantial differences by race, and so I think differences in the Armed Services will reflect, you know, racial and ethnic composition of the recruits. African-American compared to Caucasians have higher susceptibility. In adolescence, they obviously get chicken pox a bit later. I'm not sure why. They get it eventually. They just get it a little later. So they have about 10 percent risk susceptibility versus about six, you know, in adolescence, and about six percent versus three in their 20s. So they're more likely to be susceptible.

In the Cape May outbreak that CDC assisted the Coast Guard with, susceptibility in that population was lower. It was about three percent, but a very low proportion of the recruits were African-American, and the sensitivity issue that you're

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talking about was different in that data. They missed -- we missed a quarter of the true sero-negatives, if we believe the lab tests, by relying on history, and consider that in that setting, considering that lab tests weren't perfect, that that's not too bad.

LIEUTENANT COMMANDER RYAN: Doctor Stevens and I were just talking about that Coast Guard data because that's almost the best I've seen for sensitivity of history. We were wondering if possibly because you were in the outbreak setting people's histories were a little bit better, that is, they tended toward saying no or I'm uncertain of my history rather than overestimating their certainty of past chicken pox.

I'm certain that it is different in different populations. Health care workers, for example, or older people as opposed to recruits at in-processing.

DR. PERROTTA: Let's take one more from Doctor Haywood.

DR. HAYWOOD: Is there a difference in morbidity in the African-American versus the -- related to the later onset?

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DR. SEWARD: Not that I'm aware of in analyzing death data from the country. In fact, African-Americans have a lower mortality rate per population. We're just looking at hospitalizations right now. I mean, chicken pox is more severe in adolescents. So probably they get more severe cases when they get it. I mean we're not talking high susceptibilities. We're talking, you know, seven percent susceptible versus four in adolescents.

DR. HAYWOOD: But if there's a greater morbidity, there would be a greater cost savings.

DR. SEWARD: Yes, right. So I think -- I mean, the services differ in their demographics, and that may reflect -- I mean, the four percent susceptibility in the '90s may reflect different demographics of recruits coming in. You know, that's the sort of thing that could be changing.

LIEUTENANT COMMANDER RYAN: His sample is smaller as well for that four percent. I think he's got 1,000 or 2,000 in that sample. So it's possible that he's got a different demographic mix just at that point in time.

DR. SEWARD: Yes, sure.

LIEUTENANT COLONEL RIDDLE: Our

susceptibility at the Academy was eight percent overall. I mean, it ranged from six to 10.1 looking at about 1400 cadets coming in each year. I know those are a little bit different.

DR. PERROTTA: Thank you, Meg. Appreciate that.

LIEUTENANT COMMANDER RYAN: Thank you.

DR. PERROTTA: Lieutenant Colonel Riddle is a PM Officer at Health Affairs, DoD, is that right? Yes.

LIEUTENANT COLONEL RIDDLE: First, I want to thank the AFEB for having us come out and present, and this is some work that we initiated out at the Air Force Academy in '95 similar to Colonel Karwacki, as we saw this vaccine come on the market and wanted to see how we could best utilize it.

I want to thank Lieutenant Colonel Bruce Barnham (phonetic) and Major Tim Wells, who are still out there, Tim just returning from a three-month vacation in Southwest Asia, and some of this data came from some work from Lieutenant Colonel Steve Tony up at the Uniformed Services University.

So I just wanted to give a couple of overview slides. Certainly we know about varicella.

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In the United States we've seen a little bit of a change in the epidemiology given the utilization of day care. When the vaccine came on the market in '95, we implemented a program in '96. We wanted to evaluate the utilization of this. Complications are certainly seen in adults, and our population is, you know, 18 to 24 out at the Air Force Academy, and we worry about the complications in these older individuals. And just like Colonel Karwacki presented, this is the number one disease or vaccine-preventable disease as far as the military hospitalization.

The only thing I want to point out on this slide here is the high secondary attack rates. Each of these groups that we're looking at are different. Certainly at the Air Force Academy, you know, we would have one case associated with an individual that came in from overseas travel, a student on a student exchange program.

In '97, our cadet that greeted all of the incoming cadets broke out with pox the very next day.

So we have some very unique exposure scenarios, and initially we implemented a program of case investigation and vaccination based upon history and

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then followed that up with a serological screening program.

Some of this data, this is just a different presentation of similar data, but what you can see here is from 1989 through 1997, if we just look specifically at the Air Force data, we've seen a drop from 0.58 to 0.1, or an 83 percent decrease in varicella hospitalization rate per 1,000 active duty.

And this -- you know, this presents all of the services, probably some reflection of maybe less utilization of hospitalization for these cases, but certainly a downward trend in the incidence of this disease in our population.

If we just look at the Air Force data here, nearly 72 percent of all active duty Air Force hospitalizations from 1989 through 1997 were members less than 24 years of age. Next slide.

This slide here just gives us the hospitalization rate in the Air Force as a proportion of all active duty Air Force hospitalizations. And also, as you can see, that it's fell throughout the period except for a slight increase in '96 to '97. Next slide.

If we look at the Air Force Academy, we

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have a significant investment in these individuals coming to the Academy. They're there for a four-year program. We admit individuals from all 50 states and territories as well as selective foreign countries. We have, you know, certainly an environment associated with high stress, intense training, close living conditions.

Annually, if we look from 1992 to 1994 at our varicella costs, we had more than 100 lost class days due to inpatient hospitalization because there's no at-home day care for these individuals. We take them, put them in an isolation ward at the hospital. And that was \$100,000 direct cost for inpatient care, and we had those same figures. Approximately \$1100 is what we cost out for an inpatient care, and it costs us about \$300 to get an individual into the hospital.

We didn't model in indirect costs, but certainly one has to factor the indirect cost related to support these cadets in the classroom, loss of class days, impact on readiness, and impact on training. Next slide.

So what we did, the vaccine was licensed in March, 1995. We wanted to look at this using, you know, a fairly rough swag, not a sophisticated

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modeling like you're going to see in the next presentation, but we wanted to look at five options, not doing anything, vaccinate all incoming cadets, screen at in-processing using serology and vaccinate those that were susceptible, administer a disease history questionnaire or do a history questionnaire plus serologic screening, and the strategy that we selected was a strategy of screening and vaccinating.

So what -- the bottom line is implementation of strategy three. In 1996, we found 73 cadets that were serologically naive for chicken pox, which is different than what our initial strategy or modeling costs were based on. We used a 10 percent and a 1400 incoming class.

So, like I stated, in 1996, we had 73 that were susceptible, '97 113, and '98 100, range from six percent to 10.1 percent, with an average susceptibility of 10 percent in this slide. And these are some of the roughouts as far as our costs, and I present that in more detail in a table. Next slide.

So if we -- if we look, we see a similar downward trend in the incidence of varicella at the Air Force Academy. In 1995, following the release of the vaccine, we investigated case outbreaks, and that

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'95 investigation was related to one exchange cadet. A cadet coming back home from Christmas break was exposed to some children at home. He brought the disease back. And, again, in '96, when we initially started screening, those were the result of our senior cadet at in-processing who was incubating and greeted several hundred cadets coming into the Academy.

But as you can see here, in 1996, with the screening and vaccination, the rate goes from 4.23 per 1,000 to zero in 1997, and that attack rate is three percent in 1996 down to zero in '97 and '98.

This graph right here presents the downward trend and costs of and the costs associated with implementation of the screening and immunization program.

As you can see, from '92 to '94 we had 44 cases, average of 14.6 per year. Total hospitalized costs were \$344,609, an average of \$7,832 per case, and these are just direct hospitalization costs, not inclusive of indirect costs.

In '95 we had eight cases at a direct cost of over \$61,000, approximately \$7600 per case. And, again, with our cadets, our average inpatient hospitalization stay was seven days.

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With the costs of the screening and vaccination, these are the actual outlay of costs that we have. It costs us a little over eight dollars to pull the sample and have that sample tested. We already pull blood on these cadets, so it doesn't take any additional time at in-processing. And what we do on those that are susceptible, we follow up and give the two-shot series. So our actual out-of-pocket cost for this program at the academy is \$17,000 per year.

This graph right here, actually a table, presents some of the data I discussed as far as your hospitalization costs. You can see that we had 18 cases in 1992, zero cases in '97, zero cases in '98, zero cases to date in '99. If you look at the proportion of cadets hospitalized or actually cadet hospitalizations per 1,000, you can see that we've decreased from 4.23 down to zero percent in 1997 and zero percent in 1998.

This next table is a little bit difficult to see, very difficult for me over here, but this is a result of having too much time on the airplane flying out here. So I added these couple of graphs. But this actually gives the breakdown in costs as far as what the program is and the cost savings that we've

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seen.

And if you can look at the next to the last column over there, you can see that our cost of cadet hospitalizations for varicella in '92 was an average cost per case of \$7,051 or \$126,910 total, and that's dropped down to in '97 and '98 zero.

So, you know, either our timing was very good and this is, you know, a great success story of implementing the vaccine, looking at a program with a vaccine coming out, catching the downward trend of incidence, but I think the data are factual in that we have implemented a program using this vaccine in a cost-effective manner in this particular population of cadets at a Service academy and have shown now only a decrease in morbidity but also a cost savings of utilization of the vaccine. Next slide.

Just concluding, '95, following the release of the vaccine, we investigated cases and looked at an analysis of the five control strategies.

That analysis estimated an annual direct cost savings of more than \$30,000, and we've certainly realized that. This program at the Academy clearly demonstrates the importance of analyzing small populations with "unique" environments and

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requirements. This certainly is different than a recruit training scenario, but a military unique environment where a program like this has merit, and also cost benefit and other types of economic analysis aren't limited to these small populations, and we've used this -- you'll see a presentation following me on a more in depth economic analysis, but we've used this for similar things like the recent Hepatitis C work within DoD.

DR. PERROTTA: Thank you, Colonel Riddle.

Are there any questions? David.

DR. ATKINS: This is for anybody. Do we know what's happening to the incidence rate in this age cohort outside the military? I mean, presumably it's coming down because there are fewer kids developing active chicken pox to expose susceptible adults.

DR. PERROTTA: My sense is that it's still a little too early to tell the impact of varicella vaccine use in the general public childhood and adolescent population -- adolescent population. It's not being used as -- it's not being required in all states for part of the school immunization programs. It's probably used most likely in the pediatrician

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office rather than the public health clinic. And so if anybody else in the Health Department has any experience, maybe somebody else can talk about it outside. Sure, of course.

DR. SEWARD: I agree it's too early to -- it's too early to expect any impact in older populations, and to answer your question on incidence changes prior to vaccine and all the populations, we don't have very good data. I've been looking at the National Health Interview Survey and looking at ages 15 and up. I mean, incidence is so low by age 20 it's very hard to sort of detect on the population basis changes and incidence. But I can -- I mean, I have data on vaccine coverage for young children, and we suspect catch-up vaccination is still not great, but it's going up pretty fast.

I would expect though, as you imagine, that with increasing use of the vaccine, susceptibility in older populations will increase. So the need for vaccination will become much more critical in the future. I mean, it already is needed, but it will be needed more as the childhood vaccination program takes off.

DR. PERROTTA: Okay. Go ahead.

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LIEUTENANT COLONEL THOMPSON: Lieutenant Colonel Thompson from Brooks Air Force Base. My apologies to Colonel Riddle and the Board. I had no idea that this discussion was going to be taking place this morning.

We've been doing some follow-up studies on the same cohort at the Academy over the last year and a half looking at sensitivity and specificity of health history questions, with some guidance from the Board. And we found, looking specifically at varicella disease history is that positive predictive value is only about 86 percent. Negative predictive value is dismal. It's only about 56 percent. So it echoes the policy that Commander Ryan was suggesting in recruits, that history is not good enough. We miss an awful lot, and the vaccination should still be driven by serology. We are trying to compare these two different populations of Academy cadets and recruits. We did find sero-positivity of terubioli (phonetic) as our kind of proxy for a wonderful program that's received more emphasis lately over the last five years. We're getting the seroprevalence rates in our recruits have risen from 85 to 98 percent in the last five years. So we suspect that we may be

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able to soon recommend stopping even testing for measles and rubella. But, again, varicella is new enough on the horizon that we suspect that serology-driven vaccination is going to be the way to go for a while.

LIEUTENANT COLONEL RIDDLE: One of the sidelines of this is that we also test for -- among the cadets and immunize those that are susceptible.

DR. PERROTTA: Thank you very much. Mr. Lee, Varicella in the U.S. Army.

MR. LEE: Thank you.

DR. PERROTTA: Thanks for coming.

MR. LEE: Good morning, and thank you for giving me the opportunity to present to the AFEB. My name is Terrence Lee, and I'm with the U.S. Army CHPPM, and I'll be presenting the epidemiology of varicella hospitalizations in the U.S. Army.

My colleague, Colonel Nang, is here, and my other co-author is Doctor Sharon Ludwig, now with the U.S. Coast Guard.

I'd also like to acknowledge Colonel Karwacki and Colonel Rubertone and Ms. Colhas (phonetic) from CHPPM DDS and the following individuals from MEDCOM and TRADOC.

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As you know, varicella, characteristically recognized by pox and skin lesions, is a highly contagious disease transmitted by respiratory droplets, and it is known as a childhood disease, and by the age of 18 only about 18 percent -- only about seven percent, excuse me, of the population are susceptible as we've seen in the previous presentations.

But because of risks from complications, potential outbreaks, and varying rates reported in the Armed Services, varicella is still a pertinent issue for the U.S. Army.

The vaccine has been available from Merck for about four years, and the question at hand is should we use this vaccine during initial entry training, and the vaccine is believed to induce life-long immunity.

So my objectives at this talk are to present the varicella epidemiology for two populations, one for the active duty populations and a subset of the active duty, the initial-entry trainees, the recruits that are in training for about two months.

We did receive this question from Colonel

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Karwacki, and as he mentioned, he did a brief analysis, but we did a little bit more in depth, and this is what I'm presenting now.

We obtained our cases from MedCom, PASBA, our population data from the Army Medical Surveillance Activity, and our training population data from the Training and Doctrine Command.

We looked at hospitalizations over a seven-year period by searching by ICD-9 codes, and the database that we use also includes National Guard and Army Reserve hospitalized while on active duty, for example, during their time during initial entry training. And for these cases we obtained the pertinent variables.

Since the database that we had no reliable indicator whether or not a variable -- whether or not a hospitalization occurred during training, we used a filter to select initial entry training hospitalizations, and we chose -- our filter was based on time in service, rank, and by IET training sites. And for our denominator we calculated person time from the first eight weeks of training for each year from the number of entering and graduating trainees for each year.

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And -- I'm sorry. That's our slide explaining our filters for initial entry trainees. And our analysis was done on SPSS and Ki square on SMLTREE 2.9.

Now, for the active duty, as we've seen, there has been a decline. This is for the total U.S. Army active duty. There has been a decline in cases from a high of about 16 per 10,000 to about four or five per 10,000 in 1996, 1997. And in 1996, 1997, there were about 200 hospitalizations for those years.

And this chart shows risk by gender. Not surprisingly, males accounted for the bulk of the cases, 85 percent. However, females had a significantly higher risk for hospitalizations. And this shows by race, and Blacks we found had a significantly higher rate compared to Whites and comprised about 40 percent of all hospitalizations.

Hospitalization rates by age reveal that younger soldiers, those under 20, did have a higher rate for hospitalizations compared to those over 20, and as age increased, there was a decline in rates.

And our analysis by rank agrees with the previous slide, that lower-ranking individuals have a higher rate compared to all others.

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By occupation, medical personnel also had a higher risk compared to non-medical personnel. This makes sense. It's -- they maybe have a higher exposure to varicella cases.

So, looking at these variables, we found that females, Blacks, younger-age enlisted soldiers and those in medical occupations have higher rates.

We also looked at home of record or residence prior to service, and this is in your handout. It's kind of hard to read here, but we found these locations to have higher rates. This will be shown on a graph -- graphically on a slide a little bit later. And these are locations with lower rates for varicella. The high-rate locations are signified in red. Many of these are island states such as Puerto Rico and Hawaii and populated areas such as New York, New Jersey, and Washington, D.C. And lower-rate locations included rural areas, the lowest rates in Iowa, New Hampshire, and Montana.

Length of hospital stay, the median is about six days. There were some cases that had over 21 days of hospital stay. This slide shows length of service for individuals. And, as we see, 40 percent of varicella hospitalizations occur to those

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individuals in one year service, and if you look at that first year of service, you see I have a breakdown by month, and you see at the second month there is a peak which then declines over the year. And in that first and second month of service, many of those hospitalizations are those in initial entry training.

This graph breaks down the total active duty varicella hospitalizations, the blue representing hospitalizations not during training and the green representing the initial entry training hospitalizations. And it's fairly consistent throughout the years. It's about 10 or 11 percent of hospitalizations occurred during initial entry training.

And similar to the total active duty, for initial entry training there is also a decline, a general decline in cases and cases and ranks.

Colonel Nang, could you put on the slides?

Just to refresh your -- give you a little graphics here. Initial entry trainees, these are the young men and women mostly 18 to 20 years old. They enter as civilians, get their hair cut -- next slide -- and live in relatively close quarters for eight weeks. Next slide. And they are taught the Army way of life

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and taught how to be a soldier.

During this time who is more susceptible to varicella? Well, we found by gender there is no difference between males and females. Similar to active duty, we did find that Blacks did have a higher rate for varicella compared to Whites.

Now, for the IET population, we found that those younger than 20 had a lower rate for varicella compared to those over 20. But you see after 20 -- the age groups after 20 the rate goes down at least for those over 25.

By post, we found that Fort Knox in Kentucky had a higher rate compared to all other locations, but this only accounted for about 15 percent of the cases.

So for the initial entry trainees, we found that Blacks, those in the age group of 20 to 24, and those at Fort Knox had the highest rates for varicella.

We also looked at home of record for the initial entry trainees and found that some island states, particular Puerto Rico, which appeared in both as having a high rate for the initial entry trainees and the active duty, as possible important location.

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So in summary, we've seen a decline in cases and rates for the total active duty Army and for the initial entry training population. Most of these cases occur to soldiers with less than one year of service, and IET would seem a likely place to immunize if we were to immunize. However, cases in IET only make up 10 percent of hospitalizations. Higher rates were seen for females, Blacks, perhaps younger age, and soldiers from island locations.

So our conclusion is that for the Army the varicella does not seem to be a large problem. In 1996 there were 220 cases. 1997 there were 222. For the IET population there was about 20 or 21 cases each year for 1996, 1997. There has been a decline in rates, and there's a high number of individuals that have -- that are immune to varicella already.

Our cost effectiveness by Colonel Nang will now follow.

DR. PERROTTA: Any questions for Mr. Lee?

Thank you, sir.

COLONEL DINIEGA: Mr. Lee, I have a question while you're doing that.

MR. LEE: Yes.

COLONEL DINIEGA: The last statement you

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said was there's about 200 cases per year and only 10 percent in the IET population, is that correct?

MR. LEE: Yes.

COLONEL DINIEGA: Of the ones that are out of IET, are those cases all hospitalized cases?

MR. LEE: Yes. My data is data of hospitalizations.

COLONEL DINIEGA: Okay.

COLONEL BRADSHAW: This is Colonel Bradshaw. I had one other question. Did you look at marital status on any of these people?

MR. LEE: No, we did not. We did not look at that.

(Pause.)

DR. SEWARD: Can I make another comment while we're waiting? I mean, I think other available data on incidence, hospitalizations in the rest of the country definitely does not show declining trends that you're seeing in the Armed Services. So I mean, I don't know if this reflects bias, you know, hospitalization as an isolation policy that's changed over time. But definitely national hospitalizations are increasing, and incidence is definitely not declining in the adult population in the country

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overall.

COLONEL BRADSHAW: This is Colonel Bradshaw. We do have a secular trend in the military of decreasing hospitalization rates across the board.

So our entire population, hospitalization rates are reduced, but I can't speak to the specific policy for varicella.

DR. PERROTTA: Doctor Atkins?

DR. ATKINS: Has there been a change in the proportion of new recruits to the total military population over time, because clearly the rates are highest in that first year of service, and if that proportion has been changing over time, that might be reflected in the total rates in the military.

MR. LEE: As one of my slides shows that there has been a decrease during initial entry training, and for the total active duty I was not able to canvass all military hospitals to find out their policies. For the Army, initial entry training occurs at five different sites, and at those sites I did confirm with the Preventive Medicine Officers that currently if an individual has varicella, that person will be hospitalized, and this has been the policy for all five sites since 1990. So whereas in a non-IET

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site perhaps -- perhaps there may have been a shift to more outpatient care for varicella. But for these five IET sites, the policy has been consistent since 1990.

COLONEL DINIEGA: I've been assigned overseas on several occasions, and I know in the overseas theater the policy was not only for varicella but other contagious diseases or those that will require a lot of nursing support, if they were living in a barracks situation, then they would be hospitalized if they needed support services even though their disease did not warrant the hospitalization. If they were -- they had their own quarters, they were married and had their own quarters, then they would be just told to stay at home and not be hospitalized, and I think that's very much the general rule today. If they need nursing support and they can't get that at the barracks, then they would be admitted. So I'm a little bit surprised that you had that many people, although we don't know how many were handled on an outpatient basis, still had a lot of older people who were hospitalized.

COMMANDER TEDESCO: This is Commander Tedesco. One of the things also that's happened in

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the last couple of years is although those people are actually going into the hospital to stay, they may not be counted as a hospitalization anymore, and they put them in a holding capacity. In the past, getting your so-called numbers up in the hospital earned you more money from the big financial machine up above. Now it's come reverse, and to get your hospital cost down and to come in line with DRGs where some of these folks have just needed to come in to be kind of fed and watered and have the Army mom take care of them, that did not count as a true hospitalization from a DRG perspective. They just started putting them in as on an outpatient basis in a holding area and were just taken care of in a pseudo-barracks in the hospital. And that can account for some numbers coming down. They're just no longer recorded as inpatient hospitalizations, and they truly are still in the same situation.

MR. LEE: Actually, I did wonder about that too, and I asked the Preventive Medicine Officer at the five sites are these recruits formally hospitalized, and they said yes, they are. These recruits are formally hospitalized.

COMMANDER TEDESCO: Okay. So for your

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purposes they still were counted?

MR. LEE: Yes, for the initial entry training.

COLONEL BRADSHAW: This is Colonel Bradshaw again. As I mentioned, the trend overall in the military is coming down on hospitalizations, but I might also point out that a number of our MTFs who previously would hospitalize no longer have inpatient facilities, and that's a significant decrease also. And so, as he mentioned, there's about what, 10 percent of the recruits -- or the recruits represent about 10 percent of the overall --

MR. LEE: Yes.

COLONEL BRADSHAW: -- varicella cases. And so in these other areas, if you don't have an inpatient treatment facility, they're not going to be able to hospitalize unless they hospitalize them downtown, and in most of the cases they're just going to tell them to stay home on quarters.

