ARMED FORCES EPIDEMIOLOGICAL BOARD

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SPRING MEETING

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DALRYMPLE CONFERENCE ROOM
1425 PORTER DTREET
FREDERICK, MARYLAND

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WESNESDAY, MAY 21, 2003

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MS. ELLEN P. EMBREY

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P R O C E E D I N G S

(8:10 a.m.)

DR. OSTROFF: Let's go ahead and try to get started so that we keep on schedule, we have a very full day. I can't quite figure out if these are live-fire exercises that are going on overhead, or whether or not there's lightening and thunder outside, or exactly what it is, but hopefully it won't last too much longer.

Let me welcome you to the session this morning, and why don't we start with having Ms. Embrey make her required comments before we go any further, and then once that's completed, of course, we have several Board members who weren't here yesterday, that are here today, and we have a couple of new Board members. I'd like to kind of to around the room again and have folks introduce themselves.

MS. EMBREY: As the Designated Federal Official for the Armed Forces Epidemiological Board, a Federal Advisory Committee to the Secretary of Defense, which sort of is the continuing scientific advisory body to the

Assistant Secretary of Defense for Health Affairs and the Surgeons General of the military departments, I hereby call the Spring 2003 second day meeting to order.

DR. OSTROFF: Thanks very much. Because of the ceremony this afternoon, the seating arrangement has been changed, and the Board members are actually in alphabetical order. So why don't we go ahead and start over here with Dr. Campbell.

DR. CAMPBELL: I'm Doug Campbell, with the North Carolina Department of Health.

DR. CATTANI: Jackie Cattani, University of South Florida Center for Biological Defense.

DR. CLINE: Barney Cline, Tulane University.

DR. FORSTER: Jean Forster, School of Public Health at the University of Minnesota.

DR. GRAY: Greg Gray, College of Public Health, University of Iowa.

DR. HAYWOOD: Julian Haywood, University of Southern California Lost Angeles.

DR. LAUDER: Tammy Lauder, (inaudible).

DR. BLAZER: Dan Blazer, from Duke University, wondering why I'm out of order alphabetically.

COL. RIDDLE: Rick Riddle, the Executive Secretary for the AFEB.

DR. OSTROFF: Steve Ostroff, from the Centers for Disease Control. For those who aren't familiar with us, there's an explanation for everything.

MS. EMBREY: Ellen Embrey, from Public Affairs, Department of Defense.

DR. SHOPE: Bob Shope, from the University of Texas.

DR. SHANAHAN: Dennis Shanahan, Injury Analysis, Carlsbad, California.

DR. RUNYAN: Carol Runyan, University of North Carolina.

DR. POLAND: Greg Poland, Mayo Clinic, Rochester.

DR. PATRICK: Kevin Patrick, San Diego State University.

DR. LeMASTERS: Grace LeMasters, University of Cincinnati College of Medicine.

DR. HERBOLD: John Herbold, University of Texas School of Public Health.

DR. OSTROFF: Thanks very much. Rick, why don't I turn it over to you for your comments.

COL. RIDDLE: I just want to remind everybody that if would go ahead and please complete and sign your 1352s and send those in to Jean so we can process your travel vouchers. If you have any taxi needs or transportation needs to the airport today, just let Severine or Karen know and we'll take care of that. Also, for the Continuing Medical Education Credit, make sure that you turn in your evaluation form. For Board members, the evaluation form is in your notebook. For everybody else, there are evaluation forms back here on the table in the back. So if you signed the roster yesterday, when turn your evaluation form into Karen we'll get it for you.

Just as a reminder, the next AFEB meeting will be on 16 and 17 September 2003. This is the third Tuesday and Wednesday of September. Our recurring meeting schedule is February, May and September, the third Tuesday and Wednesday.

The Navy is going to host us, and the Board has expressed an interest in going to a submarine base, so we're going to have this meeting at the New London Submarine Base in Groton, Connecticut, and the host is going to be the Naval Submarine Medical Research Laboratory. In addition, because the Coast Guard Academy is just across the river, Sharon is already working and has made arrangements for us to receive a tour and a couple of introductory briefs at the Coast Guard Academy. I don't think we've ever visited the Coast Guard Academy, so this will be something new for the Board and a good experience for us.