DR. PERROTTA: Good. Okay. We do need to move forward. Lieutenant Colonel Nang, a cost-effective analysis.

LIEUTENANT COLONEL NANG: Thank you very much, sir. My name is Lieutenant Colonel Roberto

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Nang. I'm with the U.S. Army Center for Health Promotion and Preventive Medicine. It's a pleasure for me to present to the AFEB work that we've been doing with Johns Hopkins University, Ms. Rene Howell and Doctor Charlotte Gaydos and also Terry Lee of the U.S. Army Center for Health Promotion and Preventive Medicine. Next slide please.

I want to acknowledge the assistance and advice given to us by Colonel Karwacki, Colonel DeFraites, and Lieutenant Commander Sharon Ludwig before she transferred to the Coast Guard.

In brief, this is what I'm going to cover today. A lot of this has been covered by Mr. Terry Lee in the introduction. There have been some small outbreaks in the U.S. Army, the licensure by Merck of Varivax in 1995, and some of the data presented by Doctor Karwacki prompted us to take a look at the issue of the epidemiology of varicella in the U.S. Army and also the cost-effectiveness analysis. The ACIP came out with their recommendations in 1996. Next slide please.

And I just want to highlight a couple of issues with regards to the ACIP recommendations in terms of its impact on our cost-effectiveness analysis

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model and also in light of our deliberations with the policy development for varicella.

Basically in terms of the ACIP recommendations, the thing that was most interesting to us was the recommendations to provide varicella for pediatric -- the pediatric group as well as for certain occupational workers such as health care workers. Next slide please.

Again, this was previously covered, the epidemiology of varicella's talk by Mr. Terry Lee. We continue to have a decreasing trend in varicella hospitalizations. IET hospitalizations comprise 11 percent of total active duty Army hospitalizations. So that actually 89, 90 percent of the active duty hospitalizations are occurring outside of the initial entry training.

Now, the key thing about that is that these groups of people coming down with varicella hospitalizations are spread out all over the world, and so there's no centralized place for them to actually be -- be intervened, which is different from the folks in IET.

The folks in IET are in the training locations and therefore were prime candidates for us

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to look at interventional policies. Next slide please.

As previously stated, Blacks and island home of records appear to be at higher risks. Unfortunately, we also in deliberations with MedCom realized that immunization strategies targeting specific populations are not feasible due to medical legal issues.

Again, I want to point out that 93 percent of recruits have protective antibodies, and so we focus on possible interventions during IET. Next slide please.

The cost-effectiveness question was that given the epidemiology of varicella in the U.S. Army, is it cost effective to give varicella vaccination to incoming recruits, and we looked at four different strategies. We conducted a cost-effectiveness analysis model to assess the health and economic consequences of screening at the MEPS and vaccination at IET, screening and vaccination at IET. MEPS is the Military Entrance Processing Stations, which occurs immediately before the actual basic training. IET's individual entry training which is basically the same thing as basic training. Screening and vaccination at

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IET, universal vaccination at IET, and no intervention strategy. Next slide please.

Cost-effectiveness methodology used SMLTREE 2.9. Next slide please.

And numerous assumptions went into the model. The model considered expected vaccination costs, direct and indirect medical and training costs, varicella hospitalizations, varicella complications, vaccine adverse events, and the required treatment for those adverse events. Sensitivity analysis was used to range the values of the different variables incorporated into the model, and the study looked at 100,000 recruits, which is about what the Army sees on a yearly basis, considered from a one year analytic horizon for the eight weeks of basic training. Next slide please.

In terms of amortization, we used 1996 dollars and used a five percent discount or inflation rate. Our screening assay that we considered was an ELISA-STAT antibody test, with an 86.1 percent reported sensitivity and 98.6 percent specificity. The military cost for the screening test was \$11.24 per test. Next slide please.

It's important to note that the sites and

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timing of screening component was very important in the timeline regarding protective antibodies that were induced and also in administrative costs, and I'll cover that in a little bit more detail in the following slides. Next slide please.

If we were to take a look specifically at the timelines for antibody protection offered by the different strategies, let's take a look for example at screening occurring at MEPS. If the first dose is given within 48 hours -- we assume that the first dose will be given within 48 hours of IET. Preventive antibodies will not be assumed to occur until at the end of week four.

Individuals are thought to be susceptible to infection up until week four and given an average two-week incubation period later, symptoms would not be prevented or disease -- we would not be able to see disease until -- or prevent disease until the end of week six. Next slide please.

If we were to screen at the Reception Battalion during IET, in other words the very first week that they're in individual entry training, then what would happen is that their first dose would be delayed. They would be getting that first dose

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differently from all the other vaccinations that they receive during the first week, and therefore, prevention of symptoms would not occur until week seven.

With universal vaccination and no screening, the first dose would be given at the same time that all the other vaccinations would be given, and the disease would be prevented after six weeks. Next slide please.

This covers it in a little bit better detail. You can see at the top the distribution of varicella hospitalizations by week of individual entry training. You can see that the first month's distribution is there and the second month's distribution is there.

If we were to screen at MEPS and then begin the immunizations at the first -- at the start of individual training, the recruits would be susceptible to infection up until about week four. So the propagation from person to person of varicella would continue, and we would not be able to really prevent any symptoms or disease until after week six.

Next slide please.

At IET everything stays the same except

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that the screening and the immunization would be delayed one week. So screening would occur at the first week of IET, and then the first shot would be given one week later. Subsequently, varicella would not be prevented until after the seventh week. Next slide please.

We're going to cover now the cost of the vaccine. It's a two-dose schedule. It induces protective antibodies in 75 percent of individuals at four weeks after the first dose and in 99.7 percent at four weeks after the second dose. This was taken from the package insert from Merck.

The cost of the vaccine is \$29.75 to the Army, and with the ancillary supply storage costs and the cost to administer the vaccine, the total cost for the Army was \$31. Next slide please.

Other administrative costs which I'll have to go in a little bit more detail also. Given what you saw with regard to the graphics in terms of the different screening strategies, if we were able to screen at the MEPS and immunize at the Reception Battalion, there would be minimal time and cost to add varicella vaccine to the myriad list of other vaccines the recruits are normally going to get anyways. So

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basically that first dose does not require any clinic visit and would -- and the cost for that visit would be zero, minimal. However, the second dose would require a clinic visit at \$58, and this was a pretty conservative figure.

If we were to screen at IET in the Reception Battalion, and so therefore the first dose would be given at a different time in the middle of training cycle, that would require a clinic visit. So it would require two clinic visits at \$116. Universal vaccination would require only one visit because the first one would be given along with all the other vaccines. Next slide please.

Our morbidity estimates from the 1997 data was 21.6 per 10,000 recruit-person years. Given what Mr. Lee presented, this is consistent with the downward trend in the incidence rates that we've been seeing.

Since only 8.8 percent of new recruits lack protective antibodies, we actually calculated an incidence rate for susceptible recruits, and this came out to 41 per 10,000 susceptible recruit-person years or 4.1 per thousand.

Based on the time lag between

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immunizations, conferred protection would actually prevent only 32.6 percent of hospitalized varicella cases with the MEPS screening strategy and only 16.4 percent by the IET screening strategy, the last week -- prevention of the last week's worth of hospitalizations. Next slide please.

For our vaccine adverse events and costs we considered mild to moderate adverse events, but the CEA model included only generalized varicella-like rash which was estimated at 5.5 percent and which would require one-day hospitalization for hospitalization of \$659.

There's a statistic for fevers, but since we assumed that most of the people experiencing generalized varicella-like rash would experience 100 percent of the time most likely fevers, we subtracted that to get our estimate of uncomplicated fevers. That was estimated at around five percent, 4.7 percent. These would be admitted differently and would be admitted in a minimal care type setting for one day observation. That cost is conservatively estimated at \$105. Next slide please.

With regards to the military training costs, we included the operations of the military

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installations and the training programs, the cost of lost productivity, direct training costs, indirect training costs, for the total training cost per day of \$139. Next slide please.

Our estimates for the medical cost savings from the varicella complications included the complications due to the varicella pneumonia, secondary bacterial infections, and varicella encephalitis. Those were the incidence rate for those.

Cost considerations for these diagnoses were taken from three ICD-9 codes and our estimate used an average bed day cost for 7.3 inpatient stay of \$672 with an outpatient visit at \$58. Next slide please.

The medical cost savings from varicella deaths were also estimated with reports as high as 3.1 per 10,000 infections, and up to 10 to 30 percent of complications resulting in death we estimated a cost of \$1,000,000, assumed for any varicella death regardless of age or sex. Next slide please.

Our results. Basically if we take the no intervention strategy, if there was no varicella prevention program in IET, 36 cases of varicella would

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develop, costing \$5,028 in medical costs and training costs per diseased individual. A total cost for the strategy \$181,000. Next slide please.

If we took a look at the IET screening and vaccination strategy, which would be delayed by one week, this would prevent four cases of varicella, .13 complications, .03 deaths, for a total cost of \$3,436,000. It would cost \$255,000 over no intervention strategy and would represent a cost of \$813,750 per varicella case prevented. Next slide please.

If we look at the MEPS screening and vaccination strategy, which is more cost savings because the first dose could be given with all of the other vaccinations, it would prevent an additional three cases of varicella, .010 complications, and .02 deaths, again, additional over the IET. The cost of the MEPS strategy would be \$2,915,000, saving \$521,000 over the IET strategy, but it would cost \$2,734,000 over the no intervention strategy and would represent a cost of \$390,571 per varicella case prevented. Next slide please.

The universal vaccination strategy was very expensive. It would prevent an additional two

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cases of varicella over the MEPS strategy. The cost of the universal vaccination strategy would be in excess of \$18,000,000, costing \$15,000,000 over the MEPS strategy and would cost \$18,592,000 over the no intervention strategy. It would represent a cost in excess of \$2,000,000 per varicella case prevented. Next slide please.

We did sensitivity analysis and ranged the values of the variables in the model. Ranging the values of the variables do not result in significant changes in the cost-effectiveness strategies. Even if the cost of vaccine and vaccine administration were decreased to zero, even if the risk of vaccine side effects approached zero, even if the cost of screening approached zero, even if the hospitalization costs per day were increased to \$1,000 and \$1,152 for the complications -- next slide please -- even if we vary the probability of varicella complications higher, even if varicella cost for a death were increased to one billion dollars per death, even if the vaccine was 100 percent effective or the screening assay were 100 percent sensitive, even if the incidence rate per susceptible recruits were increased by four times.

We also conducted multivariate sensitivity

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analyses and they had basically similar results. Even if the adverse events decreased to zero, even if there was no cost for the clinic visit, and even if we assumed 100 percent protection with receipt of the first dose, the results of our cost-effectiveness analysis model was not changed. Next slide please.

So to discuss why we -- we were very excited when we first began this because we thought we would be looking towards recommending a screening strategy and a vaccination strategy or maybe a use questionnaire, but basically our cost-effectiveness model was significantly affected by the following overriding factors:

We're talking about the cost of screening for 93 percent of a population that are already immune. The cost of vaccinations and vaccination adverse events are not insignificant, and the delay in immunogenic protection is not going to be able to prevent disease until late in the eight-week cycle, probably in the last one or two weeks.

Now, there have been previous cost-effective analyses in the literature modeled, and they modeled much higher incidence rates. They modeled higher incidence rates in health care workers and in

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children. Next slide please.

We were conservative in our approach to therapy of vaccine adverse events because of the close training environment in IET. In other words, you can't very well leave a recruit by himself if he's got a generalized varicella-like rash or fever, and they need to be hospitalized.

On the other hand, the same could be said if we considered the varicella disease. So we accounted for that also because if a recruit came down with varicella disease, they would also be hospitalized.

We did not model benefits from possible readiness issues or from recycling of training sessions. Now, this could be important if, for example, there was a major war that we were involved with and there was a significant need to increase the number of trainees that would be processed, and in that case any kind of an outbreak would pose serious operational concerns. Given what Commander Ryan had previously pointed out were concerns for a ship far away, these operational concerns must be considered.

There may also be additional benefits beyond the IET, and in the paper that we're going to

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be submitting for publication, we took a look at this.

Basically, there's about a 25 to 30 percent turnover rate in the Army. Either as a result of retirement or ETS'ing or medical discharges, there's about a 25 to 30 percent turnover in the U.S. Army.

If we instituted an IET vaccination program, after about seven years you would get to the point where all of those non-immune people in the regular Army would leave, and they would be supplanted now by immunized recruits. So over a period of seven years, IET vaccination strategy might -- would result in about 99 percent protection of the active duty force in the Army.

Now, however, this might be negated by continuing downtrend in incidence rates that we're seeing. If we continue to see the downtrends that we've seen in the Army, Navy, or the Air Force, then the effectiveness may be negated because the recruits would be coming in immunized already or protected anyways. Next slide please.

Doctor Ryan already discussed the use of questionnaires. They've been equivocal, and she's covered that in detail already.

Again, we wanted to emphasize that despite

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the fact that we could potentially target some of the high-risk groups in the island home of records, this would set us up for medical legal problems. So we really couldn't go into a policy issue with that kind of a strategy.

And lastly, it may be a little bit early right now, but given the ACIP recommendations for the use of varicella in the pediatric populations, there is reason to suspect that the incidence rates in IET and in the Army may continue to decrease.

So our conclusion is that given the review of the epidemiology of varicella which Mr. Terry Lee presented, and based on the results of our cost-effectiveness analysis for currently available screening and immunization strategies in IET, we conclude that at least in the Army, an Army-wide policy for use of varicella vaccine is not warranted.

Now, this does not mean that we're not looking at the possibility for certain occupational groups like the health care workers or other operational concerns, but for right now, as it stands, this is the recommendation that would be given to Medical Command. I'm open for questions.

DR. PERROTTA: Doctor Sokas.

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DR. SOKAS: One is a comment that I don't think anyone here -- it seems unlikely that we would want to immunize universally against something that 93 percent of the people are already immunized. So that's kind of to the side there. But my question really has to do with the striking difference in your conclusion to what Commander Ryan presented, and the two questions I have are she apparently has a much difference cost for the serologic screening, and she's also managed to insert the screening and the immunization process into existing visits, and I was wondering if any attempt had been made to try to replicate that with the Army in terms of your cost assessments.

LIEUTENANT COLONEL NANG: Ma'am, if you recall from my discussion in the multivariate sensitivity analysis, even if the cost of screening were to decrease to zero and even if our results were still robust. In other words, what I'm saying is that we considered all those issues. The biggest problem had to do with the fact that there was, for the Army anyways, the incidence rates were still very low, and it was just too expensive.

DR. PERROTTA: Doctor Stevens.

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DR. STEVENS: I feel like I'm sort of in a schizophrenic situation here. I'd like to know what the explanation is. There's something bizarre about hearing a couple of presentations where you not only present a disease but you've saved money and now a presentation where there's no way you can save money.

Something's wrong. One of the issues I guess is it looks like your analysis, at least my understanding of it, talked about the prevention of disease only in that recruit period or initial entry period. Of course there's going to be a spill-over to the whole rest of the period in the military in terms of prevention of disease, and I suspect that may be part of the explanation.

I wonder also if there isn't some efficacy earlier than what you've calculated during the recruit period.

LIEUTENANT COLONEL NANG: Well, part of it also may have to do with our comparisons of adverse events and the need to treat or hospitalize those adverse events. Commander Ryan didn't report any, and that may be with what the Navy experiences. Our expected concerns for and treatment for adverse events is different, and I don't see --

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DR. STEVENS: Seems like you got to get the two together and get some reconciliation.

DR. ASCHER: Look, turn the problem around a little bit. Turn the problem around a little bit. We first discussed this at great length. The issue of preventing in basic is very, very difficult because of the fact they're incubating. But look at this from an HMO perspective. The Army's an HMO. They're taking people in, and now they're responsible for their medical care. A hundred thousand recruits, seven percent are susceptible. That's 7,000 susceptible people. Would you justify, if you're running that HMO, immunizing those people for their long-term prevention of cost to the system. That would be the question. That's 7,000.

The number in basic is piddling. I think that would be the argument, that the total burden on the system of those 7,000 for their time in service is considerable, and then they're spread to secondary cases and, you know, all of that. And that's where we're dealing with the state with our HMOs, and they say yes. At this rate they're doing it.

DR. PERROTTA: Doctor Seward.

DR. SEWARD: I have some problems with

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many of the assumptions you used in your model. You know, firstly, I think waiting four weeks -- I mean, antibodies are produced in the first week. In fact, this vaccine is effective if given after exposure, very effective. So I think -- I mean, you can conclude protection a week or definitely two weeks after immunization, not wait for four.

I think basing the whole epidemiology on hospitalizations is -- you know, we've all talked about the fact that that may not reflect the full burden of disease in the service, and I know you varied things in your sensitivity analysis, but would you really hospitalize somebody with a rash with 10 lesions? I mean that's what you're talking about, generalized rash after vaccination, five lesions that you can hardly see, you're going to put somebody in the hospital for that for a day?

I mean, I think a lot of your assumptions are really -- you've erred on the side of being very conservative.

LIEUTENANT COLONEL NANG: If I could address those two issues that you talked about. Number one, in terms of the concern that you had about the elicitation of antibodies after four weeks post

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the first, we understood that, and that's why in our sensitivity analysis, multivariate sensitivity analysis even if we assumed again -- I want to emphasize, even if we assumed again that 100 percent protection was conferred by the vaccine after the first dose, immediately after the first dose, our results were still robust. So I want to address that first issue.

The second issue had to do with -- I'm sorry, what was the second point that you mentioned?

DR. SEWARD: Basing the whole thing on the epidemiology of hospitalizations.

LIEUTENANT COLONEL NANG: Right. There are certain things that given the -- given the directives and the issues with regards to recruits in the training environment, there are certain things that have to be done in terms of hospitalization for recruits or there need to be seen by a physician. These are sometimes beyond what may be common sense in terms of what you would do if you were trying to go see a doctor by yourself.

But when individual drill sergeants are in charge of hundreds of people and they can't make sure and spend the time because they have to go into an

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hour-by-hour training environment, they have to send them to be properly taken care of by --

DR. SEWARD: Yes. It's not that point. The point is I think your rates may be much lower than your actual rates are overall in the Army because you're basing it all on epidemiology of hospitalizations and not cases.

DR. PERROTTA: Doctor Atkins.

DR. ATKINS: I had a question about -- I mean, I think under the assumptions you've made it's not surprising it comes out like this because you've assumed you're only preventing about 20 percent of cases in a small window, which -- of an uncommon disease. But I -- and you say you used a one-year time window. I guess I'm a little unclear about that.

Presumably the benefit of immunizing people in that eight-week window is because you said 40 percent of the cases occur in that first year, and a lot of those cases that occur three, six, nine months out are presumably prevented by immunization. And you also have the ancillary benefit that those are often the index cases that transmit the disease to people who have been in service longer and are susceptible.

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It's not clear to me did you really calculate the prevention of those cases that would occur after the eight-week basic training?

LIEUTENANT COLONEL NANG: Yes, we did. We didn't do a cost-effectiveness analysis model for the active duty Army because that -- but we did take a look at that, and we calculated for example the delayed post-one-year analytic horizon, the delay in benefits to be derived by the active duty population with regards to the supplanting of the turnovers that would be supplanted by the immunized recruits. So we did take a look at that, sir, and, again, as I pointed out, that is one of the limitations of the study because this was, again, a cost-effectiveness analysis of an interventional strategy for varicella for IET.

So whether or not there would be additional benefits to be derived from the active duty population, that would be another analysis that would need to be done. But, again, I would like to point out that if we're talking about it's seven percent, if the rates continue to decrease and if the ACIP recommendations for coverage of the pediatric population is successful, then our estimates would actually become more robust.

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DR. ATKINS: That's a valid point, but it seems that the first question should be how many cases would occur in that one year and what proportion of the cases in that one year could you prevent, and it's clearly going to be more than 20 percent because presumably all the cases that occur, you know, eight weeks and on out, you'd prevent all of those. It's not surprising you're not going to prevent a lot of the cases that occur in those first eight weeks, and the Navy has shown that, that you don't prevent all of those with their programs, but they saved money because of presumably by preventing other cases.

DR. PERROTTA: Doctor Stevens. Let's wrap it up.

DR. STEVENS: Yes. I wanted to go back to a point I think I heard Doctor Seward make earlier, which was as I heard you say sort of in passing that you would expect more susceptibles over time with immunization program in place. Could you comment on that further, because I think you said something just the opposite?

DR. SEWARD: Yes. As children get immunized, the ones who aren't are going to have less chance of being exposed until you get coverage up to

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around 90 percent plus across all age groups. So you're going to have a time where cohorts are moving forward that are not exposed and haven't been vaccinated. So I think temporarily you'll see an increase in susceptibility in recruit-age entering recruits. And catch up on vaccination is good.

DR. STEVENS: That's what I thought you said, and I wanted to come back to this because I don't think you can assume that with civilian immunization programs that you're going to have less and less susceptibles necessarily in the military.

DR. SEWARD: No. I mean, when states have a middle school requirement in place, then that may change or catch up vaccination is good.

DR. ASCHER: Dennis, a point of clarification. Dennis, a point of clarification. From the original discussion in '95, we were presented not with a concept of preventing disease in IET in the first wave of people coming in. You can't prevent incubation. But if you immunize when they hit the IET with screening, you prevent those initial cases from spreading to other recruits, which has the potential to happen and which was the problem they were facing.

Now, the fact that isn't happening doesn't

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mean it can't happen or won't happen, and it's a potential that's very serious. And so if your experience is now I'm not getting a lot of varicella in basic training, so what? That's not happening, but tomorrow it definitely could happen, and you have a strategy to prevent it.

And then if you take those numbers and say what does it happen if you spread to that seven percent. If everyone of the seven percent get it, how many cases have you prevented? That's much more than what your experience is. So I'm saying that the potential for all susceptible recruits to get varicella in basic is a huge number. It's much larger than your actual experience potentially. Is that clear?

DR. PERROTTA: Yes, and that ties in with the use of hospitalization data which is a reasonable thing to use, but we're learning this morning, those of us who don't know it already, that's susceptible to the vagaries of who gets hospitalized and what's the real cost of that hospitalization and all that. So that makes it even more variable.

I like all this stuff, but I think I do need to move on for our last presentation this

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morning, and, Doctor Seward, if you'd talk about the ACIP recommendations.

DR. SEWARD: I was so focused on the recent ACIP changes to the recommendations that occurred in February that I just prepared slides for that, I'm sorry. I thought I was being asked to present on the updated ACIP recommendations. So verbally I will just quickly give you the general ACIP recommendations that have already been presented by some other speakers today.

The vaccine, as you know, was licensed four years ago and was available through the federal contract a year later. ACIP recommendations were passed in June, 1995 and became effective from that date, although they weren't published until the following year. And the vaccine is routinely recommended for children in infancy at 12 to 18 months. It's a routine recommendation, and then it's recommended for catch-up vaccination of children 19 months through 13 years. So every child should get varicella vaccine.

For persons older than 13, so people greater than equal to 13 years, the vaccine is -- was recommended for those at high risk of exposure to

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people with severe disease. So that was health care workers and family contacts of immunocompromised persons, and then it was should be considered for people at high risk for exposure, but that was changed in February, and I'll give you that update now.

Contraindications and precautions, probably you're familiar with those, but just quickly, if you're allergic to any vaccine components and gelatin and neomycin are the two major components that you need to worry about. There's no egg in the vaccine. Any moderate or severe illness, high fever you shouldn't vaccinate. Immune-compromising conditions, there was a change in that that I'll go over in a minute as well at the recent ACIP meeting, but children with acute lymphocytic leukemia can get the vaccine under protocol, and then you shouldn't vaccinate people during pregnancy. You should wait one month after pregnancy to vaccinate, and then there are precautions for waiting five months after receiving any blood products or immunoglobulin, and people on systemic steroids that can produce immune compromising conditions should not get this vaccine.

So now I'll just give you an update in the recent changes in the ACIP recommendations because

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they are definitely applicable to today's discussion.

Next slide.

The vaccine just -- I'm just going to give you a little overview to put the recommendations in perspective. There've been 14,000,000 doses used of the vaccine until the end of last year. So I would guess that there's over 15,000,000 doses now that have been used, a little more in the private sector than in the public sector. Next.

Coverage among children 19 through 35 months through the National Immunization Survey has slowly and steadily increased from 14 percent the first quarter that it was available in the second quarter of '96 to 39 percent in the second quarter of '98, but that's nine months ago. So I would guess that it's well over 40 percent at this point, but we're still a fair ways from the Healthy People 2010 goals of over 90 percent for this age group. Next please.

Now, there's been three post-licensure effectiveness estimates conducted in the field that shows that the vaccine is very effective. It's performing very well in the field with vaccine effectiveness estimates ranging from 86 to 91 percent

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in three different studies. Two were child care center outbreaks, and one was a case control study conducted in pediatric practices. Next please.

So at the recent ACIP meeting, there were some additional recommendations made for the vaccine, for child care and school entry, and these were based on the fact that, as you know, varicella is a childhood disease. These are data from the National Health Interview Survey showing incidence by one year age interval, showing that most children get varicella in the preschool years or in kindergarten and first grade, and incidence drops dramatically by the time they're seven. So you're going to have most impact if you get children in the preschool and early elementary years. Next please.

Draft, Healthy People 2010 goals for varicella have coverage goals of 90 percent, over 90 percent for children 19 through 35 months and greater than 95 percent coverage for school entry, and those goals won't be achieved unless states put requirements in place.

So the ACIP voted -- updated their recommendations in February to suggest that all states should implement requirements for children entering

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child care facilities and elementary schools and that they should consider implementing a requirement for middle and junior high school entry. And if there's evidence of varicella vaccination, a physician diagnoses a varicella -- a reliable history of varicella or serological evidence of immunity, a child obviously doesn't need vaccination.

The next thing the committee considered was use of varicella vaccine for outbreak control and use post-exposure. And just background information on this, the vaccine's been used in Japan since 1974, and they've done a lot of work in Japan on post-exposure use of the vaccine. It's a live attenuated vaccine. It's very similar to the Merck product. There's not very much difference in how these things are made, and also there was some work done in the United States with the previous formulation of the vaccine, and these all showed a high effectiveness if the vaccine was used within five days of exposure using vaccine doses lower, similar to, or higher than the ultimate vaccine licensed in the U.S. Next slide please.

This slide shows the range of the currently licensed vaccine. The blue shadowed area there shows that the vaccine ranges from a minimum of

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1350 platforming units. When it's reconstituted, up to 10,000 platforming units, and this graph is from a study done in Japan showing that the vaccine, the effectiveness per exposure depends on dose, but it also depends on timing since vaccination. So doses lower than the Merck vaccine currently licensed were effective if they were given within three days of licensure, but doses much below 500 PFUs were not effective, and then after five days, although numbers were small, doses in the current -- in our licensed vaccine range were not effective. Next slide.

So some unpublished data that's just been submitted for publication actually from a homeless shelter in Philadelphia where there was varicella cases and 52 exposed susceptible children less than 13, vaccine was given to all these children 36 hours after exposure, and only two cases of varicella -- or two cases of very mild rash, 15 lesions each, occurred in two out of three siblings, and the one child who escaped vaccination because he had an erroneous varicella history at three months had a full-blown case of varicella. So the vaccine was 95 percent effective in preventing disease in this setting and 100 percent effective for prevention of severe

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disease.

As the Army has found in using it in Fort Knox, it is quite effective in preventing disease after exposure. Next slide.

So the ACIP voted -- recommended the use of the vaccine in susceptible persons following exposure and also recommended the vaccine for outbreak control and suggested that states could use it for outbreak control by -- you know, they didn't have to run out and vaccinate because they probably don't have the resources to do that right now, but they could at least send letters to parents and things like that.

The third area was varicella among adults, and this is what's applicable to this discussion today. And, as you know, adults have a higher risk of hospitalization and death compared with children. Outbreaks may occur with lower levels of susceptibility, especially in closed settings.

CDC over the last 18 months has helped the Coast Guard, an INS detention facility, many correctional facilities, and states probably with about 15 outbreaks in adults in closed settings, and susceptibility has ranged from three to about eight percent. So outbreaks can occur with three percent of

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people susceptible, adults in closed settings.

And then we've also -- there's varicella deaths are notifiable now, and they're nationally reportable, and we've had reports of deaths of healthy fathers who've gotten chicken pox from their children.

And so with that in mind, the ACIP voted to change the recommendations for vaccination of persons greater than 13. So the vaccine is now recommended. As Captain Trump pointed out, the wording differences between is recommended and should be considered is considerable or it is used as such by whoever uses these recommendations. So it's now recommended for persons at high risk for exposure, and that includes people who live and work in environments where transmission can occur such as the military.

And there was an addition to this high-risk group. The former groups are listed there, but men living in households with pregnant women or children were added as a new group to this high-risk-for-exposure group.

Then there were changes in the recommendations for immune-compromised persons. Previously the vaccine was contraindicated for persons with primary or acquired immune deficiency. The ACIP

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now recommends that varicella virus vaccine is contraindicated only for persons who have T-cell immunodeficiency.

And then on the basis of results from a trial of the vaccine in HIV-positive children, it was a small study, 41 HIV-positive children with a negative varicella history and negative antibody and CMI responses, they were in asymptomatic CDC stage one with CD-4 four counts greater than 25 percent, received vaccine, and they got two doses of vaccine three months apart. Results were that the vaccine was safe and effective, more reactions than you would see in immunocompetent children but not nearly as much as you see in children with leukemia, and they didn't form as good an antibody response as immunocompetent children but pretty good CMI responses, and as far as exposures have been followed, the effectiveness was very good.

So on the basis of these data, the ACIP recommended that the -- based on these limited data weighing risks and benefits -- and children with HIV do get more severe varicella, and if they've had varicella have a higher risk of getting recurrent herpes zoster. So weighing risks and benefits, the

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vaccine should be considered for these HIV-infected children in CDC class one asymptomatic with CD-4 counts greater than 25 percent.

And, lastly, although these were not recommendations, they were updates on safety that were presented to the committee. There've been three -- there were 6,580 VAERS reports received in the first three and a half years of use of the vaccine. Most common reactions were rash and possible vaccine failure. The serious adverse reporting rate was 2.9 per 100,000 doses. And serious adverse events include, as you can see, the herpes zoster, encephalitis, pneumonia, thrombocytopenia, seizures, and death. There had been 14 deaths notified to VAERS, but essentially all of them had definite or plausible other explanations or insufficient information to determine causality but certainly did not look like varicella deaths.

Updates on safety, herpes zoster due to the virus, reporting rate after vaccination 2.6 per 100,000 doses compared with a rate of 68 per 100,000 for children less than 18 in a community study. However, that comparison should be viewed somewhat cautiously because there's been less follow-up time

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for the vaccines.

However, in leukemic children, the rate of herpes zoster was much lower, and so we do expect that it will be lower too in immunocompetent children. Notably though, some cases of reported herpes zoster after vaccination if there's been strain identification of a rash, a number of the cases have been due to wild virus. So there can be antecedent wild virus infection before vaccination. Last slide.

Transmission, everybody is interested in transmission. It's very rare. There's been three documented cases with 14 million doses of vaccine distributed. That doesn't mean other cases haven't happened, but there's only been three documented cases, and they're all from healthy children. One happened to be to a pregnant mother who elected to have an abortion. Fetal tissue was negative for varicella vaccine virus, and there were no adverse consequences in the other two transmission settings. So transmission has never been documented in the absence of a rash post-vaccination.

So, in summary, the ACIP recommends the vaccine routinely for children and now recommends the vaccine for adults at high risk of exposure to people

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who may get severe disease and adults at high risk for exposure, which includes most adults actually.

Questions?

DR. PERROTTA: Any questions for Doctor Seward? Captain Trump.

CAPTAIN TRUMP: Just for the record, I'm not sure Doctor Seward introduced herself. She's the Chief of the Varicella Activity with the National Immunization Program at the Centers for Disease Control and was interested in coming. So I drafted her to do this presentation.

DR. PERROTTA: There is a question. Doctor Poland.

DR. POLAND: The issue with men living in a household with children, is that with children or with susceptible children?

DR. SEWARD: We didn't get into the difference. I mean, I think it would be susceptible children I guess, but I think we didn't differentiate.

I mean, I just think it's good for any adult around young children. I mean, other children may come into their household. I mean, we're getting frequent reports of deaths in healthy moms and dads.

DR. POLAND: Could you put a number on

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that when you say frequent?

DR. SEWARD: Well, of the adult deaths -- I mean, 100 deaths occur a year from varicella or they did before the vaccine was licensed. That's data from death certificates. Death surveillance is just starting now nationally, and it's nowhere near complete, but of the death reports we receive -- and, as I said, it's just starting. So we've probably had -- we've had 12 death reports since surveillance started. Six of those are from Florida, and that will be published in an NMWR next month. Six of the deaths in Florida, four were in adults, and one of those was a healthy father exposed to his children. One was a healthy 21 year old exposed in a family day care setting, and two, the other two adults were older, and they were both from Cuba.

DR. POLAND: So it's been reported?

DR. SEWARD: Yes.

DR. POLAND: I might not have used that modifier. The last question is you said that transmission of vaccine virus had never been reported in the absence of a rash?

DR. SEWARD: In the absence of a rash post-vaccination.

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DR. POLAND: Is that true in the study of leukemic children who got vaccine? I understood there were.

DR. SEWARD: No. I mean in immunocompetent -- well, let --

DR. POLAND: So in immunocompetent recipients?

DR. SEWARD: Yes. I don't want to get into that study. I don't know if you want to comment, Christina. There were certainly questions with some problems with that study.

DR. CHAN: My name is Christina Chan. I represent Merck. In leukemic studies that we have done the vaccine, a secondary transmission only occurred with the one that have a rash post-vaccination, but no secondary transmission has been noted in people that did not have a rash.

DR. PERROTTA: Let's close up with Doctor La Force and then Doctor Ascher.

DR. LA FORCE: Short question. The varicella-related deaths were with antiviral chemotherapy as well?

DR. SEWARD: The reported deaths to VAERS?

DR. LA FORCE: No, no, the deaths in cases

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that were treated with antivirals.

DR. SEWARD: Yes, some of them were, the adults, but by the time an adult presents with respiratory distress, you know, with pneumonia four days post-rash, antivirals aren't going to do a whole lot.

DR. LA FORCE: As a clinician I respectfully disagree.

DR. SEWARD: Yes.

DR. LA FORCE: It works quite well.

DR. SEWARD: They were not given oral antivirals after rash. They were given IV antivirals when they got in the hospital. It wasn't effective enough.

DR. ASCHER: The phenomenon you mentioned where susceptibility will increase until vaccine becomes almost universal, is that something you would use as a stronger case for the military to immunize or it's about the same as any other population?

DR. SEWARD: I wouldn't use it as a stronger case. I mean, I would use it as a case for the military that you're not going to be able to stop varicella in closed settings. I mean, even with a small proportion susceptible, you're going to continue

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to have varicella outbreaks and cases unless you get a completely immune population. It's just so transmissible.

DR. ASCHER: But in the next few years, the incidence is actually going to go up of susceptibles, as you said.

DR. SEWARD: It may. I mean, the susceptibility may increase. They may not be exposed.

I don't know what will happen to the incidence. You know, those things --

DR. ASCHER: You could put some models out that could give you some interesting numbers of that in terms of cost benefit.

DR. SEWARD: Well, we hope incidence won't go up in adults. I mean, the whole purpose of the childhood vaccination program and catch up is to ensure that that doesn't happen. That's the scenario we don't want.

DR. ASCHER: Well, where this window of increased numbers of susceptibles occurs, you're saying you hope that they don't get infected --

DR. SEWARD: Yes.

DR. ASCHER: -- until the rest of the world gets immune. But I'm thinking in the military,

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as you're adding more susceptibles to these settings, you just have more possibility of outbreaks, and I would make it a stronger case.

DR. SEWARD: Yes.

DR. ATKINS: I mean the exposure -- exposure has to go down. I mean, even though we've only got 40 percent childhood immunization, that's still a 40 percent reduction in, you know, primary cases out there. So, I mean, some of the defining trend in hospitalizations may be real and would be expected to --

DR. SEWARD: No. That declining trend is not seen anywhere else. I mean, I've reviewed every bit of data in this country. I mean, Peter Chew's study from HMO in Boston, you know, incidence is much higher in adolescents reported there. A study Merck's done in California, much higher incidence in adolescents than you're describing in the military.

DR. ATKINS: But increasing trends? What do you mean by --

DR. SEWARD: No, there's no -- there's no trend data available. I'm looking at it right now from the National Health Interview Survey, and adult incidence is increasing before vaccine came out, not

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declining for sure. It's not declining. What you're seeing is very different from the rest of the available data.

DR. ATKINS: But why wouldn't you expect, you know, as there are fewer kids getting active varicella that adult cases will go down?

DR. SEWARD: Well, there will be. That will take a while. I mean, there's no evidence yet in surveillance data or maybe just this year we're seeing it. I mean, 40 percent of one cohort of children are immunized, it's still going to take a while for enough children to be immune for incidence to decline.

DR. SOKAS: Annie had an example where if you've got a whole classroom full of kids who are all getting it, it's so transmissible that you're exposed, you get it, and if you only have one kid in the class and you're susceptible, you get it. So it doesn't matter that you have 40 percent fewer kids in your class.

DR. ATKINS: Well, it depends if you're a teacher or a parent. If you're a parent who's susceptible and you don't have exposure to 70 kids but you have a lot of exposure to two --

DR. SOKAS: Well, unless you're a soccer

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parent. I mean, so that's the thing.

DR. PERROTTA: We can certainly continue this and its relation to Force protection during the meeting tomorrow. My official naval observatory time is sort of around 11 after. We're going to need every bit of 60 minutes. So let's start again after Colonel Diniega gives a couple of announcements, at 10 after 1:00, and we'll work with discussion time and remain flexible.

(Whereupon, a luncheon recess was taken.)

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

(1:20 P.M.)

DR. PERROTTA: Would you please regather for the afternoon.

COLONEL BRADSHAW: I'll just reintroduce myself once more. Colonel Bradshaw from the Air Force Medical Operations Agency. I'm the Chief of Preventive Medicine there, Preventive Medicine Officer representing the Air Force.

I just wanted to briefly put this slide up in regard to the secular trend we were talking about in hospitalizations. This is just Air Force active duty hospitalizations, rates per 1,000. But you'll notice that in general the hospitalization rate's been going down, and this is for a large number of diseases, not just varicella.

I just wanted to briefly show this slide to you so you could kind of see that it is a trend that we're dealing with as we kind of move to a capitated system, more managed care-like where we are trying to hospitalize fewer people. That's only probably one of the factors in the secular trend, but just to demonstrate what's at work here.

(Pause.)

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COLONEL BRADSHAW: Do you want me to read the question first?

DR. PERROTTA: Yes, please.

COLONEL BRADSHAW: All right. This question is on the use of inactivated polio vaccine or IPV for recruits and officer accessions.

"Request the Board review the available data and provide a recommendation concerning the use of inactivated polio vaccine in new recruits and officer accessions. Request the following courses of action be considered."

(a) is to continue present policy of a single dose of trivalent oral polio vaccine or trivalent OPV in all enlisted accessions and officer candidates or cadets, unless a previous adult booster is documented. IPV would be used as an alternative to trivalent oral polio in selected individuals when indicated according to the Advisory Committee on Immunization Practices recommendations.

(b) would be to change policy to require a single dose of IPV in all enlisted accessions and officer candidates or cadets who have not had an adult booster, unless the individual is considered unvaccinated and therefore requires full primary

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immunization with IPV.

The last course would be to discontinue routine polio vaccination of accessions, except for those without documentation of a primary series. Those individuals would receive a primary series of IPV. Adult boosters would only be indicated for travel to high-risk, endemic or epidemic areas.

Okay. Just to set up what we're going to talk about briefly here, we read the question already to the AFEB. We'll look at a little bit of the background on polio and polio vaccines. We'll look at the current policy that we're using in the military in the various services, and we'll talk about some of the issues relative to the different vaccine types and the problems with the vaccines, and then look at what the various options are and afford a little time for discussion hopefully.

The question has essentially been read, and the background is this. Polio has probably been around for a long time. Descriptions of lameness and descriptions that would be consistent with polio as a disease have been around since antiquity. It was first clinically described by Michael Underwood in Britain in the 18th Century in the year 1789.

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In the U.S. the first outbreak described was in 1843, and then actually the peak U.S. incidence was only in the last about 40 years or so. It was in 1952, at which time we had about 21,000 cases reported. Ever since then, for the most part the decline has been coming down considerably.

As far as the virus itself is concerned, it's an RNA enterovirus, a gastrointestinal virus. It has three serotypes. Being gastrointestinal, it's mainly spread by fecal-oral contact or route, although it probably has or can be spread by oral contact as well as it is resident sometimes in the pharynx during infection.

Incubation period lasts for about three to 35 days. Overwhelmingly only up to 95 percent of the infections are actually asymptomatic, and only about two percent or fewer actually go to the flaccid paralysis that we're familiar with as far as polio is concerned.

The virus is present in the stool in infected individuals for as much as three to six weeks afterwards where it will continue to be shed.

This just kind of demonstrates graphically how the cases clinically parcel out. The largest

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number of course are asymptomatic. There are a few that will have kind of very minor sort of illnesses with this, that being about five percent of cases. In about two percent, they may develop an aseptic meningitis, but without any other associated sequela.

They'll just have a stiff neck and a headache and some other symptoms. And then in about one or fewer -- one percent or fewer cases, you'll have the paralytic polio, and that can either be spinal polio or it can be a bulbar kind of paralysis in which case the mortality rate and other problems are increased.

The vaccines themselves, the first one came out in 1955. It was the inactivated or Salk vaccine, which is known as the IPV or the first version of IPV. In 1961 they came out with oral, two types of oral vaccine. This is the Sabin vaccine, and there was Types 1 and 2. And in 1962, Type 3 monovalent oral polio was developed, and by 1963 they had the trivalent vaccine that included all three serotypes for protection. Later on in 1987 they came out with an enhanced form of the inactivated polio vaccine.

Now, as far as epidemiology is concerned of the virus, the transmission of wild poliovirus in

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the United States, the last cases were actually in the year 1979, and that actually involved Amish communities throughout several of the states in the northeast and midwest, but there have been no further cases of wild poliovirus in the United States since then.

In 1991, in Peru was the last documented case of wild poliovirus in the Western Hemisphere, and as of 1994 I believe, we have been certified free of wild polio in the Western Hemisphere.

However, world-wide endemic areas still exist. These are predominantly in Sub-Saharan Africa, Indian sub-continent, and to a lesser degree in the Eastern Mediterranean areas.

This shows the secular trends for polio in the United States from 1950 or early period is when the peak was. You'll notice that inactivated vaccine occurred in -- or the use of inactivated vaccine occurred in 1955, and shortly thereafter the incidence of new polio cases dropped significantly. In 1960s the live oral vaccines were introduced, and since then the incidence of wild poliovirus has been pretty much flatlined. Last indigenous case shown there of course was in 1979 as we mentioned.

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Now, looking more specifically at what has happened in subsequent years, since 1980 up until the last year, there were 147 confirmed cases of polio in the United States. Of these, six were imported. They acquired the wild poliovirus outside the United States and then came back and developed their flaccid paralysis once they were back in the United States.

The remaining number of the cases, the largest majority, about 95 percent, were associated with oral polio vaccine administration. Inactivated vaccine of course does not cause polio, not being a live attenuated virus, and it's only the oral version which is a live attenuated virus that you get the vaccine-associated polio, and that's probably because of reversion of the live virus to a more aggressive form.

Now, what are the characteristics of the inactivated polio virus? Well, it is inactivated, and it's highly effective in producing serologic immunity and protection against polio, 90 percent immunity after two doses, 99 percent after three doses, which is the full series.

However, there is less local GI immunity. Now, this creates a situation where if somebody had

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been immunized solely with IPV, went overseas, that they could actually contract and enterically carry wild poliovirus and bring it back with them, but I don't know for sure of what cases have actually been documented as actually occurring that way, but theoretically I guess that could happen.

It has some advantages. It's not live. Therefore, when somebody's immunized with this, it's not shed in stool, and it can be safely given in immunodeficiency situations. As you're aware, the oral vaccine is not given to people who are either immunodeficient themselves or if there is someone in their household that is immunodeficient, it should not be given. And there is no vaccine-associated paralytic polio.

Disadvantages are of course it requires an injection which with kids and others is a little bit more problematic. You have to deal with the needles.

It is a bit more expensive than the other vaccine, and it's not sure how long this duration of immunity lasts if you only get the IPV.

In terms of the oral polio vaccine, it's live attenuated, trivalent viral vaccine. It is given orally. It is very effective also in producing

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immunity and protection. However, because it's trivalent, there is some interference between the different serotypes of vaccine, and so only 50 percent or about half are immune after the first dose. But after three doses, more than 95 percent are immune to all three serotypes. It does provide the local GI immunity, and that immunity is felt probably to be life-long as opposed to the IPV which we're not sure.

Of course the advantage is it's easily administered since it's oral, although you have to give it three times. It also has had the very good advantage in terms of the vaccine programs across the world in that it provides herd immunity through enteric spread to contacts, and that's actually been a useful characteristic when we've been looking at national vaccine programs. It's less expensive, as mentioned, than the inactivated polio vaccine. However, it does carry this risk of vaccine-associated paralytic polio, and I already mentioned the interference between the serotypes that requires multiple doses.

Now, what about the vaccine-associated paralytic polio? The overall recipient risk is about one in 2.4 million doses. The first dose risk is the

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most significant actually. It's about one in 1.4 million doses, and subsequent doses it goes up to one in 27 million doses. so it's mainly a problem of the first dose of the oral vaccine.