Make sure all attendees for the meeting sign in with Severine at the table coming in the door and, again, we'll have refreshments this morning and this afternoon. We're going to have a catered working lunch here at USAMRIID for the Board members, the Preventive Medicine Consultants and the speakers. So if you'll just hang around over the lunch hour. For everybody else, there's many restaurants out through the gate here at Detrick, and they also have the cafeteria over at

NIH.

Restrooms are just right outside the door here to the right, and then down that center hallway to the left. If anybody has any questions or needs any assistance, please let myself or Severine or Karen know. And, again, we express our appreciation to USAMRIID and all the folks here that have helped us out and supporting another very successful meeting of the AFEB.

DR. OSTROFF: Thanks. We have a series of issues this morning, some of these were carried over from the previous meeting. Because of some scheduling conflicts, we decided to put both of the questions together for this meeting, and so we'll hear a series of presentations, and the first presentation will be by Col. DeFraites, who is going to brief us on the first question that is before the Board.

COL. DeFRAITES: Thank you. I don't have any slides for this part of the presentation, but I'll be introducing the question from Gen. Peake, the Surgeon General of the Army.

G6PD screening has long since been a

point of contention among the services. Currently the Air Force and the Navy screen all personnel upon accession or soon thereafter for the presence of glucose-6-phosphate dehydrogenase deficiency.

The issue for the military specifically has to do with the use of primaquine for terminal prophylaxis for the relapsing forms of malaria. Army does not presently screen, and the question for the Board from Gen. Peake this time, just to be brief, is essentially to reevaluate whether G6PD screening, as currently practiced, is effective in preventing post-primaquine adverse events, and quantify the degree of effectiveness, if possible. And if it is judged to be effective screening the way 8it is currently done in the military, make recommendations on the need to screen military personnel for G6PD taking into consideration a number of factors in terms of cost-effectiveness and timing.

I think one of the issues the Army has had with screening at accession is whether or not this information is specifically related to primaquine use, whether the information on

screening is actually available for use at the time the decision is made whether the person needs to go on primaquine or not. Most of the time -- well, I don't know about most of the time -- but a very common scenario is that this decision of using primaquine is done either during a deployment or soon thereafter. Almost immediately thereafter, as the troops are boarding aircraft returning from a malarious area, there is sometimes a decision made at that point, or the decision is made that primaquine is indicated. The problem comes up that most times in those situations there are no medical records available to be screened to see who is G6PD deficient or not. And so in that case you end up with a situation where you have to make some arbitrary decisions of who gets primaquine or not.

So, with that as kind of the background from the Army perspective, that's why this question, even though it had come before the Board in 1998, we wanted to reintroduce the issue to the Board at this time.

In order for us to get a little better perspective and for the Board to get some

additional background information on the use of primaquine in the military, Col. Shanks is here with this presentation and is prepared to give a little bit more background.

I'll be happy to entertain any questions about the particular questoin before the Board, if you have any right now.

(No response.)

Okay, htanks.

DR. OSTROFF: Any questions before we get started?

(No response.)

If not, Col. Shanks -- and let me just point out a couple of things before he gets started. His sildes are at Tab 6 in your briefing book.

COL. SHANKS: Good morning. As has been said, I'm Col. Shanks, and will be reviewing G6PD deficiency for the Board, who last reviewed this in 1998.

(Slide)

First, I would like to recognize the other people who appear on the title slide, who

assisted with this presentation.

(Slide)

G6PD is an enzyme and is part of the biochemical pathway that produces hydrogen molecules for reducing equivalence in biosynthesis. It's a gene that falls on the X chromosome, and thus is sex-linked with full expression in males. G6PD gene has been extensively selected over the past 10,000 years apparently due to its survival advantage for malaria. The pracitcal problem for people with G6PD deficiency is that they can have hemolytic anemia when they are exposed to a variety of drugs. The exact mechanism that this occurs with oxidizing agents is clear, but the mechanism is not clear with primaquine which also initiates hemolytic anemia.

(Slide)

Now, there are many G6PD genetic variants. For the purposes of today I'm going to discuss two broad categories, and these are the A- and the B- minus form. The A- is the most common form and is primarily found in persons of African descent. It is a relatively mild deficiency, most

people having greater than 10 percent of the normal enzyme activity. They are sitll deficient, but they have greater than 10 percent.