In terms of contacts of people who have had the oral vaccine, little bit higher -- or actually lower rate, but it does occur, 1.71 in 7.6 million doses. Again, this is also a higher risk in the first dose, one in 2.2 million doses, and subsequent doses again that goes up similar to what happens in the recipient risk.

Again, probably the reason for this first dose higher risk is that in a non-immune individual that gets the oral vaccine, they probably have prolonged carriage or prolonged shedding of the virus, and that allows more time for there to be replication of the virus and to allow reversion to occur to a more aggressive form of the virus rather than remaining attenuated.

Another fact that we should note here is that the risk of vaccine-associated paralytic polio increases with age. It's much higher for individuals over 18 years of age.

This just kind of shows how it plays out.

Again, the majority of people that would be getting this or be associated with someone who gets this would be healthy, and that is where you see most of the vaccine-associated paralytic polio.

However, immunodeficient people are much more at risk, and so they're probably disproportionately represented here in that respect.

Now, current ACIP policy and APA policy are these. They recently changed the schedule from an all oral polio schedule to getting the first two doses as the inactivated polio vaccine. With the third dose and the dose at age four to six years being the oral polio vaccine. The reason for that being that with the first two doses you get a significant degree of immunity using inactivated polio, and that hopefully protects you against the prolonged replication once you get the third dose of OPV. And so they're feeling that gets over that first dose effect where you have the higher incidence of vaccine-associated paralytic polio, but you still get some of the advantages of the long-term OPV life-long immunity and herd immunity situation.

Now, in terms of this, they are looking forward to actually going to an all inactivated polio

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vaccine schedule by year 2000. And so that's the current thinking is that they are going to do away with this hybrid schedule and go to an all IPV schedule soon.

The adult booster is recommended only in those that are for risk for travel. IPV because of the reasons we mentioned is preferred in unvaccinated adults with no primary series, and also IPV is preferred in immunodeficient households, either for the individual or if somebody's in their household that's immunodeficient.

Now, the current service policy as contained in the Instruction on Immunization and Chemoprophylaxis, for most of the services except for the Coast Guard, all recruits get trivalent OPV. The Coast Guard actually gives it to all their active duty the way it reads in the current regulation -- or instruction.

Officer accessions also get trivalent OPV unless they have documented a previous adult booster, and other boosters will only be given for high-risk travel.

IPV as an alternate OPV based on the ACIP recommendations that go beyond what we previously

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mentioned. The problem being, however, is that many recruits do not have shot documentation. So in effect, you almost have to consider them as being unvaccinated adults. At least they don't have documentation of that.

In practice, however, I think we just assume that they haven't, and the technicians, at least in the Air Force, most often just go ahead and give them the oral polio vaccine, and that's part of the reason that the dilemma was raised initially to us.

Now, these are some of the issues. Essentially all cases of polio in the U.S. since 1979 have been vaccine-associated paralytic polio, which is associated mainly with the oral vaccine. However, when you look at world-wide epidemiology, there's still 5,410 cases of documented polio in 1998, and that's statistics from the World Health Organization.

Many endemic areas also have civil wars. That prevents them from having national immunization days. It prevents them from having good vaccine programs. It also makes it more likely for us as a military to have to go in there and straighten things out as a police force.

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Polio also persists in other areas such as Bangladesh, India, Pakistan where maybe they're not having a civil war right now, but there are areas of the countries adjacent to places we might have to go.

This is just a map from the WHO that shows the current areas that have either known or probable wild polio virus which is the red areas, and then in the yellow areas are areas that the surveillance is insufficient, and they are considered high risk still or relatively high risk. The other areas is where it's zero with good surveillance and low risk.

Now, what are the options? Well, we kind of read these off before, but I'll go back over them.

We can continue the present policy, which is essentially routine trivalent oral polio to all accessions, and IPV as indicated in other situations.

We can change to IPV for all new accessions, either officer or recruit, and the last one would be go to basically what the ACIP recommendations are, which they consider everyone in the U.S. at low risk, so they don't recommend an adult booster, but if somebody's traveling to one of these countries or areas that we discussed or they're a health care worker or other reason to be considered

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high risk, then they would get an adult booster.

Okay. I'll leave it open to questions or discussion here.

DR. PERROTTA: Doctor Poland.

DR. POLAND: Dana, are there any documented VAPP cases in the military or on military dependents?

COLONEL BRADSHAW: Okay. What I attempted to do here was I looked at some of our databases, and the SIDR and SAID are the inpatient and outpatient databases. There are currently 69 records in the inpatient database that have a diagnosis of polio associated with it. About 30 percent polio might be the principal diagnosis, and that's from I think 1989 on.

The problem being is difficult to ascertain if those are old cases or incident cases, and I suspect, given that there's only an average of about eight incident cases per year in the U.S. at large, that it would be hard to believe that those were all incident cases.

From the outpatient database from the year of 1998 there were 59 reported outpatient visits that had an associated diagnosis of polio, and of those

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there might be 45 percent that that would be the principal diagnosis listed. But, again, it's hard to ferret out if these are old cases, people that have had polio for years and years.

So without actually going back and doing a record review of that, it would be difficult to say. I know as far as the Air Force reportable disease database, looking back through our database which extends back for almost a decade, we have zero reported cases.

DR. POLAND: And also, do you know anything about the cost differential to DoD?

COLONEL BRADSHAW: Of IPV versus OPV, I don't have the figures on that. I'll try and get those to the Board though.

DR. PERROTTA: Doctor La Force.

DR. LA FORCE: No. The question's been asked.

DR. ATKINS: With regard to that question, Dana, I mean, could you look at the age of the subjects to get a sense? I mean, if it's VAPP, wouldn't you expect it to be in new recruits?

COLONEL BRADSHAW: The person, the officer that I worked with was supposed to send the

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spreadsheet, but I didn't get it. He had about 28 pages I guess from the printout, but I'll look at that, and I'll try and get that information to you as far as what the age spread was.

DR. FLETCHER: When did you say the last case in the United States was reported?

COLONEL BRADSHAW: 1979.

DR. FLETCHER: That was in the Amish?

COLONEL BRADSHAW: Yes. That's the last wild poliovirus case.

DR. FLETCHER: Thank you.

DR. PERROTTA: Anything else?

DR. LA FORCE: Just wonder if it would be -- it would be hard for me to think that there's a problem unless you've been sued. Virtually every single vaccine-associated case is associated with a tort, and this is not a secret. You would know about this I would think immediately. This is why I'm faced with the sort of problem if it ain't broke, why fix it. My sense is there is no problem here, and -- because if there were vaccine-associated cases, you would have been sued. You'd know about this right away. Is my logic flawed?

DR. REINGOLD: But if in fact the U.S.

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civilian population has been moved to an all IPV schedule next year, then the military is going to have to do something in terms of either becoming consistent with that policy or deciding not to continue to vaccinate routinely all recruits. So --

CAPTAIN TRUMP: And associated with that transition, the expectation is that, you know, the oral polio vaccine will eventually be out of production because there won't be any demand for it. CDC is concerned about issues as far as, you know, should we have a stockpile of OPV in case there is reintroduction or some sort of outbreak and how that's accomplished because it -- so at some point the decision will have to be made about, you know, what we need to do.

As part of this transition to an all IPV schedule, they are revisiting the polio recommendations and in particular will be looking at things that apply to the military population such as the recommendation now for the adult booster of OPV for those who will be traveling through endemic areas.

I'm not aware of any discussion as far as how that recommendation might be going.

DR. MUSIC: I enjoyed -- this is Stan

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Music. I enjoyed your overview of this whole arena, but one area that I think needs some emphasis is that CDC working with WHO is now mounting a very smallpox-like effort in sending cadres of epidemiologists and others overseas to work on polio eradication over the next months to a couple of years. So I expect the global epidemiology to change significantly.

DR. ASCHER: And the reading that I get long-term is that OPV will be a BSL-4 agent.

DR. LA FORCE: Thought it would what?

DR. ASCHER: That's their -- I didn't make that up. OPV will be a BSL-4 agent. When the eradication is declared, the vaccine strain will be worked with only under the most extreme biosafety conditions, and it will be like smallpox, like you said.

DR. MUSIC: And the eradication won't be declared until quite a few years off.

DR. ASCHER: Yes. We won't have to worry about that this week.

DR. MUSIC: Is the WHO campaign using oral?

DR. ASCHER: Yes.

DR. MUSIC: So the supply problem

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shouldn't be an issue?

DR. ASCHER: Right. But then they plan on switching long-term and putting the oral away.

DR. REINGOLD: But, Stan, I guess the only -- I mean if the issue you were raising is that within a year or two all polio will be gone --

DR. MUSIC: No, no, just --

DR. REINGOLD: The cases may be gone, but obviously the issue of whether the virus will still be there in the environment in these countries is --

DR. MUSIC: Exactly. No, just that there was this major effort that somehow is going to accelerate a lot of decisions.

CAPTAIN TRUMP: But their projection with that effort is that in 10 to 15 years, we may be in a -- they would like to be in the position of saying that we're polio free and stopping immunization programs.

DR. PERROTTA: One more, David.

DR. ASCHER: Is the recommendation for a booster based on serologic data or is it based on clinical data of infection inadequately -- in people who've had an inadequate primary immunization?

COLONEL BRADSHAW: I'm not sure I can

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speak directly to that. Does anybody else know?

DR. LA FORCE: Yes. I know what the answer to that is. It is based on some unfortunate cases in missionaries that had received polio vaccine at a relatively young age and then as missionaries in their 20s or 30s went out, and there were a cluster of these -- Stan may remember these -- in the '50s and '60s -- no, actually it wouldn't have been the '50s. It would have been late '60s, early '70s, and it was at that time that it was decided that booster doses, particularly with OPV, if you were going to an endemic country should be done, and that's how that got all started.

DR. ASCHER: Do you think that still applies to the current cohort who have gotten newer vaccines?

DR. LA FORCE: I don't think so, but it is hard to argue against the level of success that this very simple initiative has. The incidence of paralytic disease is zero after institution of that very simple strategy.

DR. MUSIC: You made a statement, Marc, about the tort business, and I'm wondering if that in fact is true because of federal law and military law

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and maybe if there were vaccine-associated cases in the military or their dependents, there would be not the usual civilian tort response but something attenuated or do you guys get sued as regularly as happens in the civilian area?

DR. ASCHER: Well, there's a fund. I mean, it's not --

DR. MUSIC: I don't think the Federal Government, you're not immune from suits, are you?

COLONEL BRADSHAW: No. We get litigations. It's just they don't sue us as individual doctors. They sue the government.

DR. MUSIC: Right. They sue the government, and I think the federal protection under the Vaccine Compensation Act applies only to infants and doesn't apply to new recruits, and this is why I'm sure that there's probably never been a case of this in a recruit.

DR. ASCHER: Actually it applies to the product.

DR. POLAND: I think it's vaccine specific, not age specific. What you're thinking though is most all of the vaccines we think of as pediatric vaccines that are covered under the VICP

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schedule.

DR. LA FORCE: I was on the ACIP when this came out in '86 or '87, and to my knowledge, adult boosters were not covered, were not covered, because there were a whole phalanx of lawyers that were there in that room.

DR. ASCHER: We could ask them, we could ask the compensation people. (a) you'd find out if there are any cases and (b) if it's covered.

DR. LA FORCE: Correct. I'll bet there aren't, but it sounds like the policy sort of has to catch up with the times is the --

DR. POLAND: We're in this funny time warp where we maybe -- and I say maybe -- should continue a booster for what will likely be a short period of time before there's no need for it, and the question is whether to switch to yet another injection I'm sure a magnitude of order or two magnitudes of order higher cost and not knowing whether there are really any -- like you say, not knowing whether it's broken in the meantime.

DR. ASCHER: You already have a program. It's not like choosing between them. You're changing.

DR. PERROTTA: Anything else? Thank you

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again, Colonel Bradshaw. Appreciate that and that slide about AGE. I've got the gray hair. I get to say that. Anthrax Vaccine Immunization Program updates from our colleagues in the United Kingdom and Canada. First, Colonel Warde.

COLONEL WARDE: Thank you, Doctor Perrotta. First of all, I'd like to thank the Executive Secretary for going to so much trouble to -- painstakingly to translate immunization program into English for the benefit of the appropriate agenda, and you will see that I've been to equal trouble to translate it back again.

The text of this short presentation will be available before the Board meeting is over tomorrow. The program in UK began in March, 1998 when the British Government announced that anthrax vaccine is to be given by informed voluntary consent to protect armed forces and civilian personnel deployed to the Gulf region against the potential use of anthrax as a biological warfare agent.

The voluntary policy was adopted to comply with the ethical direction of the General Medical Council in the United Kingdom, in which all treatment is by patient informed consent.

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The UK vaccine is produced by the Centre for Applied Microbiology and Research, and the Department of Health holds the license. The vaccine is an alum precipitated cell free filtrate of strain 34F2 anthrax bacillus, rendered sterile by filtration and containing .005 percent of thiomersal as a preservative, and the culture is grown to maximize production of the protective antigen.

The dose regime, four doses of .5 milliliters should be given intramuscularly. The first doses should be given at intervals of three weeks, followed by a fourth dose at an interval of six months. Reinforcing doses of .5 mil intramuscularly should be given annually.

The vaccine was first used in 1963 and was licensed in 1976. The batches of vaccine used in the UK military program in 1998 were ampouled in 1991 and given a shelf life in common with all previous batches of two years. These ampoules were tested in October, 1996, and the shelf life was extended until January, 1998. The vaccine underwent potency testing by the National Institute of Biological Standards Control in January, 1998, and in view of the results, the Medicines Control Agency extended the shelf life

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to November, 1998.

It is not known how many doses were administered since 1976, but a total of 55 adverse reactions from 19 reports had been filed prior to the military program, all of a minor nature such as pain and redness at the injection site, some nausea, and some general malaise.

All personnel deploying to high-risk areas are briefed by a medical officer prior to immunization. After the briefing, individuals may discuss their concerns privately with the medical officer. All personnel also receive a briefing pack and a letter from the Secretary of State, and on completion of the briefing, personnel who wish to receive anthrax vaccination complete and sign the consent form and retain a duplicate of it. No disciplinary action is taken against those that decline the vaccine.

All immunizations are entered into the individual's medical record, and the Surgeon General maintains a database of all those that have been offered and accepted or declined the vaccine.

After each immunization session, medical records are cross-checked with the ampoules, and the

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number of those declining is recorded, and any adverse reactions are reported via both the National Medicines Control Agency yellow card system and up the medical chain of command.

Uptake has been disappointing. Thirty-four percent of those offered the vaccine have accepted it.

On the 2nd of November, 1998, the Government announced a temporary suspension of the policy with effect from the 30th of November, 1998. The reason was that the CAMR, the manufacturer, was unable due to manufacturing difficulties to supply new vaccine in time for the license expiry of the current stocks. It is hoped that the supply will be restored in early 2000. The issue is not one of safety, but of production and supply. And the suspension of the immunization program does not affect the ability or willingness to deploy forces, and this is because immunization is one of a range of protective measures available.

That concludes my presentation. If there are any questions, I'll do my best to answer.

DR. PERROTTA: Any questions for Colonel Warde?

COMMANDER HANSEN: The thirty-four percent that accepted, why so many declines? What are the reasons that Soldiers and Marines give for declining?

COLONEL WARDE: Any answer I give to that is speculative, and it is clear that there is a lot of uncertainty on the part of the individuals as to whether they should accept it or not, and I don't know the real -- the answer to that. Clearly people do -- are vulnerable to information which spreads far and wide as occurs in this country on safety issues. I'm sure that in people's minds there is an association with Gulf War Syndrome, although there are considerable differences in the way the anthrax vaccination was administered in 1998 compared with how it was administered during the Gulf War. People do have residual fears about that, and despite all the effort that was made to overcome those fears and to reassure people about the safety of the vaccine, which after all, has been used for a very long time with no severe side effects, people still opt to decline the vaccine.

When the supply is reinstated, I know that it is government policy to do better, and we have had images on the television screen of the Secretary of

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State and senior members of the government in public receiving their vaccine to reassure people. Whether it in fact does reassure people is very interesting to speculate.

DR. REINGOLD: Jerry Ford took Swine Flu vaccine on TV too.

DR. LA FORCE: May I ask if the same latitude is given for tetanus toxoid, influenza vaccine, or other antigens?

COLONEL WARDE: Yes. There's certainly no distinction in the principle of informed voluntary consent with any vaccination in the Forces. There are compulsory vaccinations in the Force.

DR. LA FORCE: And what's the -- may I ask what the take rate is for tetanus toxoid?

COLONEL WARDE: I don't know the answer, but I can try and find that out.

DR. LA FORCE: Thank you.

COLONEL WARDE: My guess it will be higher.

DR. ASCHER: The TBE, Marc, the TBE when we had both local commander option as a filter and consent was 25 percent less I think is in the ballpark, but there was the two filters, not the same

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exact situation, but definitely an informed consent issue, and it was definitely after the Gulf War.

DR. PERROTTA: Colonel Bradshaw.

COLONEL BRADSHAW: This is Colonel Bradshaw. Do you have some figures on your adverse reaction rate?

COLONEL WARDE: No, I don't. This information I believe is kept by the Surgeon General, but he has not vouch-safed it to me, and -- but the only information that I was given when I -- clearly I thought this question would arise, I said what is the situation, and it is -- the answer was that the adverse reaction rate does not cause any surprises or concerns, not very helpful to a meeting of epidemiologists, but --

DR. ASCHER: This is a dumb comment, but it has to be in the informed consent, what the rate is. You have to tell the person the number.

COLONEL WARDE: Yes. I don't believe that number has been given because --

DR. ASCHER: What Human Subject Committee reviewed this? It has some rate of reaction, but don't worry about it.

COLONEL WARDE: Yes, exactly right, and

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the reason is because nobody knew how many doses had been administered prior to the introduction of the program. We know that something like 55,000 doses of the vaccine were issued between 1976 and 1998, but the shelf life of two years accounts for by far the majority of that, and actually I think that the use of the general population -- as a veterinarian, I'm actually quite interested in this -- is relatively low, and it is not possible to be able to tell potential recipients exactly what the adverse reaction rate is.

DR. PERROTTA: Okay. Very good. Thank you, Colonel. Colonel Souter, from our neighbors to the north.

COLONEL SOUTER: I didn't come here today to upstage Colonel Warde, but I will be able to tell you a little bit about adverse effects in the Canadian program.

We have a somewhat different policy than the UK in terms of immunization in general to BW agents. We look at each operation, do a risk-threat assessment on each individual operation, and then at the Deputy Chief of Defense staff level or above, the decision is made as to what BW immunizations we go

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with.

Again, unlike the British, our Queen's regulations and orders -- same Queen -- dictate the mandatory nature of immunization when deemed necessary by military authority and in the absence of any contraindications, be they religious or medical or whatever.

That having been said, consent is not necessary, and the uptake is considerable. If you refuse a mandated vaccine, you're subject to disciplinary action for disobedience of a lawful command, and unvaccinated personnel are not deployed if it has been determined that that vaccine is required, whether it's a BW vaccine or not for a particular operation. The only exception to this is when not receiving the vaccine will only compromise the individual's security but not the security of the operation, an example being individual UNSCOM observers who may choose to go unvaccinated on a specific mission.

We've got some licensing issues that are a little bit difficult with regard to BW. Again, the Surgeon General can authorize the use of unlicensed vaccines -- unlicensed in Canada that is -- under our

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National Defense Act.

If we want to use that same vaccine within Canada, however, we need dispensation from our Health Protection Branch, Reed FDA, part of Health Canada, and under their special access program, they can grant us authority to use these vaccines. The special access program was not designed for large scale of usage of BW vaccines and has a lot of cumbersome baggage attached to it such as naming potential recipients of the vaccine which might not always be possible where we have to use it for civilian purposes in an emergency.

The bottom line is our Surgeon General has determined that he will use licensed products wherever practical, and upon obtaining adequate stockpiles, we'll have a look at this whole policy issue, but we're really fighting the stockpile issues right now.

Anthrax itself, over the years we have received our supplies from the U.S. Department of Defense. We've received them directly from Michigan Public Health before they went out of business, and we have used CAMR in the UK as well. None of the -- neither of the vaccines are licensed for use in Canada.

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On the other hand, our uptake rate when we've used it, based on the policies that I stated, is pretty good, compliance being 99 plus percent. In fact, I'm only aware of one case of non-compliance in the Canadian Forces, and this is under court-martial right now.

We do provide the recipients with a comprehensive information package with all the information we possibly can put together. It's quite a fit. Plus we provide our health care providers with a more detailed health care provider orientated package. Hopefully they can answer the questions. And we do maintain a registry of all recipients of the vaccine.

To go back a little bit, back pre 1991 we had no stockpile. When the Gulf War happened, our intent was to immunize our entire deploying force. Unfortunately, we learned a hard lesson there that everybody wants to use it at the same time, and our traditional sources, there was none available through Michigan Public Health.

Late in the war or just before the ground war, we did manage to get some of the CAMR vaccine, and about 500 of our actually medical personnel with

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our field hospital did receive anthrax vaccine.

At that point a decision was made to obtain and maintain a small stockpile, holding 6,000 doses earmarked for rapid deployable elements and UNSCOM inspectors. We didn't have a routine anthrax immunization policy, as I said, because it's a threat-risk base type of thing.

For the last eight years that was variably supplied directly from U.S. DoD if they had surplus, and in the later years we were dealing directly with Michigan Public Health under contract buying directly from them.

We got into a bit of a problem last February with a fairly major redeployment to the Gulf.

Our stockpile was time expired. We went off to Michigan Public Health, and they said you can't have any because the U.S. DoD wants it all. So we had none available in that particular deployment.

We did actually by dealing at the Chief of Defense Staff Minister of National Defense level with the UK Minister of National Defense and Mr. Cohen down here, get small quantities that were sufficient to meet our requirements for that particular deployment.

We -- actually, it was just enough to get us going

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there, and none of the people who deployed received more than two doses as we used it all up.

Again, in October of last year we went to Bio Port now who bought out Michigan Public Health, and requested resupply. We couldn't get it. We went around the pipe several times. Finally in February of this year, we got our current stockpile replaced, getting 215 10-dose vials -- requesting 215 10-dose vials and receiving 89 vials.

This 89 vials were given to us through DoD completely consistently with the U.S. current policy on supplying of products to other than U.S. Forces. If you're familiar with that policy, it lists out a number of requirements, and what we got was for the specific activities that we were doing that were consistent with that such as supporting the U.S. in coalition operations.

Way ahead, as of last week, DoD has authorized Bio Port to supply the Canadian Forces with 30,000 doses. That's quite a different number than what you just read. That's of a total of 70,000 doses that they've authorized for foreign release. The way we're going to receive this is 2500 doses every six months for six years, and we're paying \$49 Canadian a

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dose, which is a fairly good price.

We are also negotiating with Bio Part to establish a Canadian manufacturing capability and for DND to license the vaccine in Canada to get around some of these other issues.

Finally, I'll mention the Canadian Reactogenicity Study. This was started during that February deployment where we were able to get 572 people some anthrax, two doses each. As I mentioned, we did have to discontinue it after two doses, but these people have been followed.

The definitions of what we're looking at in terms of reactions I think you're all familiar with here where we classify the systemic effects and the nodules separately from the mild, moderate, and severe effects.

The expected rates, what we expected to see, are listed there. Our initial analysis of the data suggests the Canadian rates will be marginally higher in the moderate and severe categories. In the systemic categories, we have from one to four cases. None of them of Guillian Barre sort of thing.

I would emphasize we are doing active surveillance in these cases. We've gone back. We've

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had the people actually follow them up after their immunizations. We're just reviewing the data right now. It should be ready for publication within a week or two is what we anticipate. Four weeks is what I said there. And it is our intent to share it with this group and U.S. DoD before we formally publish it to make sure nobody is blindsided by it if it is slightly different. Thank you.

DR. PERROTTA: Thank you, Colonel. Any questions? Wayne.

COMMANDER MCBRIDE: Thank you. I have a couple of questions. I'm Doctor McBride here. Of those that were immunized and received two doses, when you have additional supply, how will you handle those that have been partially immunized? Will you restart the series where it was or what's your intent?

COLONEL SOUTER: The intent is to restart the series where it was. I actually have a policy document where we addressed this to the troops so that they were reassured that we were doing the right thing.

One thing I might add too is that even though we did get UK and U.S. supplies during that deployment, we only used the U.S. supplies. So we

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don't have the problem of mixing and matching the two vaccines fortunately.

COMMANDER MCBRIDE: That's what I was going to ask, if you were interchanging the product at all.

COLONEL SOUTER: No, no. And our intent even when we got the second supply of the UK vaccine was to keep that as a strategic emergency, if we really get into trouble we're going to use it, and we really hadn't figured out how we were going to use it, but there was such a problem just getting vaccine at that time. We may have incorporated it into a treatment regime or something. I don't know the answer to that. It was dicey.

DR. FLETCHER: This may be a question for just anyone. I was just looking over this book here, very nice, the biological warfare threatdiceys. Anthrax is still number one. How big a threat is there still continuing to be in the world?

COLONEL SOUTER: That's an interesting question. I think you have to look at it from each country's point of view. You have to look at it from the military threat point of view, from the civilian threat point of view. I think most people would put

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it if not at the top, in the top three in any of those contexts that I'm familiar with.

DR. MUSIC: Just as an anecdote, we had in North Carolina two turned out to be spurious anthrax episodes in the last month.

COLONEL DINIEGA: Hoaxes or false positive?

DR. MUSIC: Hoaxes, yes, but labeled anthrax.

COLONEL SOUTER: There's an interesting debate on that topic in something called "The Defense Monitor" which has just recently started publishing in D.C. where they have reviewed the Public Health Symposium on Biodefense Issues that was held about a month ago in Arlington, and Defense Monitor has gotten hold of one of the intelligent analysts from the UK whose opinion differs somewhat from the John Hopkins group, and it's a good little article that they put together. I have a copy in my briefcase if anybody's interested in seeing that. I'll provide it to the Chairman if he wants to get a copy.

DR. ASCHER: The reason it's an important issue is that, as I'll get to later, the civilian preparedness plan involves a lot of this vaccine as

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well, widespread use in the event of a large-scale episode, and the purchase of it and the qualification of it, further qualification through FDA and all the rest.

DR. PERROTTA: Commander Tedesco.

COMMANDER TEDESCO: Yes. This is Doctor Tedesco. You had mentioned that the refusal of anthrax vaccine is a bar to deployment.

COLONEL SOUTER: Yes.

COMMANDER TEDESCO: Does that go with other immunizations also if they refuse?

COLONEL SOUTER: Yes, it does, most certainly.

COMMANDER TEDESCO: Okay. Does that then apply if someone has a medical contraindication? Will they be allowed to deploy?

COLONEL SOUTER: We'd have to look at the issue related to what the threat or risk to him personally was on deployment and the threat or risk to the operation on the deployment, and they have deployed without vaccines, I know that, in certain cases, but we deal with it individually.

COMMANDER TEDESCO: I just talked to the other military services, and my understanding is

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American Services are deploying those people in spite of their refusal, is that correct?

COMMANDER MCBRIDE: Yes, that's right.

DR. REINGOLD: They are or they are not?

COMMANDER MCBRIDE: They are. If I could comment on that, the policy of the DoD is that if there are individuals who refuse to receive the vaccine, then they are subject to administrative action. They are kept in the high-threat area or they are deployed to the high-threat area even though they may not be immunized. It was felt, as I understand it, that they did not want to allow people to refuse the vaccine and then get out of deploying, and they felt if they allowed that, then people would say, well, I don't want to go on this deployment so I'll refuse the vaccine and get an opportunity to stay back.

DR. ASCHER: Use them as canaries, early detection.

DR. PERROTTA: We call them sentinel units.

DR. POLAND: I understood -- I mean the UK vaccine only takes four doses. Ours takes six. You finish in six months. It takes us 18 months. Do you

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happen to know -- I don't know that you were necessarily prepared to get this question but is that efficacy based on animal studies or is it known from occupational exposures or --

COLONEL SOUTER: I believe that it would be animal studies, surrogate studies.

COLONEL WARDE: Yes. I don't think we have any greater freedom to expose human into studies than you do.

DR. POLAND: No, I meant in terms of certain occupational groups might, you know, have anthrax exposure, and for example with our own vaccine we know it's effective. I'm not talking about weaponized anthrax.

COLONEL WARDE: No, I am perfectly certain that this is -- what Colonel Souter said is true, that this is based on animal surrogate models it's arrived at this dose regime, and it is clearly a significant difference in the data sheet instructions. Whether in fact it reflects such a big difference in the immunogenicity of the vaccine is not necessarily so -- a conclusion that you draw from that distinction.

DR. POLAND: It just strikes me in any kind of either military deployment or widespread

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civilian use there's a major difference between six months and 18 months.

COLONEL SOUTER: I've heard it said that were we to attempt to get either of these products licensed today, we might have a lot more trouble than back in the '70s. It would be possible, but a lot more work would have to be done before. It will be interesting to see what Health Canada has to say with the U.S. data that we are supplying them.

DR. PERROTTA: Let's take a concluding comment from Captain Trump.

CAPTAIN TRUMP: Just to answer Doctor Poland's question, we use six doses because that's the way it's licensed is for six doses.

DR. POLAND: Right. I know.

CAPTAIN TRUMP: U.S. Army Medical Research Institute for Infectious Diseases is working on the studies, one, to try to get that down to five doses by getting rid of the two-week dose.

The other thing they're looking at is subcutaneous, which is what the U.S. product is licensed for, versus IM. Some indications that that is just as immunogenetic -- whatever -- and actually causes less local reactions because of the

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intramuscular versus subcutaneous applications.

So they're working on that, but that obviously has to go through appropriate studies, FDA approval, and until that happens, we'll stick with the licensed schedule.

DR. ASCHER: And for the record and transcript, what I was saying about post-exposure use is a whole new indication and would require a whole additional series of review. That's what I was referencing. In other words, you can give it after an episode. That's a whole different animal, and how you get licensing for that is a real interesting problem.

COLONEL SOUTER: We would be interested in the views of the Board on post-exposure use in all three of our countries actually. We are looking at this in another form.

DR. PERROTTA: Thank you. We appreciate it. We're scheduled for a break. Let's take a 15-minute break until 20 minutes until 3:00 o'clock.

(Whereupon, a recess was taken.)

DR. PERROTTA: We have a command brief from the Naval Health Research Center here in San Diego. Providing the brief is Doctor Nice, correct?

DR. NICE: Yes.

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DR. PERROTTA: Doctor Nice has a BA, MA, and Ph.D. all in psychology from a variety of universities, DuPaul, William and Mary, and the University of Virginia. From '67 to '71 he served as a naval officer, gunnery officer aboard a picket destroyer and did a tour in Vietnam. His primary research interests include operational health care delivery, prisoners of war, and he's currently the Scientific Director at the Naval Health Research Center. I appreciate you coming to our meeting. And please go ahead.

DR. NICE: Thank you. I would hope to have this very informal. If you have questions, please ask. I'll try to finish a little bit early. So if you have questions at the end, we can entertain those. It's a great pleasure to be here.

I think in starting, I'd just like to say that the best part about my job is really the privilege of serving with so many wonderful people at our center like Greg Gray and Megan Ryan and Rick Schaffer and until about a year ago Stephanie Brodine, Frank Garland, and a number of others on their team. So we just have a tremendous epidemiology capability. We work closely with the other services and with the

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private sector and universities, and that's probably the best thing about my job.

Our mission statement, and then we have -- next slide please -- we have a -- being a military organization, we have a perfunctory wiring diagram. We always want to show we are within -- I guess it was last October we reorganized Navy Medical Research and Development Activities.

There's the Navy Medical Research Center now which used to be NAMRY (phonetic), and they have the overseas laboratories. The Naval Health Research Center is now a third echelon headquarters command reporting to the Office of the Surgeon General, Admiral Engle at MED-02.

So we have the headquarters function, no new staff anything like that of course, but we now get the opportunity to serve with a number of other organizations as well. So we have our laboratory. We have the Submarine Laboratory in Groton, Connecticut, the Aerospace Lab in Pensacola, and then a Detachment, the EMR Detachment, which is a tri-service detachment at Brooks Air Force Base in San Antonio and a bi-service detachment in toxicology working with the Air Force at Wright-Patterson in Ohio.

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Recently, the Surgeon General came out with his strategic plan which has three pillars which are the Fit and Healthy Warrior, Casualty Prevention, and Casualty Care and Management.

Now, of course health protection, as you know, fits into the Joint Vision 2010 along with dominant maneuver, information superiority, precision strike, those kinds of things.

What we did recently was kind of reboxed our research thrusts to fit into these pillars. And so -- next slide please, Ed -- under Operational Readiness and Performance, we do things like injury prevention, cognitive assessment, lifestyle and quality of life issues, deployment health.

Under casualty prevention, there are operational environments, and in the Navy of course we have a number of these. We have atmospheric issues aboard submarines. We have hyper and hypothermic issues, thermal stresses, acceleration, spatial orientation, those kinds of things.

The ID program -- or NBC program is primarily out of NMRC in Bethesda. The Infectious Disease Program as well resides there along with the overseas laboratories and some threat assessment, the

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HIV program.

And then on casualty care, most of the resuscitative medicine also is at NMRC, and the medical planning and situational awareness issues are at Naval Health Research Center.

We like to remind folks that we have really a strategically positioned forward laboratory doing primarily applied research. We are about half reimbursable, which means the line is paying for our products. We are totally reimbursable, which means we compete each year through the proposal process many of you are familiar with for our dollars.

The other half are Program 6 dollars, research dollars, but most of that is 63 level, 63 on up. So we do very little 61 and 62 research. Next slide.

We have a number of active duty units close. We also have some major commands here, COMNAVSURFPAC, AIRPAC, and COMNAVSPECWAR. In addition we have the Naval Medical Center here and three major Marine assets, Marine Corps Recruit Depot and MCRD -- at MCRD, Miramar, and Camp Pendleton is very close. We do very active research with all of these units.

Our primarily goal is on the one hand,

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because we work so closely with the line, both Marine Corps special forces and the ships, the line officers -- or line commands, one of the things we do is identify emergent biomedical needs as well as provide a lot of direct consultation. We are with -- you're going to be visiting the SPECWAR community, the boats community. We are literally with those folks everyday.

We transition our products primarily through peer-reviewed journals. We realize the importance of that QA, that quality check. We've published in each of these journals within the last year or two and see that as our priority. Some things aren't really appropriate for journal publication like software documentation, et cetera. We put that out in technical reports, engage in a number of military briefings as well as we encourage our scientific staff to attend academic meetings as well each year.

We have -- I think one of the best things we do is we know what we don't know, and we partner vigorously with academic communities. We partner with folks locally here in the San Diego region as well as around the country. This allows us to use our research dollar to leverage literally the best talent

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in the country to apply that talent to Navy-Marine Corps issues.

We also have a number of government collaborations. The white are the Navy active collaborations that we currently have. In yellow are the Air Force collaborators. These are our Army partners on a number of studies, and we also have a number of government partnerships working with CDC, FDA, Department of Transportation, others. And, finally, we are doing some work with DCIEM and also Oxford now, but I haven't updated the slide yet.

You'll remember the brief I showed or the slide I showed that we boxed everything under the Surgeon General's Strategic Plan. Well, that -- this is a little bit -- I'm out of sync on the slides here, and I didn't have -- I can't really translate these, but these are kind of our thrust areas under a different name.

One of the areas that we focus on are field medical technologies, and what we do here is we try to design, develop, and evaluate technologies that will improve the performance of the caregiver, the medical personnel in operational settings.

We have, along with Colonel Stuart, who's

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the head of this for the Army, we're working -- we're the Navy lead on the ACTD, the Advance Concept Technology Demonstration project for the Joint Medical Operations, Tele Medicine, ACTD that just came onboard. We're evaluating these applications in forums like Colonel Blitz which will be happening very soon up at Camp Pendleton.

The Mobile Medical Monitor is a device that we're putting far forward with the Marine Corps.

We've also developed and patented the Med Tag which reads the personal information carrier. Now, that's kind of a debate going on whether we have a pick that's kind of a dumb pick, dumb cheap pick or a smart expensive pick, but we've developed some technologies to read that and do casualty documentation far forward in the field, and this then helps our planning models.

It helps field medical surveillance for NBC threats, et cetera.

We also do a good deal of modeling and simulation, primarily to forecast. We're the Navy lead for disease non-battle injury as well as battle injury projections, and we use empirical models. We have -- through Doctor Garland's efforts, we have linked all of the hospitalization data from MTFs in --

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around the world for the Navy but also Vietnam data, Falklands data, Korea data, World War II data. So from those empirical files, we project DNBI rates for any theater or any battle intensity.

We also look at configuration. With the new "From the Sea" strategy, we need a much smaller footprint, logistics footprint. So we are rescrubbing the authorized medical allowance list and dental allowance list for the Marine Corps. We've just completed that, and we're now working on SURFPAC and SURF -- the Surface Force, and we'll work with the air carriers soon.

What we've done with the Marine Corps is reduce their weight in cube by 30 percent while actually increasing their medical capability in the field. We are optimizing some casualty evacuation through modeling, and also we're working with Sandia (phonetic) Labs on some virtual reality simulations for medical trainers.

In the neuroscience technologies we've lost some of our capability in this area through funding cuts, but we are working with the SMART Ship Program. As you know, the staffing of our ships is going down dramatically with the next generation ship.

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Our carriers are going to go from 5,000 to 6,000 down to 2500. Our destroyers, the SMART Ships are going to go down to about I think 190 people.

This is going to create a lot of trouble because we have trouble with sleep discipline right now or getting enough time to sleep because these folks are very busy. So we're looking at technologies to monitor alertness using both EEG and eye movement technology, and we're waiting for the dry electrode. Everything else is set.

We developed the physical readiness standards for the Navy. We worked closely with the Army on that and are now revisiting those issues. We developed the body comp equations for the Navy and Marine Corps. We are about to go tri-service working closely with Carl Freedle (phonetic) in the Army on those issues, and we are also looking at occupation-specific areas like explosive ordnance disposal folks need more rigid standards, and they come to us to help develop those.

We use -- we have Dexiscans. We've developed now a new floor compartment model of body composition so we can use anthropometric measures and get rid of some of the biases, racial biases with bone

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density that we had in the past.

We have an applied physiology group that has both an excellent lab space here, but also we have a remote field medical unit at the Mountain Warfare Training Center where we're currently working with Air Force and Army in oxidated stress. I'd like to refer to this group as freezing and boiling Sailors. We have very powerful thermal chambers we bring folks into on treadmills, and we can go from very cold to very hot and regulate the humidity as well.

We evaluate chemical -- or NBC protective ensembles in different thermal climates to look at stay times on the job. We also look at -- in the cold we evaluated a lot of equipment, the north face tent.

Light discipline creates problems because the ventilation is not too good. So when they light the stove, there were carbon monoxide problems. So we look at a lot of the evaluation of equipment for the field, load carriage, et cetera.

The Seal you see in the second photo is Petty Officer Toms (phonetic). I don't know if he'll be there tomorrow. Is it tomorrow you're going to visit the Seals?

DR. PERROTTA: Yes.

DR. NICE: But that's an actual Seal. We do a lot of work. We designed the specs for their dry suit. We also -- we're in daily consultation with them and hope to get closer to actual real-time mission hookups for them.

DR. PERROTTA: I'd like to ask that everybody be really nice to this gentleman right here whose arms are larger than my legs, and he's got a gun.

DR. NICE: We've done a good job on him on some nutritive supplements and things like that. That's not -- don't say that.

We evaluate load carriage systems, and Commander Schaffer's group helped design the new Marine Corps boots. So we're very active in the equipment design and also in the slide on the right is some damage control thermal flooding. We looked at some protective gear.

Finally, the most important for our group here is the operational epidemiology. We call it that just because the military doesn't -- we don't use ology. So if we make it operational, it sounds more important.

As Commander Schaffer frequently points

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out, we not only want to use epidemiology tools -- epidemiologic tools to define incidence or prevalence rates, but we want to also then identify important correlates and then follow through to conclusion and actually field interventions that make a difference.

You've probably heard in the past about a lot of Commander Schaffer's work in injury prevention.

We've been able to cut stress fracture rates in the Marine Corp training environment by one half through just changing the training regiment. Next slide please. He's also working on some very interesting HIV and unplanned pregnancy interventions as well as binge alcohol reduction, changing the culture of the Marine Corps.

Captain Gray's work in Gulf War Veterans is very well known both from the hospitalizations, birth defects, Goldenhar, testicular cancer, a number of studies, and we work very closely with the VA and with the Army in a DoD capacity on these studies.

We are now the Navy hub for DoD surveillance and emerging infectious disease. We are looking at Greg's group with -- Lieutenant Commander Ryan are looking at Influenza A and B, adenovirus, mycoplasma pneumonia, chlamydia pneumonia,

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streptococcus pyogenes and streptococcus pneumonia.

We are building -- Greg's group has built a wonderful laboratory capability now that we are hoping to become a DoD referent lab for serological studies, PCR, culture, serotyping, and antibiotic sensitivity testing.

In the global surveillance arena we are currently conducting studies for adenovirus. Greg has done some studies on azithromycin as a prophylactic with the Marine Corps. We are now looking at that with BUD and also looking at some pathogens at the -- documenting the pathogens at the Academy where they have frequent epidemics.

We have a number of partners in this surveillance system, and the specimens are sent to Greg's lab where they are analyzed and fed back to the participants I think on the Internet.

Recent accomplishments in terms of general publications in the global surveillance arena, and that's as fast as I can brief on the Naval Health Research Center.

DR. PERROTTA: Very good. Thank you very much. Does anybody have any questions for Doctor Nice?

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PROFESSOR BAKER: If you could tell us a little bit about the collection of data from shipboard and whether there's any possibility of adding to that collection of data on how injuries are occurring on shipboard.

DR. NICE: That's a good question. Thank you, Captain Beddard. Captain Beddard at EPMU-5 has a vision for bringing -- making preventive medicine more -- having a greater positive impact using the preventive medicine technicians from the EPMUs in terms of an outreach basis. So rather than just inspecting and finding what's wrong with each ship, the PMTs are going aboard the ships every week or two weeks. To fully execute that mission, they really need real time data on what's happening on that ship so that they can plot trends, do interventions, and do adequate surveillance.

Some years ago we did a study of independent duty hospital corpsmen, and one of the things we found -- it's a roundabout answer -- but one of the things we found was that the corpsmen on small ships particularly -- most of the ships in the Navy don't have a physician as you know -- and they spent relatively limited time in clinical care. Most of it

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is occupational health, heat stress, hearing conservation program, et cetera, and they needed ADP support. So we were able to get a requirement to get the Shipboard Automated Medical System aboard ship. We tried at that time to get a port in for epidemiologic surveillance, but we were not successful because of big brother issues and somebody second guessing the corpsmen, et cetera.

We've now been able to get that port in, and we have what's called the NHRC Extract, which extracts the SAMS encounter file and the inoculation file, the vaccine file, et cetera, and the roster so we have a denominator, ship's roster, and load that into a flat file.

What we have done then is taken that flat file and put it into Excel so you can load a pivot table and have very easy access to drop and drag surveillance of any variable demographic or occupational or ship class or deployment or anything else that you want.

We are trying very hard. I have -- Captain Beddard and I talked recently. I have instilled a sense of urgency among our personnel working on this to get this product to him. We're

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very, very close, and I think it will have dramatic implications for not only the PMT going aboard but for the aggregation of these data for management at the Force Medical level and the SINC level but also for research purposes.

Now, our hope in participating here is that NHRC would have access to this aggregate information and through that vehicle I would see access to the safety center and also academic institutions. But this file will need to build over time. Doctor Garland did a study on shipboard health care delivery. I did a study as well. So we have some resident in-house data, but it's always sporadic and periodic. You go out and capture this information. We really need a system to capture outpatient routinely, and we're working that issue, but we're not quite there yet.

DR. PERROTTA: One of the findings of this Board as part of one of the subcommittees on injury found in the report the hidden epidemic injuries that you have seen suggest that access to medical information is only part of the issue and access to the information about, for example, an injury, specifically in injuries, what happened to cause this

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injury is really going to help your epidemiologist direct the builders of ships, the commanders of ships or the captains of ships to do things that can make a difference and make a difference quickly, and so as you continue your process and your encouragement, I would ask that you put a placeholder there and take some action if possible to figure out a way that information not only about the medical outcome but the cause of that gets into place. If that means training your corpsmen to ask specific questions, if that means putting an extra sentence on there, asking the question, those are the kinds of things that some quick fixes could probably really increase the quality of information that would be used by an epidemiologist. We were talking about that at lunch today, and it would be something that we'd certainly like to recommend and support in any fashion.

DR. NICE: That's really an excellent point, and I should have -- I should have mentioned, any time there's an accident ashore or afloat on these ships, there is a special report filled out in the SAM System, and it gives the location, the circumstances, alcohol involvement, medevac, et cetera. And so these data are currently captured and will be very useful.

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DR. PERROTTA: They just need to be linked.

CAPTAIN BEDDARD: If I might, Captain Beddard. One of the observations we've made here is with the Surface Pacific Fleet that 60 percent of people that deploy on a six-month deployment have never deployed on that ship previously. We think that there -- with this constant, you know, training cycle, there are the same injuries occurring over and over and over as new people come onboard. So hopefully with this data we can focus our interventions.

DR. PERROTTA: Okay. I appreciate that. Doctor Haywood.

DR. HAYWOOD: In that regard, one thing to include would be repetition of those in the training cycle as opposed to wait until they get to the scene to have the accident. My question though had to do with exchange with NASA. Do you have an active program for technology discussions with NASA space and monitor and et cetera?

DR. NICE: We do not.

DR. HAYWOOD: Is that allowable?

DR. NICE: With NASA?

DR. HAYWOOD: Yes.

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DR. NICE: Sure. We have active programs with NASA, and we have some with our sleep -- not on accident but with some of our sleep studies. In fact, we just sent Commander Neary (phonetic) to NASA, and our aerospace laboratory of course for their G Force studies work closely with NASA, but not in accident work.

DR. PERROTTA: Any other questions? Again, thank you, sir, for coming and briefing us. Next to talk to us about "Adenovirus Infection Among Army Recruits: A Vaccine-Free Cohort Study," is Doctor Shellie Kolavic, and I had the opportunity to know Shellie as an EIS officer in the state of Texas, and I'm glad to get to see you again. Please go ahead.

MS. KOLAVIC: As Dennis said, I'm from the Army Center for Health Promotion and Preventive Medicine. My fearless leaders, Colonel Sanchez and Colonel DeFraitcs, send their regards. They couldn't be here today.

Okay. This afternoon I'm going to give you an update on a project that we did in Fort Jackson, South Carolina on adenovirus in a vaccine-free cohort. This is still a work in progress. Unfortunately, I did not have all of my results yet by

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the time I got here, but we'll work around that as we go through.

In September, 1998, an epidemiological consultation was requested by the Commander of the U.S. Army Training Center at Fort Jackson, South Carolina to investigate the increase of acute respiratory disease, which I'll refer to as ARD, among basic trainees in the absence of adenovirus vaccine.

This was going to be a long project, and the first question that came up was who was going to go to Fort Jackson for four months. I had just arrived at CHPPM right from Texas, and having no other projects going on at the time, I was elected to go down. So before I even got my feet wet up at Aberdeen Proving Ground, I was finding myself on the road to Fort Jackson.

Our objectives were to define the extent of ARD due to adenovirus, identify the risk factors for adenovirus infection, determine proportion of recruits susceptible to adenovirus infection, describe the characteristics of adenovirus infection, and recommend potential non-vaccine interventions to control these outbreaks.

We employed a prospective cohort design,

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678 recruits in three companies undergoing basic training for 7.5 weeks. Normally this would be eight weeks, but it was abbreviated for the Thanksgiving holiday.

We used various data sources. We had self-reported data from survey cards, diary cards. We had unit data from unit rosters and bunk assignments.

We had hospitalization data and medical record review data. We collected serum and throat swab samples, and we collected environmental samples.

We define a febrile ARD as an oral temperature of greater than or equal to 100.5 degrees fahrenheit and one or more of the following: sore throat, cough, rhinorrhea, nasal congestion, sinus tenderness, rales, rhonchi, or wheezing. An afebrile ARD were the above signs or symptoms and an oral temperature below 100.5 degrees fahrenheit.

We also have self-reported febrile ARD. Now, these were Soldiers who reported these same signs and symptoms, but they said they felt feverish or they had chills.

The mean age of our cohort was 20, median 19. We had 46.2 percent White, 32.7 percent Black, 12.2 percent Hispanic, 2.5 percent Asian, and about

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six percent other race/ethnic groups.

We are equally distributed among our three companies. Now, the question will come up where is our Bravo Company. This particular battalion that we worked with had their Bravo Company designated as a motivational company, and by this I mean Soldiers who normally would be dismissed from the Army for various motivational reasons were going to this as a last effort, to see if they could rehabilitate them, slide them back into another battalion.

We had about a 60/40 split in gender, and our male/female ratio was one to one in Alpha and Charlie but three to one in Delta Company.

We start off with 678 recruits. We lost about 83 of them. Fifty-four were discharged for various reasons. Twenty-four went to the Physical Therapy Rehab Platoon after injuries, and five of them went to the motivation company.

And we had our self-reported data. This is just a photograph of our Soldiers filling out their weekly diary cards. Every Saturday morning I addressed the morning formation, passed out 678 diary cards, asked the Soldiers to put a check mark next to the symptoms that they had experienced the week

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before. 92.3 percent of our Soldiers indicated that they had one or more of our ARD symptoms. This is in the absence or having fever. As you can see, we had over 50 percent up through the third week that were indicating that they had the respiratory illnesses, and it starts to decline after the third week.

Those who reported having a febrile ARD -- again, this is self-report -- 52.2 percent. This, again, peaked in the third week, and it also peaked in the third week for males and females. We had a slightly different pattern by sex, and we had a different pattern by company. Charlie Company had the epidemic much earlier than Alpha and Delta Companies.

We looked at hospitalization data. Our hospitalizations peaked actually during the fifth week of training. By gender we did not see differences in the odds of hospitalization. Alpha Company did tend to have a significantly lower odds of hospitalization than Charlie and Delta Companies. We didn't see any differences by smoking.

We also did a medical record review on 94 percent of our cohort. 53.2 percent of our cohort indicated they had at least one documented ARD visit. Alpha Company had the fewest visits.

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We also collected serum and naso-pharyngeal samples. Right now our serological data is pending. It is still undergoing analysis at WRAIR. For our naso-pharyngeal swabs, I can only offer you preliminary data today.

Seventy-two percent -- let me back up. We have samples on 97 of our hospitalized recruits, 114 hospitalizations. This is actually 111 Soldiers. We had a few readmissions that were at least two weeks apart. Of our 97 throat cultures, we had 72 percent were adenovirus type four, seven percent type three, two percent type 21.

And if we weren't already busy enough, we also took environmental samples of the air filters in each of the sleeping barracks. We took a swab at 14-day intervals. Right now they're 100 percent negative for adenovirus. However, I did find out last night that on PCR testing we're starting to show some adenovirus, and we hope to have an update for you at the next meeting.

We looked at bunk assignment. This is just an example of what we did. We mapped every Soldier, where every Soldier slept, in which bunk, in which bay, in which company. By the end of all of

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this, we have 97 maps which you'll be glad to hear I'm not going to show them all to you. I'm going to just give you an example of one platoon in Charlie Company.

This I believe is Third Platoon.

Just to get you oriented, the bottom of the slide here is the front of the room. This is the door. The latrine was in the back of the room. These Rs are the returns for the HVAC system, and along the side right near the windows, these squares are the supply vents.

This is a top bunk. This is a bottom bunk. The circles are where the head placement is. And it's not important for you to know the names, but they were there for us.

A blue bunk indicates that the Soldier was not ill. An orange bunk indicates that the Soldier reported a -- had a self-reported febrile illness.

This is week zero. In week one you can see here's our first case in that platoon. The red indicates that they were hospitalized. Week two, week three, week four, five, six, and seven.

We have Captain Steve Cersovsky who is at Preventive Medicine at WRAIR has been looking at that data, the bunk assignment data. He's going to attempt

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to do some cluster analysis on it. He hasn't started yet, but he's doing all the preparations, and we hope to have it -- he's being assigned to a preventive medicine position in Germany, so we'll be doing some long-distance work with him.

This is some of the work that he did. We found that we really didn't see greater odds of hospitalization with a neighbor having an ARD. Curiously though we saw that being in the front of the room or being in the back of the room, you had almost twice the odds than when you were in the middle of the room, if your bunk was in the middle of the room.

The bunk position top or bottom didn't seem to make a difference, and we looked -- it looks like we might have something going on with being near -- having your head near the supply, but we'll look into that a little bit greater later, and we didn't see anything with the head near return.

Now, the question is how does this impact on training and readiness. Well, what I can tell you is that we're looking at 92.3 percent of our cohort who are saying that they're having an illness. We lost 5,082 duty hours. This is also self-reported. The mean lost duty hours for any ARD was 8.1 per

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Soldier, and 52.1 percent of our cohort reported having a febrile ARD. Almost 17 percent of our cohort was hospitalized with a cumulative almost 260 days with a mean of 2.3 days hospitalization.

Then this is our self-reported missed training. In our current situation -- I wish I had better news, but our lab analysis continues. Our barracks data analysis continues. Our risk factor analysis continues, and our recommendations are pending further analysis, and I'd like to thank everybody who worked on this project with us. It took a lot of man hours and a lot of effort, and this is just the tip of the iceberg. Are there any questions?

DR. SOKAS: I just wanted to ask how the hospitalization rate compares to before when the vaccine was available and utilized, if you have that comparison?

MS. KOLAVIC: I actually don't have that comparison. We may be able to get that information for you later.

DR. ARMY: I can comment on that a little bit having been hospital Commander at Jackson until last year, and the admissions -- Doctor Carroll Army, Preventive Medicine Consultant. I was hospital

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Commander at Jackson in '96, '97, '98 time frame. At the time we ran out of vaccine, the admissions for ARDs, adenovirus in particular, when the vaccine disappeared just went sky high. The first year I came within one bed of having to start sending Soldiers down to the VA because I just didn't have enough beds to put sick Soldiers in.

DR. PERROTTA: Shellie, you had a slide in there, a pie chart in there that had a significant number or percentage positive for adenovirus four from your hospitalized patients. The question I had was -- I think I probably know the answer -- that reflects the experience of what's been going on in the nasopharyngeal area of the hospitalized patients. Do you have anything about the men who did not end up going to the hospital? Do we have any background carriage rates of adenovirus four for folks that weren't hospitalized?

MS. KOLAVIC: I hope to have that information. Right now I have very little information from the laboratory analysis. I was lucky to get what I showed you. That's all I have for laboratory. It's taking a terribly long -- a frustratingly long time to get results right now.

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DR. PERROTTA: But did you swab folks that didn't end up in the hospital?

MS. KOLAVIC: What we did, when we were -- we started this all at the Reception Battalion, and we swabbed Soldiers who said that they felt feverish that had adenovirus symptoms. Then what we did is we followed right behind them with the first well Soldier in line after them, and I hope to have some results.

DR. PERROTTA: Thanks. That's reasonable.

DR. GRAY: This is Greg Gray from the Naval Health Research Center. We're collaborating with a number of institutions doing febrile respiratory illness surveillance, and one of the sites has been Fort Jackson, and we've collected specimens from people who've met their case definition outpatient and inpatient, and since June of '98 through January of this year, we have cultured 393 and 66 percent were adenovirus positive.

DR. PERROTTA: Doctor Ascher.

DR. ASCHER: One of the meetings a number of years ago, in addition to the vaccine problem, there was a cry for help in terms of lab capability. So you seem to have improved that. How is your lab capability? There was really a concern expressed that

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there was going to be no lab capability and therefore the problem would go away. It doesn't seem like that's the case.

MS. KOLAVIC: It's tough for me to answer the question about the lab capability. I had hoped to have all my results by now, and it is running very slowly. Having -- this being my only -- my first and only experience on an outbreak with CHPPM, I can't compare it to anything else right now. And I really wish that Colonel Sanchez was here. He would definitely be able to answer that question for you.

DR. GRAY: This is Greg Gray again, Naval Health Research Center. The resources for public health laboratory backup in DoD are abysmal. They're terrible. I mean, we just don't have capabilities. It's not changed too much. The global emerging infectious disease moneys have given us some startup, but there's a major understanding that we're greatly in a deficit. In fact, this very month a number of investigators from all the services will be meeting in Washington to plan to figure out some solutions for laboratory -- public health laboratory support because of this issue, and there's a -- I think it's a three-day meeting with Carol Fisher -- two-day meeting on

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that.

DR. ASCHER: So this is a patchwork, it's a Band-Aid. It's not a fix.

DR. GRAY: Yes, exactly.

DR. ASCHER: Okay.

DR. PERROTTA: Colonel Bradshaw.

COLONEL BRADSHAW: This is Colonel Bradshaw. I just wanted to ask if you did any other environmental sampling other than the air filters. For instance, did you do the faucets in lavatories or anything else?

MS. KOLAVIC: No. There was -- there was some air sampling done independent of our project. I did not have -- I did not have any information for that yet.

DR. PERROTTA: Let's take one more. Rosemary.

DR. SOKAS: This is just a general question. This topic came up, and I think we all said gee, it's a bad idea to run out of the vaccine, and now it shows that gee, it's a bad idea to run out of the vaccine. I'm just wondering if there are any plans now to gin up vaccine production or if there's been a response to any of the comments that have been

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made or if there's any kind of follow-up.

DR. PERROTTA: Let's put Doctor Trump on the spot.

CAPTAIN TRUMP: For the next fiscal year there is \$14,000,000 that has been identified and essentially is with Medical Research Material Command on the research side to look at the options as far as what's the best way to go with reinstituting vaccine production of this or a different vaccine for adenovirus.

DR. PERROTTA: So do we read that as saying that there's a commitment that something will move forward?

CAPTAIN TRUMP: There's a commitment for \$14,000,000.

DR. PERROTTA: To study the problem.

CAPTAIN TRUMP: For this year.

DR. ASCHER: That's research money. That's not buying vaccine.

CAPTAIN TRUMP: Right. There's no vaccine to buy. I mean, it's too -- you know, figure out how to get it.

DR. PERROTTA: Is it to build infrastructure to make vaccine or is it to study

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what's the best way to go forward or --

CAPTAIN TRUMP: I think there's about \$12,000,000 that's actually for procurement and about \$2,000,000 for planning, development, you know.

COMMANDER MCBRIDE: Very briefly, let me explain further. Wayne McBride. There's an effort to identify another vendor, another manufacturer who will come forward and they've gone out with a request for proposal, and they've had a number, I believe two or three, potential manufacturing companies have expressed interest in this. And so over the next months, there's -- this will continue at this effort.

They're also again looking at the issue about the transfer of the technology to a prospective manufacturer, perhaps directly or via DoD. And so this effort is moving forward. It's not as fast as we would have liked to have seen it certainly, but it is being very purposeful, and we're hoping that this will work out. What will be key is to have continued support from Health Affairs in the next couple of years as this effort continues and as the manufacturer is identified, for this to continue. If I may, I have one question --

DR. ASCHER: That's not research then.

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COMMANDER MCBRIDE: It's not.

DR. ASCHER: That's acquisition.

DR. PERROTTA: MRNC is the material acquisition center.

DR. ASCHER: That's why I asked the question, because I knew about this RFP, and that's not research that's serious.

COMMANDER MCBRIDE: If I may add further, the intent was just to probably match the same production that they had with the same serotypes of four and seven. If they stray beyond that and do anything else, that would be a longer process of getting a replacement vaccine.

If I could ask a quick question if I may, at Fort Jackson, remind us what they're doing in terms of non-vaccine interventions to deal with this. Are they, you know, institutionalizing handwashing procedures and all that kind of stuff?

MS. KOLAVIC: I can confirm that the handwashing procedures are in effect. As for what else is going on, perhaps, Roberto, do you have any ideas of what's going on down there right now?

DR. PERROTTA: As Roberto does that, I'll remind the Board members or the new ones that for the

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five and a half years I've been here, we have repeatedly received these kind of briefings that make it very clear that adenovirus four, back to the days of Langmueller (phonetic) and currently are humongous issues for recruit situations, and I may talk to our friend Doctor Poland to see if we can't craft something to try to help whatever. Maybe we'll ask for more advice. Go ahead, Roberto. Thank you.

LIEUTENANT COMMANDER NANG: This is Roberto Nang from the U.S.A. CHPPM. With regards to some of the environmental measures that they've looked at to take a look at preventions of adenovirus, they've tried making sure that there's good separation between the bunks, that there's some kind of adherence to some World War II studies done before with regards to the amount of square footage per person in a building. There are environmental science officers and engineers who have looked into the issues with regards to air exchanges and ventilation issues.

We at CHPPM have actually done literature searches, and Mr. Terry Lee's done some different work in taking a look at other administrative controls such as the use of iodinated tissues or the -- or consistent with Doctor Ryan's previous efforts, also

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encouragement of handwashing. Those are some of the things that we've been looking at.

Whether or not -- we wanted to do a more detailed study about this. But, again, funding has become an issue, and it's going to take a significant amount of time and effort to be doing these things, especially on a prospective basis. So we're not sure if that can be done.

One last thing too, there is a recent paper published by Doctor Snuring (phonetic), Doctor Mitch Snuring (phonetic) in the general clinical microbiology -- I was one of the authors on it too -- that looked at the circulating strains of adenovirus within the Army and the Navy, and unfortunately, there seems to be some strain variation between what's circulating now for adenovirus four and what was in the prototype vaccine. So that's going to throw a monkey wrench a bit in terms of maybe the clinical efficacy studies that the FDA may require for licensure of the vaccine.

DR. PERROTTA: Anything else?

COLONEL DINIEGA: I have one question.

DR. PERROTTA: Go ahead.

COLONEL DINIEGA: You put up there the

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mean days lost, but you never said anything about number recycled, which is probably the biggest impact on training. If they're not recycled, they complete their training with their cohorts.

MS. KOLAVIC: I don't know if I could even go back, but our Soldiers that were recycled either went to that motivational company or they went to PTRP. I don't have any other information about -- once they went to the motivational company, I don't know where they went after that. We just simply had such a volume of things going on down there, and at times were literally a one-man operation. We couldn't follow up on everybody. So I do know that they either went to motivation or they went to PTRP. And most likely, once they went through PTRP, they were recycled. As to whether they were recycled after they went through the motivational company I don't know because those were -- those were tough cases there. But there was an effort -- every effort was being made when you were injured to go through PTRP.

At the very, very beginning of our project, the Soldier had the choice of whether they could go home or go to PTRP. And within the first, second, and third week, they were no longer given that

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option. Everybody went to PTRP with the intention of being recycled.

COLONEL KARWACKI: I can address the admin question. This is Colonel Karwacki. There were no recycles from the adenoinfections. Because they stay -- their hospital stays were two to three days at most. A Soldier only gets recycled if he misses seven consecutive days of training. Then he is necessarily recycled. So two or three days, they can usually make that up in extra sessions somewhere along the way if he misses very important aspects of training. So, although through the peak epidemic we saw last fall and the lesser one, the one we saw this past fall, there were no recycles due to that particular infection alone.

COLONEL DINIEGA: Even with a shortened training cycle, huh?

COLONEL KARWACKI: Right.

DR. LA FORCE: Just one brief question, it's small. No other Army has this vaccine in the world, the French, the Germans, the British? Nobody probably cohorts people to the magnitude that we do either, though.

DR. ASCHER: Dennis, coming in with a

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four-year gap here, the last time I remember the Board, there was a -- this issue of the thing was a nightmare. I had it in Utah, and we wrote a recommendation without being asked, a very serious one that said we're very concerned. Has anyone written since? And I think if you were to write anything, you'd say something to the effect you're very encouraged that a solicitation has produced some responses, because that was the question, and, you know, I was told earlier there was no vaccine. Well, now you've heard that there's an RFP and they've gotten the answers. Whether they're any good or not and whether it will go anywhere, I don't know, but that's the best news I've heard in years.

UNIDENTIFIED SPEAKER: And you might want to see the recommendation from the immunization report tomorrow before deciding whether to do anything. I mean, there's been an appropriate response.

DR. ASCHER: I'd hate to see this initiative fall flat because some bureaucrats say, well, I don't like the proposals.

DR. PERROTTA: Thank you.

COLONEL SOUTER: Can I just add?

DR. PERROTTA: Yes, sir.

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COLONEL SOUTER: The question of other countries, I think if you approach Admiral Call (phonetic) in JFOR at the Pentagon, he could give you a read from the NATO CoMed's point of view on whether this is an issue in other countries. So -- he would be the representative that sits on the preventive medicine board there.

DR. PERROTTA: Major Carol Fisher is going to give a briefing on the Pandemic Influenza Preparedness for DoD. She has to stay on time?

MAJOR FISHER: Contrary to what most of you probably think, I do other things besides try to work audiovisual equipment, and I think if there's one thing that I've learned today, if I had to do this for a living, I'd be out on the street somewhere.

I actually work in the central hub of the DoD Global Emerging Infections Surveillance and Response System we affectionately refer to as GEIS, and our director, Colonel Pat Kelly, has actually given the Board a general overview of our program probably a year or so ago I guess.

And since that time, since he gave the overview of the program, we've actually put together a five-year strategic plan, and I gave one to all of the

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Board members. And this strategic plan identifies, you know, the high priorities for DoD when it comes to emerging infections, one of which happens to be influenza.

Just to give you a little background, the appearance of the H5N1 strain back in '97 prompted DoD to go back and assess its ability to detect or to recognize and to deal with a highly virulent strain of influenza, and one of the things that we found was that we didn't have a coordinated DoD laboratory based influenza surveillance program. The Air Force was the only Service that had any sort of institutionalized lab based influenza program with a history of about 20 years, and it's called Project Gargle. And the cornerstone of Project Gargle is sitting right back over there, Ms. Linda Canas who's done some wonderful work over the years, and now we're trying to migrate that into a DoD lab based program.

So after we identified that we had no DoD lab based surveillance program, we put together in early '98 a joint influenza working group that actually drafted a program, a DoD program.

Then in February of this year, Doctor Bailey, the Assistant Secretary of Defense for Health

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Affairs signed out a policy letter that said DoD would conduct laboratory-based influenza surveillance and named the Air Force as the executive agent for the program. I've also given you a copy of that policy letter. You should have that in your pile of handouts.

Now, we see the next step now as dealing with influenza pandemic preparedness planning for DoD.

There actually was a plan that was written I think around 1995. It was written by five individuals who represented the Army, Navy, and the Air Force. Only one of those individuals is still on active duty today, and to my knowledge, the plan was never staffed and approved. It went in some black hole somewhere I guess.

So DoD-GEIS, my office, under the direction of Health Affairs, and we've been working with Captain Trump, are beginning the process of developing a final plan that we can staff through the services for approval.

The plan -- the draft plan, while it identified a lot of needs, never -- and it raised a lot of questions -- it really didn't address the specifics of implementation of any of that. So we're

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really going to have to do a lot of work, and it's probably going to take quite a few months to get a final plan that's ready for staffing.

And the bottom three bullets here are -- they kind of indicate where we are now. We met about three weeks ago I guess, our office along with Health Affairs, and we tried to identify the DoD agencies that needed to be part of this process. And we're going to send out a letter from Health Affairs that will -- that will go out to these agencies and ask them to supply a representative that will -- and then those reps will make up the Executive Planning Committee. And we've also started collaboration with the Department of Health and Human Services.

These are the different agencies that we identified that would be part of the Executive Planning Committee, Health Affairs, our office GEIS, Defense Supply Center Philadelphia, JFOR, the joint staff, a representative from the Offices of the Surgeon General, Medical Logistics, and DoD Emergency Preparedness.

And the responsibilities of the Executive Planning Committee would be to establish command and control, not only within DoD, but also with other

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federal agencies. They would oversee the whole process. They would make sure that the DoD plan is aligned with the national plan, and they would also make sure that the DoD plan does get finalized, and then they would -- they would come up with the procedures for periodic review of the plan.

These are the priority areas that we've identified, and they're consistent with those of the Department of Health and Human Services. And there are a lot of questions that we have to answer within these priority areas like what role, if any, will DoD play in vaccine development. As far as antivirals go, will we stock antivirals themselves or will we stock raw materials to be able to make the antivirals, will we use antivirals prophylactically or therapeutically or both. And with the limited availability of antivirals, how are we going to prioritize who within DoD will get them.

We need to know what our contingency plans are for providing health care services in the event of a pandemic, and we also need to identify what are the services we consider critical. And then we need to -- we need to know what and how we're going to communicate within DoD and also with other federal

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agencies.

So this is just really an overview. We're just now really getting started into the process. There's still a lot of work to be done, like I said, before a final plan can be staffed to the Services, and that concludes my briefing, if anybody has any questions.

DR. PERROTTA: Any questions for Colonel Fisher?

DR. POLAND: Just one. Carol, I'm on the National Vaccine Advisory Committee's Pandemic Preparedness Planning Group, and I'm not sure we've ever had any -- at least in the last year or two, any direct liaison with DoD.

MAJOR FISHER: We're just now starting that.

DR. POLAND: Okay.

MAJOR FISHER: As I read through the draft national plan, the different pieces of it, there were places where they talked about DoD involvement, but I have no idea who that might be, probably Colonel Hoke (phonetic).

DR. POLAND: I was on the first couple of meetings when the group first got together to talk

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about the plan years ago, and it was Colonel Hoke.

MAJOR FISHER: He's the only one that's still on active duty out of the ones that put it together.

DR. POLAND: How does this fit in with FEMA's role and also DOMS, the Director of Military Support?

MAJOR FISHER: I think these are things that we're going to have to figure out. Captain Trump might be able to address that a little bit better.

CAPTAIN TRUMP: We had a meeting, Doctor Fisher and I, with some of the representatives from Health and Human Services just last week, and really the people there included Doctor Canas with the Office of Emergency Preparedness, and those are certain issues that we have to look at for DoD is we don't necessarily want to reinvent or invent a whole new response to influenza separate from what we already have for national disaster response. And that does -- you know, on the national level is FEMA. For how military gets involved, especially if we're called upon to provide services, would go through DOMS, which is the Director for Military Support -- or of Military Support.

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COLONEL DINIEGA: And in that one of the specialty functions in the medical piece of it belongs to the Public Health Service.

CAPTAIN TRUMP: Right. And that's one of the reasons why, you know, HHS really, up to this point their plan was developed primarily internally, some with their advisory committees like the National Vaccine Advisory Committee, but where it's moved now is up to the Office of the Secretary and at the policy level where they really want to start talking not about the "what we should do's", but what is the policy, where is the money going to come from, who's responsible for what, and starting to move out of the Health and Human Services focus to involve other agencies like DoD, involve FEMA, and others that would be appropriate.

MAJOR FISHER: One of the differences that we would see from a natural disaster versus influenza pandemic is, you know, when you have a natural disaster, you pull resources from one place, and you put them in this other place where this disaster occurred. And with an influenza pandemic, there might not be anywhere to pull anything from. Everybody might be affected. Any other questions?

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DR. PERROTTA: Very good. Anything else?
Thanks again, Carol.

MAJOR FISHER: If there are any AFEB members that are interested in, you know, working with us as we try to come up with the final plan for staffing, we certainly would welcome their participation.

DR. PERROTTA: And now she puts on her other hat, audiovisual queen.

(Pause.)

CAPTAIN TRUMP: I will try to keep this pretty short. What I would like to talk about is our Department of Defense input into the influenza vaccine composition, and I give a very abridged history of the Armed Forces Epidemiological Board and DoD's role with influenza vaccine issues.

The history of this Board goes back to the Board started during World War II, including the Board of Investigation of Influenza and Other Epidemic Diseases, which became the Commission on Influenza in 1946 and whose responsibilities carried on to the current date with the Armed Forces Epidemiological Board.

If you look into Doctor Woodward's history

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of the Board over 50 years, the list of recommendations from the Board that he has there starting in December of 1961 up until 1989 had almost an annual recommendation on -- from the AFEB regarding the composition of the vaccine. Essentially based on what was going on nationally, DoD accept the national formulation or have alternative recommendations. And while I first started attending these meetings in the late '80s, routinely a member of the AFEB would be participating in what is now the Vaccine and Related Biological Products Advisory Committee meetings with FDA and others on vaccine composition and would report back to the Board.

This year Colonel Diniega got a call from Doctor Roland Levandowsky with FDA asking for some at least DoD presence at their meeting to discuss the vaccine composition because of an issue that came up regarding the composition that they I think rightly felt may have some impact on the military, at least needed to be considered.

The World Health Organization had recommended and published in February of this year a composition for the vaccine for the 1999/2000 season for the Northern Hemisphere that would include as the

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H3N2 component the 5/97-like virus. For the H1N1 component, a Beijing 262/95-like virus, and then for the decomponent, either the Beijing 184/93-like virus or the Shandong 7/97-like virus.

And the recommendations for the Influenza B was that the vaccine containing B Shandgon-like virus would be for the countries of Asia and that the B Beijing-like virus would be for those other areas.

And essentially Influenza B, similar to B Beijing 18493 had been found in all areas of the world, was really the predominant one in Europe and in the United States, but in the countries of Asia, B Shandong 797-like virus has been isolated as becoming increasingly more predominant and may be really the most predominant type of B virus circulating there.

One of the pieces of information that had been presented to the WHO had come from Doctor Norome in Tokyo at their National Institute of Infectious Diseases, which showed in 1998/1999 season that of the B isolated, 65 percent were of the B Shandong-like virus which comes from B Victoria lineage, which compared to only 25 percent of those B isolated from the previous year.

And there had been a very limited study

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done in Australia that showed that a vaccine containing a B Shandong-like virus would produce antibodies against both the Shandong and also against B Beijing 18493-like strains, but the 184 -- the Beijing 18493-like virus did not provide any significant protection against B Shandong.

The FDA-convened Vaccines and Related Biological Products Committee that had met in January of this year reviewed the data at that point and decided on the H1N1 component and then awaited the WHO recommendations and additional -- and laboratory data and met again on March 11th to approve final vaccine composition. I attended that meeting along with Doctor Fisher. Doctor Poland is a consultant to the -- for that meeting also. And their final recommendation was after looking at the data and the additional isolates was that the H1N1 component would essentially be retained from the 1998/99 vaccine, as would the AH3N2 component of the 597-like virus, that the U.S. would retain as the B component of B Beijing 184/93-like virus, but actually they have decided to replace the current isolate with the B Yamanashi 166/98. I ought to get to say these numbers very fast.

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So in the discussions there is very little -- a serious -- a specific decision was made not to include B Shandong or not to pursue that as the component for the United States. We had not been seeing any isolates in this country of anything other than B Beijing 184/93-like viruses, although the risk certainly concerned that if the B Shandong-like virus was introduced into the United States, that we would not have any protection from the previous vaccine we had available.

Some of the issues that were considered and essentially shared in E-mail and the like prior to this VRBPC meeting, that we really have used what is the standard U.S. vaccine for the -- especially in recent years. We do continue to have the annual influenza vaccine requirement for military members, and we actually acquire in excess of 2,500,000 doses of influenza vaccine annually each year to meet those requirements and those other members of our beneficiary population.

I really went into that meeting expecting that the VRBPC recommendation would be for Influenza B Beijing 184-like virus in the vaccine component. There was concern that production base would not

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support a quadrivalent vaccine, but the FDA was ready to do the support work that would be necessary to support and eventually license an alternative vaccine if that was felt necessary. But also many of the manufacturers here in the United States may actually be producing vaccine against -- or containing B Shandong 797-like virus for some of the international customers.

Also some of the things that we pulled together with the help of Linda Canas and the Project Gargle efforts and others was on the influenza experience for the military. You know, here in the U.S., again, B Beijing 184/93-like virus has predominated. During the '97/98 season, Project Gargle had only had five Influenza B isolates. For the preceding year, there had been up through February or mid February, 1999, however, there had been 48 Influenza B viruses isolated, 39 of those in February alone. Of the numbers, seven had come in from the Pacific Rim samples, again, six in February. And as of that time, all of those however had been -- that had been further identified were B Beijing 184/93-like viruses. She's told me here this afternoon that that still is the case, that all the additional isolates, B

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isolates have been B Beijing.

This is on the background though, but we obviously do have a significant military presence in Asia that potentially could be at risk if a different virus became more predominant in that area. Over 95,000 members who are assigned ashore in primarily the Republic of Korea and Japan, including Okinawa, in excess of 12,000 people on ships, 74,000 family members and DoD civilians, and 200,000 plus people here on the west coast and elsewhere who could be deployed on very short notice into that theater.

So some of the potential issues for DoD in the future. If we have a similar situation, you know, how are we going to address questions like should DoD pursue acquisition of an alternate vaccine for use in military personnel? Should we use an alternate vaccine for all Forces or just for Forces in areas where an alternate virus poses a significant threat? How should we make those decisions, and should DoD revitalize its role and that of this Board's in the national decision-making process for influenza vaccine composition. The FDA is certainly open to that. Hopefully we would get the expectation of being invited to participate in that effort again next year,

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but this is, again, one of those disease control issues that had been very active in the past. For many years probably was almost a non-issue but has the potential again as part of our response to pandemic influenza threats in the future that we're going to have to look at what our priorities are for vaccine, what the threats are, and how we as an organization would make rational decisions. That' it. Thank you.

DR. PERROTTA: Thank you, Captain Trump. Any questions for David? Rick?

DR. POLAND: I would second what Captain Trump said that this is likely to be an increasing issue for DoD simply because the surveillance mechanisms are increasingly in place to identify variant strains that are relevant. For example -- and Jim may know more about this -- I just heard the end of last month an H9N2 has been identified from two people in Hong Kong, which has never been documented or seen in humans before. How big of an issue that will be no one knows, but those kinds of issues I think are going to be very relevant.

CAPTAIN TRUMP: And, you know, the same with the increased surveillance. There's an expectation that in a short period of time WHO could

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be making recommendations every six months for vaccine combinations, you know, specific -- different vaccines for the Southern Hemisphere, and, you know, how we look at those vaccines for our troops who are deploying into those areas and how we would use them are going to be issues.

DR. POLAND: And it's not so far-fetched in that fairly near-term technology may allow in fact the manufacture of different vaccines for different settings.

COLONEL DINIEGA: After I got the call from Doctor Hoke and also Doctor Lebedowski, I made a query to Korea to find out if they had any additional information, being that the number of specimens sent to Project Gargle was very small. If you remember, it was six or seven from the Pacific countries and very few from Korea where there's probably the larger concentration of troops. And they've been sending some specimens to the Korean NIH equivalent, and they had some data, and they did not recognize -- no Shandong was circulating in Korea, but we also talked about the need to increase participation in the influenza surveillance program. So they're going to be working on that and getting the policy out in Korea

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to get increased participation through the flu season.

MAJOR FISHER: This is Major Fisher. I think they received more specimens. I think six was just the number of isolates. Is that right, Linda? But you're correct. I mean, participation does need to increase, and we're going to work on that.

DR. SOKAS: We have actually broken out our Asian isolates from this year. Up through last week we had received 437 specimens. Of those we have 59 type A and nine type B, and all of those that have been typed so far, the Bs have been the B/Beijing.

This afternoon, our latest update -- which is actually kind of exciting because the network works -- you've probably read in ProMed about all the problems in Nepal, and CDC contacted us, and we contacted the people in Thailand and Nepal, and within a week they had 24 samples collected working with the Ministry of Health over there. And after all of that, British Airways lost them, and I lost a lot of sleep.

But we did receive the box two weeks later, and because they had packed them in 86 kilograms of dry ice, we got good specimens on Friday, and this afternoon I was told we have six type A's and four type B's so far out of 18 specimens from Nepal. We

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have another six from the embassy in Thailand. So we'll type those within the first part of next week probably.

And these could be very interesting because it is late in the season. We do have outbreaks of people they say are dying and could lead us to what's going on. We're also getting a lot of specimens from South America, outbreaks that they're talking about, and we're seeing mainly A's, although we're getting B's, but the A's there have been H1's, which is a vaccine strain.

DR. PERROTTA: Amazing. Good news.

DR. POLAND: It's particularly important for DoD to have this kind of influenza surveillance program because just as a denominator from the FDA point of view, we're looking at isolates of about 80,000. So 24, even a couple of hundred get lost in that in terms of what's immediately relevant to DoD. The other thing is we get few isolates from the areas of concern.

So, Dave, I was just going to ask one other question. Is there anything the Board might do that would be helpful in this program?

CAPTAIN TRUMP: I think the one invitation

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was to participate in, you know, DoD's planning for pandemic influenza preparedness, which obviously is basically planning for influenza preparedness all the time, and then the other would be -- is potentially to participate as one of the representatives to the VRBPAC or at least attend that in the future. I think this is just a reminder that influenza continues to be an issue as far as military preparedness.

DR. LA FORCE: In the past, have DoD influenza vaccines been different than the vaccines that were available commercially?

DR. CHIN: Yes, the answer to that is yes, used to have special military formulation.

DR. PERROTTA: Different virologically than what the public -- I guess I read your slide saying recently you'd been using commercially available.

CAPTAIN TRUMP: Right. In the last 10 years, you know, that I've been here, I'm not aware that we used anything different than what was being used nationwide.

DR. CHIN: The reason --

CAPTAIN TRUMP: Historically I think DoD was very active in influenza vaccine productions and

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decisions and essentially deciding and making vaccines early on in the '60s and up through the --

DR. ASCHER: It set the standard.

CAPTAIN TRUMP: Right.

DR. ASCHER: Led the nation. The other group has supplanted them, but DoD was the other player for a while.

DR. CHIN: No, but the question, has there been a sense among epidemiologists within DoD that the match hasn't been good regionally or nationally?

DR. LA FORCE: Or has it all worked?

MAJOR FISHER: This is Major Fisher. I think over the past years since the Board has stopped getting involved, it's worked quite well. But the question came up this year -- I didn't quite mean it like that. But this year with the question of WHO recommending a different strain of B, the Shandong for Asia and the fact that we have troops there and then a different strain, the Beijing still, you know, remains the strain for the U.S. vaccine, there could be some question.

DR. ASCHER: Marc, you can stretch it that if last year Sydney had not hit the Continental United States that it could have hit our troops first, and

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had someone been thinking ahead of time, we might have thought about a formulation that was -- had Sydney in it before it happened. And that's the old style of thinking that I think Jim Chin is referring to where you're looking outside the system, but things move so fast that it got here and bit us in the ass all over the place before anybody knew about it.

DR. POLAND: I think -- Greg Poland -- that's right. I mean, three years ago A/Sydney roared in after the vaccine production had already started, but in the near term it may be possible to recognize that increasing threat and make a vaccine relevant to DoD or even other people.

DR. LA FORCE: But also we do exist globally, and it may not be necessary for us to make this -- a second vaccine that may be more appropriate regionally. I mean, we are part --

DR. CHIN: Part of the situation was that the civilian vaccine was designed primarily for the elderly whereas the military population is sort of a much younger population so that different dosage of different components would be specifically recommended for the military compared to a civilian formulation. So there were some little differences. But I -- over

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the past decade there hasn't been any, but I think the Swine Flu thing was the perfect example. There was a very specific military formulation.

DR. POLAND: I think the other thing to not lose sight of though, and obviously I'm not suggesting that you have, Marc, but the issue for DoD is these variant viruses that we're increasingly capable of detecting. I mean -- and weird things are happening. For example, this coming year, this will be the third year that A/Sydney will be in the vaccine, which is unprecedented in anybody's recollection at least of 15, 20 years, to have the same H3N2 virus circulate world-wide. It hasn't happened before. Why is it happening now? Why this H5N1, why this H9N2? Is it really something different happening or is it our surveillance capability? Regardless of whichever it is, we need the capacity to respond.

DR. LA FORCE: I just sort of finish by saying that presupposes we understood what we were doing before.

DR. PERROTTA: Okay. Doctor Ascher.

DR. ASCHER: On that note --

DR. PERROTTA: We'll talk about another

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weapon of mass destruction besides influenza.

DR. ASCHER: The difficulty for me today is to make this coherent and build a link to something to do with the AFEB, and that I think I'll do quickly and then see if you can follow it.

My computer died. I lost my screen, so I'm going to do this from just notes. 1995 the plan to destroy smallpox was up for review at the National Security Council. And, as you all recall, Secretary Sullivan had announced at the World Health Assembly that the United States was going to do this, and when it came before the National Security Council as a consent item, it is alleged that someone said, "Well, we're going to destroy smallpox. Is that all right?"

And DoD said, "Say what?" He said, "Well, just destroying smallpox. That's -- we've talked about this before." "No, we haven't." "Really?" "Really."

So there was a gulf perceived at the National Security Council between the Public Health Service and DoD, meaning that one had a very clear idea of destroying this virus, and the other wasn't so sure. And some of the issues that were related to that were the issues of national security.

So a meeting was convened by the Disease

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Control Committee of the AFEB and the council of NCID to thrash this out. And a session was held that basically concluded that smallpox should not be destroyed for a number of reasons.

It was my concern in talking to people on the Board that this recommendation had sort of gone nowhere and that there was motion afoot to sort of reverse it or ask other people the same question until somebody got answers they wanted. But, indeed, what has happened is the national consensus of all the same people has now come to the conclusion that probably on scientific grounds, at least the scientific community is saying don't destroy it. At least that's as of last week changes. But the Board is on record at least indirectly as not supporting destruction.

Now, one of the eye openers to the Public Health Service at this meeting was the fact that anthrax -- I mean, anthrax, hello -- smallpox was a weaponized threat against the civilian population by the Soviet Union, had been going on for a number of years. The military had stopped vaccinating as well as everybody else, and the military had not considered it a military threat when they had been vaccinated and when they had been vaccinating and the fact that

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they'd never weaponized it or even thought of weaponizing it.

So the Federal Government of the United States was a little bit blindsided on the program that the Soviet Union had targeted against civilian populations. So this was the eye opener at the federal level that biological warfare was not just DoD and opened the specter of biological terrorism. The meeting occurred the day before Timothy McVeigh blew up the Federal Building. That was also an eye opener the next day.

The National Security Council took many of the same people from the panel, added D.A. Henderson, a couple of other people, Phil Russell, some of the people you know, and asked us whether biological terrorism was a problem and whether we were prepared.

It was a fairly short meeting. Long break, very short agenda.

Now, at that point a number of people began to take it very seriously, and led by D.A. Henderson, some in-roads were made to the Public Health Service to find out what was going to be done, and the Public Health Service was really not well prepared not having thought about this, as I said, but

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over the last couple of years has made extraordinary progress -- please don't quote me in the newspaper -- but prodded to a fairly large extent by D.A. I think you know the kind of force he can be.

And one way to approach getting things to move forward is to get Congress to do something, and indeed that's what happened. And in this year's budget, there was \$179,000,000 allocated, led by at least in the Senate side Senator Faircloth, for the purpose of building national domestic preparedness and response to biological defense or biological terrorism defense.

The largest item was a stockpile of antibiotics and vaccines, including anthrax obviously we talked about, and the rest of the money, \$121,000,000, being given to CDC to develop a national program to counter at the local and state level the threat of biological terrorism.

The first time I have in my knowledge heard the concept of biological terrorism actually expressed within the halls of CDC was a meeting last fall. This is a radar screen that has a new item on it. Two meetings were held. It is now a very serious item on their agenda. They have appointed I think

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very, very well qualified individuals from their cadre of people to work on this problem, to wit, Scott Wolobridge (phonetic), Steve Morris, Ali Khan, a few others from other groups.

It's an office within NCID, and they are scrambling to get money on the street as soon as possible to build a response system. Now, the five parts of the program they are putting together through this RFP is local planning, how planning is done for the purpose of public health.

Now, what had been done before at the local level and in the military was building up capability of first responders. But what this initiative says is that covert attacks of biological agents are not going to present as booms or bangs or people falling over where the fire department shows up.

This is going to be the occurrence of some unknown illness in a community. And if it's anthrax, for example, by the time you've recognized it, you may have a severe problem. So this is an orientation to rebuild public health for the purpose of picking up these issues or these agents. And, of course, if you rebuild public health for this purpose, you rebuild

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public health for all purposes. So this is the rebirth of public health as we know it.

The second component, surveillance and epidemiologic response. Obviously you have to pick up these diseases. You have to be able to report it in a timely way. You have to be able to go out and do risk assessment and find out how many people are exposed and what do you do about it.

Chemical attacks you're cleaning up bodies and treating people. Biologic attacks you're following people around like who did you talk to, where were you, et cetera, very, very different, very difficult.

Major piece of initiative, not a lot of money but a lot of detail, is in the biological lab capability. Again, off the record, the original specifications of this program had \$9,000,000 dedicated to the University of North Carolina School of Public Health for a laboratory. Senator Faircloth didn't fair so well. He lost. Hope the people from North Carolina aren't offended. But that got transmogrified into three laboratories and then in a CDC initiative got further transmogrified into a network of laboratories. So I'm not sure North

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Carolina has a laboratory in this anymore, but it certainly was a startling change. We were supposed to go to a meeting about building a \$9,000,000 laboratory in North Carolina, and it became a whole different ball game after he lost.

His replacement on the committee is Diane Feinstein. I won't tell you what that means.

The fourth component of the program -- and I'll talk further about the bio labs -- is a chemistry laboratory program in support of backup of CDC, really a strong thing for detection of chemical agents.

And the last piece, which is actually the largest chunk of money, is a health alert network, which when it was presented Ed Baker said, "This is not just a computer on every health officer's desk. It is that, but it's not just that."

Well, it's mostly that because they really are saying that for thirty some million dollars that they want every local health officer on the Internet with a network connection that can talk to each other, which is a very, very extraordinary program I think.

Now, the agents that are of concern, one of the things that happened at CDC is that this is all deer in the headlights kind of stuff. They're shown

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lists of organisms, 20, 50, 60, and they don't have any idea kind of what these things mean, what are the threats? They've never seen weaponized threat lists. They've never seen classified information.

So basically through some previous planning, it turned out that a consensus was obtained that there are only five organisms that are of concern for the perspective of domestic preparedness and defense, and you know them all by heart, anthrax, smallpox. As the big players, botulism in its own category, its military relevance not perhaps as great as even the civilian relevance, and then plague and tularemia sort of a little bit category of themselves, and that's it.

Now, what was interesting is the CDC program had room for a lot more, so we had to pick one more, brucella, brucella. Go figure.

Now, I think the CDC would have been very pleased if they could have given all the money to one laboratory to build a program because what they were left with is an interesting problem which is how do you build a national response capability for bio which enhances laboratory capacity if the goal is to recognize covert events. And to make a long story

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short, what they basically said is that they will build a national network of local, state, federal, and other laboratories in a tiered fashion that has redundancy and interconnectivity to respond and detect these things.

So what this means, at the first level, all clinical laboratories will be told don't throw out your brucella species from blood cultures, okay. Make sure the algorithm in your Vitech is correct for plague, a few things like that. That is actually the hardest part because there are many, many more of those laboratories.

The next level will be to equip all states and most of our large counties with the ability to confirm biologic agents, those five agents -- forget smallpox because that's a special case -- those five agents, including brucella, with state-of-the-art 1930s microbiology, which means culture, fermentation, antibodies, no whiz bangs, no rapid tests, no nothing.

This is a trained -- program of training where microbiologists use conventional microbiology to identify.

The second level of these laboratories will be connected very quickly to all jurisdictions so

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that they can also provide support for FBI and other people that need to bring samples in from events or hoaxes and things.

The third level laboratory will be the states. It will be involved in R and D, tech transfer, preparation of reagents, validation of new technology, collection of strain repositories, et cetera, et cetera.

The level C laboratory is the major states, Texas, California, New York, a few others, will then be a high level R and D applied research adjunct to the national laboratories. And so USAMRD will not be taking phone calls in the middle of the night of I want this anthrax tested. CDC does not have to build their own capability. They basically work through this network, and they are so relieved, and they are so pleased that they can focus on their mission, which is real research, and not be bothered by some of these routine things. So that's a win all the way around as far as I can tell.

I'm reading the flier on emerging diseases in the military, and I see this need for a public health network for the military. You're talking about building a parallel program. It might be possible to

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hook into this for your own needs as well. Once the thing is defined and once the thing is set up, it should be fairly easy to add other capabilities.

Next year's funding is supposed to be greater. Donna Shalala announced there's \$230,000,000. So that is getting to be a fairly reasonable amount of money.

The other pieces that are kind of interesting is that D.A. convened a group at Hopkins called the Civilian Center for Biodefense Studies, with the goal of bringing in the partners to talk about various aspects of this, and we have written now three, and others are being started, manuscripts on the public health implications and management of these five or so threat agents, and I say three are done. Anthrax is in press. Smallpox and plague are coming along very nicely.

JAMA next month, long, fairly detailed, but a fairly important document. This is where the federal partners, the Army, other people, have been participating.

Now, why does D.A. have to convene all the federal partners? Do I have to tell you? No, because the federal partners really were slow in figuring it

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out, but it was a favor. I will consider it a favor.

I'm not going to be nasty, but from the perspective of goosing the system, the federal partners have really gotten up to speed and I think are about ready to take this over in spades. Secretary Shalala has designated Peg Hamburg, some of you know, to be really serious on this problem. She is up to speed very well, and I think the Feds will be off and running with the support and as I say the persistence of D.A. in trying to do the right thing.

The other group that is quite active now as we speak is the National Domestic Preparedness Office. This is designated by President's directive to be the overall lead for this problem in the civilian sector, and it is just -- it is an office with an FBI. It is a virtual office where they have no administrative authority. It's a convening of partners. All the people are there. The military is there. CDC is going to be coming, and it's building coordinated response systems so that one group doesn't go in and train certain people to do this and other people train certain people to do that and then when an incident comes they bump into each other which is very likely to happen under the present arrangement.

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That's a very serious program.

The military -- and this is the other hook back -- has a place at that table, and Ellen Embry was at the most recent convening meeting of that group, and the reason for that is that most of the medical assets of the military or the Army for sure, 59 percent I believe are in the reserves.

Now, when the money -- when one pot of money was put forward, in addition to everything I've mentioned, it was given to the National Guard for the purpose of building a response system. Well, whoever wrote that didn't realize that the National Guard had no medical assets. They'd just given them all to the reserves. The reserves had given all their helicopters to the National Guard.

So you had National Guard with lots of money and no assets. Now you have National Guard with authority to go in and help in civilian disasters and the reserves that don't have them. So all of a sudden the word DOMS comes up, how you put reserve assets into a disaster. This is all being discussed. The role of the active component is also part of the program as well. So this is proceeding quite rapidly.

And, as I said, that's the nutshell of the program.

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I want to close by telling you about one hoax that occurred in Northern California. Then I'll ask for any questions.

Around the first of the year, just after Christmas, L.A. started having anthrax hoaxes. And those of you who don't read the paper out here don't realize how it went. It went from six people in a building to 20 people in a building to 20 other people in a building to 90 people in a building to 1500 people in a building, and now the response was to take people outside, take off their clothes and shower them down with some spray.

At that point, they threw up their hands and said we can't do this. This is crazy. It doesn't make any sense. These are not real. Announced threats are not going to be real because if you want to do bio you don't tell somebody. You let it happen. You don't want to tell people what you've done.

So they've kind of backed off. But, again, what drives our reality? Board of supervisors in Los Angeles asked them how much money they were spending on these little episodes, and it turned out it was a very, very significant amount of money, and they decided if they were being ridiculed in the press

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for doing unnecessary things and were spending a lot of money, they ought to quit.

So the FBI as the lead agency backed off.

And the reason these things stopped at some level is they stopped responding. You call up and say you have done something with anthrax, that by definition is a hoax. They'll come out and talk to you, and they'll run you down, and they'll do various things, but they're not going to come and do a full court press on this club right now if somebody makes that phone call.

So don't worry about it.

Now, in Northern California, we had the good fortune of being in conjunction with a very good FBI group that had set up some programs, and they were very different in terms of their relationship with first responders. And a man called in to 911 number in Newark, California up near Fremont, and "I've released anthrax -- I'm sorry -- I've released AMTRAC in this building, and there are 400 people here." And the 911 operator said "AMTRAC?" And he said, "Listen, I've released AMTRAC in this building," and so she heard the word AMTRAC, so not sensitized asked the supervisor, and the supervisor said well, that doesn't sound right. That may be anthrax could be possibly

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they're talking about. I'll call the FBI. You call the police. So the police rode down to the scene and the FBI was called, and the FBI said, "Well, what's going to happen? Are the firemen going to take the people's clothes off, and are we going to evacuate this building," and the person said, "I don't know, but I'll patch you through on the phone." So the FBI guy said, "Well, what are you going to do?" And they said, "What?" "What are you going to do? This is an anthrax threat." "Yes." "Don't you know what to do? Haven't people taught you to take people outside and take off their clothes?" "No, no, we never had any training on this. We have no idea what this is." "Could you all go home?" "Yes, sir, be glad to."

All the fire department disappears. All the police department disappears. FBI walks in the building. FBI walks in the building and says to the manager, "Ma'am, we have this tape of a 911 call, can we play it for you, and do you know who that is," and they said, "Yes, that's Dennis Perrotta. He sits right over there." "Dennis, can we come talk to you?"

They call Bob Peterson in the room, and they say, "Bob, what are you doing here calling up, you know, an anthrax threat? We want to know more about it," and

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he was a little bit less than forthcoming. But at the very end of the story the punchline was he said "I wanted to go home early."

Bob's in Federal Prison, no bail, 15 to 30, first person ever caught on a hoax, on a threat, under the new regulations, the new law. So the answer is if it's AMTRAC or anthrax, it doesn't matter. Get out of the way and call the FBI.

DR. PERROTTA: Any questions for Doctor Ascher?

DR. ASCHER: Are you getting the same message, Dennis, or is that --

DR. PERROTTA: I've got the same message.

DR. POLAND: One question, Mike, before you leave there. Particularly with the idea of domestic biologic terrorism and detection being the issue, is there any tie-in with proposals that DARPA had out three to five years ago looking for early detection mechanisms?

DR. ASCHER: Loosely. The problem that was faced when the idea of deploying direct detection into these events was the issue of the reliability of single tests that are running in a screening mode.

Very briefly, if you want to -- if you

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find someone out there with a powder that has aerosized this room and you run a rapid test on it, the one thing it has to do is be absolutely sensitive because you only want to react to a negative. It's like an HIV screening test. You transfuse the blood. Everyone goes home.

The technology that's there is very, very insensitive compared to available technology. So, yes, the DARPA Initiative is to try to leapfrog over this first generation stuff and get something on the street that would be practical as a screening test.

Now, if you bring that to a laboratory, they put it in culture, it tells you more than rapid test. It tells you whether it's viable. It tells you whether it's bacillus thuringiensis, which is a surrogate, et cetera, et cetera.

So the reasons we have de-emphasized rapid tests are two. They're confounded by surrogates, and they're not very sensitive. They're older technology.

But the goal in the future is to have detection systems that at least as a screening test can be used for calling off responses, with some false positives not being a problem.

DR. PERROTTA: The Institute of Medicine

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formed a committee about two years ago, and I sat on that committee, and it was a committee to improve -- research and development to improve civilian medical response to biological and chemical terrorism, and our report came out in January of this year, and there's a whole chapter on it, and it was written by this lady from the university -- or Utah State up in Logan who had a DARPA grant who has some amazing stories of technology that exist in laboratories, not public health laboratories, but these are light cyclers that can get you an answer on what this powder is in 15 minutes and that they're this small. The Air Force is working on that in San Antonio where they're trying to make it into a field tested kind of thing where somebody can walk in and do it and put it in the back of one of those things that does the chemical stuff.

And so it's all there. It's not in our hands yet, and it's not available for people to use in those situations. So we're still using the old technology. I mean, the best technology that we have that we hope to develop at the state level for example is to get BFA reagents for bacillus anthracis, and we can get you an answer in a couple of hours, and that drives the policy of how civilians are going to now

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respond to an anthrax request.

Let's say you open up an envelope. You're in the mail room of the AFEB office and you open up an envelope and out drops a powder, and you got a little sign in there that says "You've just been exposed to anthrax. I hate the AFEB" or whatever, it's signed by AFIP or somebody else.

Now, the response has been for over 200 of these hoaxes that the FBI and CDC has responded to, many of the responses, mostly in the beginning parts of this, were to rush this entire room through the decontamination line of a fire department. And that's not even the right thing to do if it was anthrax.

DR. ASCHER: That's what they were trained to do for chemicals.

DR. PERROTTA: But that's what they were trained to do for chemicals. And so that you know, the right answer is that you call the police. The police secures the area. Nobody leaves or comes in until somebody writes down the name and the address and the telephone number. Somebody picks up, puts this in a plastic bag, your lunch bag or some box, and gets it to a laboratory that can do the DFA in a couple of hours. That may take an hour's travel. It

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may be the other side of town, or you may have to put it on a plane to Austin from San Antonio or something. That's, you know, 15 minutes or so.

While they're working on that, you send the people home, and you tell them, "Take your clothes off and wash them in your washing machine. Go take a shower. Take a couple of showers if you want, nothing special, and then wait at the phone. And by the end of the day, we will have an answer, and we will have an answer in plenty of time, even if it is bacillus anthracis, because then if it is, then we've got to turn on the switch for, okay, how are we going to get you your supply of CIPRO or other appropriate antibiotics --

DR. ASCHER: And vaccine, smallpox.

DR. PERROTTA: Well, maybe and smallpox, but in the civilian sector right now, people are saying CDC is telling me 60 days of antibiotic treatment because we're not going to have our hands on vaccine right now. We don't understand. We don't yet know -- we don't have that capacity yet in our hands. And so for the time being, they're talking about 60 days of antibiotics.

Well, what is there, 50 people here times

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60 days times however many. What if somebody did this in downtown Baltimore as the meeting in Arlington talked about, where they had the pro football game going on and somebody drives on the highway right next to it and releases anthrax spores, the wind blows it over there, and nobody knows anything, and by the time the first case of a flu-like illness results in a death, these people are in some other country.

Interesting scenario. I suspect many people -- and my experience in traveling around Texas and talking about this as part of our awareness program that we're trying is that a lot of people have answered -- and these are city officials -- well, we have an Air Force base nearby. We'll call them. Well, we have an Army post here. We have Fort Sam Houston. Guess where that came from --

DR. ASCHER: Or the National Guard can take care of people.

DR. PERROTTA: Or the National Guard. We'll call the National Guard because the guy that works down in this office here in my office is a National Guard guy, and so we'll just call them.

There is some expectation that we are fighting desperately in the education mode that the

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military has all of the answers and can mobilize everything necessary. Clearly the military has a lot of knowledge about this and expertise. We expect to get the Matt Dollans of the world in San Antonio to be part of San Antonio's response, but not to be all of San Antonio's response.

Police department chiefs are asking whether or not they should send their policemen in to determine if it's a credible threat or not. And if they do, do they send in a SWAT team, do they send in people with -- in moon suits. Do they call HAZMAT team, do they call the Medical Management Strike Team, which is now known as part of the Medical Management Response System, and these are some of the larger cities that have received some HHS money to create systems to respond locally, which is exactly where it needs to be -- this is a local issue -- with response mechanisms from state health departments to include how do we get respirators, how do we get antibiotics, how do we get vaccines, how do we mobilize CDC, how do we talk to the Guard, how do we follow up epidemiologically and help folks figure this out.

And this is all when somebody said "You've been exposed to anthrax." What happens in the covert

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situation where in your city where you and your families live the first thing that will happen will be an increase of folks to clinics and hospitals and emergency rooms with most likely flu-like illnesses that will be sent home under viral syndromes and will come back -- perhaps several of them will come back later that day near death, dying by the end of the day, and the first clue that we may have will be cultures from autopsies.

Now, from day zero, let's give us 48 hours for those first people to start getting sick and die.

How long is that autopsy going to take, and how long will those cultures take to come back, a day, two days, three days, more? We're five days down the road now, and in those additional three days, everybody else that was exposed in whatever incident this is has gotten through the phase that they're not sick, and now they are, and my understanding is that 80 percent of those people will die no matter what we do.

The social disruption of this event is enormous. For those of you who have a computer with Internet capability and you can listen to things, I would recommend that you go to the address WWW.BIODEFENSE-HOPKINS.EDU, and I'll -- if I've messed

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that up, I'll send the right address. This is the -- you can find the recordings of the lectures on this meeting that Mike talked about in Arlington, and one of them by one of D.A. Henderson's guys, Tom Inglesby, a bright young man, was simply entitled "Anthrax, a Possible Case Scenario." It scares the dickens out of you because it's very plausible. It's very conservative, and the social disruption that occurs.

Think about the fact that the FBI had gotten a call that this was going to happen but they couldn't find any credible evidence so they didn't say anything.

Think about the couple of dollars a person that city government would have to pay in order to stockpile these things but they didn't really think that was a big -- credible or a big problem, and the lawsuits that will occur, the dead zone that will occur in the area that the anthrax was spread. Commerce will not happen. People will not come to your city for a long time because they will know that as a place where a lot of people got anthrax, huge problem.

Mike -- and I'm going to close it real briefly in saying that Mike's described that the

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federal response had in the beginning been very, very slow, and the slides that I use in my talk, I just changed the slides last week, the last slide I said was that the federal response was large and chaotic because indeed every one of the Services has a unit. The guard now has a unit. Ten states have \$5,000,000 a year to build a response unit. Mike Osterhom talked about those guys as having the finest fire truck in the world and not being able to find out where the hell the fire was. And so that helped build the mechanism or the interest in trying to get state health departments and local health departments money to build the response.

The only thing I can tie this to the AFEB is that (a) you guys live in cities, and I will tell you that there are precious few, fewer than this many cities out there that have an exercised competent response capability to biological terrorism, and that's even giving some of those cities some credit.

In Texas we have none. They've all got people working on it, and they're really good folks, and they've asked really good questions, but one of our major cities, our biggest city -- and you can do the geography -- their health department had not even

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attended any of the meetings on planning.

I don't know what I can recommend to the Armed Forces about how you as an organization or a series of organizations can work to help biological terrorism on a domestic perspective, but my recommendation is that we all live in cities, and each one of our cities is a target, and you can come up with your own theory on whether or not you're a big target or a small target, but I would submit for your consideration that if I was a terrorist, I would not have picked Oklahoma City. And so what that makes me conclude is I do not understand, do not understand what is in the mind of a terrorist when he or she wants to do this kind of work. So therefore, I suspect that all of us are at some sort of risk that is perhaps not zero, but it's -- perhaps it's not large but it's certainly not zero.

Maybe you can bring these thoughts and figure out what you want to do on your particular bases and posts and naval stations. I don't know how this could result in anything organizationally speaking. We wanted to begin to broach the idea of thinking between the military services and domestic preparedness because you guys now have an additional

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responsibility, at least the military in general has been given additional responsibility to assist in domestic preparedness for biological or chemical or even nuclear or as we in Texas say, nuclear terrorism.

DR. ASCHER: Comment about the general rebirth of public health in terms of things like surveillance systems and just the general opportunity, communications.

DR. PERROTTA: Absolutely. This -- everybody at Congress said more money to this program, and they hung their hat on bioterrorism, and so we in the states were thinking, okay, when we write our proposals for this money, we have to really push bioterrorism, but then the word came out from both CDC and from one of the fellows who was an aid -- he was at the meeting in Arlington -- he basically says, "No. We know what this is for. This is for a reversal of the decade-long decay in public health infrastructure support, and it's the first step we hope. It's to build laboratory capacity that on a day-to-day basis is going to be helpful when we do shigellosis outbreaks and tuberculosis problems. Our chemistry laboratory is -- these people are going to be on call to do CDC work, but in the meantime, they'll be

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working on our pesticide samples and our water samples. The epidemiology is to build the infrastructure with our partners and health care facilities. Then on a day-to-day basis, we'll improve the reporting of the conditions that we had reportable in our state that are in hospitals that we don't get right now for other reasons."

It's gotten a lot of people charged. It's not all about bioterrorism. It really is about the rebirth of public health and the reversal of that decay. I hope to be around long enough to really see it come up to speed, because we have an awful long way to go. There's not enough money for the states to do their kind of work, so there's going to be some creativity, and I'm hungry, so I'm going to stop there. Henry.

DR. ANDERSON: The only thing I would add to that as far as what the Board or what the military can do is one of the issues is the money is being put out in a competitive mode so that the haves are more likely to have successful applications than the smaller have-nots, and I think the real challenge here is there's a lot of excitement. It's from a public health standpoint a fair amount of money to start

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with, and I think the threat to the system is the strength of the system is only as strong as the weakest link. And in Wisconsin to get our governor and legislature to sign off on this, it was, well, if we don't compete, we'll be at greater risk because we'll be viewed as being complacent and therefore an easier target kind of a thing. And I think if you're a terrorist and you're looking for where to go, you aren't necessarily going to target an area that's the strongest. So I think what we really have to be sure as we work through this through the next couple of years is to be sure that it in fact is not a patchwork of projects like Sentinel Surveillance just isn't going to work for a terrorist type activity, that we really need to be sure and that this group can look at that in the military as well to be sure in fact that we do end up with a national-based system that is infrastructure across the board, not just in big cities or big states.

DR. ASCHER: The issue of the lowest common denominator is truly clear in the health alert network, where I said a computer on every desk, and that seems trivial, but that means that there's nobody doesn't have a computer. And you say, well, I want

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seven. No, if there's even left over, you can have them, but no, that's not the way it works. The same thing in laboratories. They basically say the laboratories -- the first priority in the first year is to get everybody up to at least the second level. Now, the concern is that some of the players aren't capable of even putting in applications at that level. And so that's going to be very embarrassing, but it would only be in later years that the fat cats will get fat. At least that's our intention.

DR. ANDERSON: Well, I would just point to the emerging infection laboratory program as an example of the rich getting richer and the poorer getting poorer. So I -- it still is competitive. There aren't going to be -- I mean, every state is not going to get money out of this, and there needs to be a plan for those that don't. As you say, how are you going to build a capacity when there isn't any? It's one thing to build on capacity. So it's tough.

DR. PERROTTA: Well, I would welcome any wisdom and use this as an opportunity to lay some groundwork down. No answers or recommended -- or requested today, but the thoughts are that we'll have more of these discussions in the future. So, Mike, I

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appreciate you giving a good overview. You saved me having to pull my slides. Do you have some announcements?

COLONEL DINIEGA: Yes, just real quick. Lunch tomorrow at the golf course will be barbecue buffet, and I've asked them to reserve the tables up against the windows for the group, whoever goes there.

If you can re-sign in the morning, that would be helpful so we know who came on the second day. And the tour will start promptly at 12:15, and so we should plan to break for lunch at 11:00. The Board has essentially three hours to work on recommendations to four questions and pretty much finalize the DoD immunization report, and we'll start promptly at 7:30.

Carol?

MAJOR FISHER: Will the bus pick up the people that are going on the tour?

COLONEL DINIEGA: Right.

MAJOR FISHER: Where?

COLONEL DINIEGA: Here.

MAJOR FISHER: Here, okay.

COMMANDER TEDESCO: What time is the tour over?

COLONEL DINIEGA: The tour should be over

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we calculated by 1530, 1600.

DR. PERROTTA: The ship tour will be about an hour, and then the BUDs tour will be a couple of hours.

COLONEL DINIEGA: Should be back here by 4:00.

DR. PERROTTA: Okay. that's good.

DR. SOKAS: If the people want to do like half the tour, you know, the ship, but not the BUDs, is there going to be another run back here?

UNIDENTIFIED SPEAKER: Some of us have 3:15 flights.

COLONEL DINIEGA: We talked about cars. Is that available for people to come in a separate car?

UNIDENTIFIED SPEAKER: They would have to have a car. The ship tour is just going to take an hour. So we'd be back by -- over by --

COLONEL DINIEGA: You could follow the bus and then leave from -- could they do that, they can follow the bus or a vehicle, we can get a vehicle to follow the bus and --

MAJOR FISHER: How many people are we talking about and do any of those people have a car?

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LIEUTENANT COMMANDER FALLON: No.

COLONEL DINIEGA: We'll talk about it tomorrow. We'll be able to do that.

COMMANDER TEDESCO: Is there a particular way to dress tomorrow for this?

COLONEL DINIEGA: No. Just what you have on today is fine.

UNIDENTIFIED SPEAKER: Man, I brought my sweatshirt to wear. I wanted to -- are we going to be jumping out of planes or --

COLONEL DINIEGA: You can do the rope over the pool where they pull you from the side and you fall in the mud pit.

DR. PERROTTA: For those Board members or anybody else who'll be staying at the Navy Lodge, I've been asked if there'll be dinner arrangements tonight, and why don't we meet as a group as you wish at 6:20 at the front desk of the Navy Lodge, and if I can get a show of hands of who might be interested, then I'll make reservations at the Chart House, which is a very nice place right across the street from the Del Coronado, and we might even make the per diem that way.

DR. ROLAND: How about 6:30, Dennis, so we

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can run and shower.

DR. PERROTTA: We'll meet at 6:20. We'll leave at 6:30. If Greg's not there, tough. Okay. Good, anything else?

MAJOR FISHER: Let me just -- Colonel Karwacki brought up a good point. Any women that are going on this tour tomorrow, pants might be better than dresses. I don't know if any of you remember in Norfolk when we went on the ship there. No, skirts, no heels.

CAPT. BEDDARD: And just for your knowledge, when you're boarding the USS Essex tomorrow, which is a large amphibious ship, they're going to be boarding 1200 Marines at the same time. So it's going to be very, very busy. You'll get to see it in full operation. So there will be lots of equipment on there too, tanks and other things.

DR. PERROTTA: Appreciate you setting that up for us. Thanks a lot.

(Whereupon, the meeting was adjourned at 4:50 p.m.)

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