The B- is a much more deficient variant. It's found primarily in people of Mediterranean descent such as Greeks, Italians, Turks, Lybians and Moroccans. It's a more severe deficiency and has a much higher likelihood if you give these people a drug, that they ewill actually hemolyze.

(Slide)

This map is just to illustrate that although I'm only talking about two kinds, there are many, and the concentration in the tropical areas is again consistent with its selection due to malaria.

(Slide)

Now, a single dose of primaquine can cause hemolysis. This was certainly observed in the Vietnam War when teh CP tablets were given weekly, which have 45 mg of primaquine, but 15 mg can also cause hemolysis.

The actual hemolytic event is not

immediate. You usually see it within 1-3 days following taking the drug, so the person may have taken several doses of the drug prior to the onset of clinical hemolysis.

In highly deficient people, primaquine-induced hemolysis can truly be a life-threatening disease. The deficient erythocytes are hemolized. The new erythrocytes with relatively more enzyme are spared. In female heterozygous variants, one can see hemolysis of one-half of the blood volume, the ones that have that particular X variant.

Blood transfusion and hemodyalisis for acute renal failure and cardiac failure are common in very severe cases with massive hemolysis. Although this usually happens with the B- G6PD variant, the greater number of A- G6PD variants with smaller risk of smaller risk of hemolysis means that many of the hemolytic cases are still due to the A- variant.

(Slide)

Now, although the A- variant is the most common in the U.S. military population by far, the B- variants are the most important to any

recommendation becuase these persons will greatly hemolyze on receiving primaquine. The estimated incidence of B- variant is shown here and, again, as you can see, these are estimates, but they vary quite a lot depending on where your mother is from -- not where your father is from, where your mother is from.

The hemolysis rate in A- variants is quite variable, and most of them actually do tolerate primaquine rather well, although many will show laboratory evidence of hemolysis. Severe hemolysis remains a risk for A- variants, but the actual proportion of those who would be affected on receiving primaquine is fairly difficult to estimate.

(Slide)

Now, since ethnicity and G6PD status is linked, I want to show you some recent data on the evolving ethnicity of the U.S. Army. Now, this isn't as useful as it could be because the Army doesn't classify people as to whether they are Italian or Greek or other things, these are the categories that it gives us. But a large proportoin

of the Army are African Americans. The Asian category is growing, and there are some other veyr severe G6PD variants seen in that population. So we can't comment directly on people who have joined the military as recent immigrants from Eastern Europe and the Middle East, but this change is important in terms of the risk of hemolysis on those receiving primaquine.

(Slide)

Now, there's a whole laundry list of drugs that have been shown to cause hemolysis in G6PD deficiency. The one we're really discussing today is primaquine, adn I point that out becuase it is not known to be an oxidant, which is what triggers the hemolysis in many of these cases. It may be that a metabolite is an oxidant, but the actual mechanism is not understood.

(Slide)

Now, relapsing malaria, such as Plasmodium vivax, they have latent forms known as hipnozoites in liver. These cause clinical symptoms months to years after the actual mosquito infection has occurred. Most malaria in the U.S.

Army is due to exposure to vivax malaria on the Demilitarized Zone in Korea, but increasingly we are seeing cases from Afghanistan to include a recent outbreak of 23 cases of vivax from Fort Benning, almost certainly contracted during Operatoin Enduring Freedom in Afghanistan.

Falciparum malaria is usually seen in soldiers returning from Africa, and the falciparum parasite does not have a latent phase in liver, and so does not specifically require primaquine treatment.

(Slide)

Now, since we have been giving primaquine and since we do have records, we tried to review the Defense Medical Surveillance System over the last ten years and see what we could find in terms of G6PD hemolysis. The short answer is, not much. It's very difficult to estimate the level of under-reporting becuase many soldiers are cared for in civilian hospitals. It's also very difficult in the acute event to make a specific diagnosis of G6PD deficiency becuase once you have hemolyzed, almost by definition, the surviving

cells have some G6PD activity. So you have to bring the person weeks to months later to test them, and sometimes that doesn't happen. Our best-guess estimate is that there's about 1 case of severe hymolysis a year currently -- and I would point out this is not just the Army, this is all of the services.

(Slide)

Now, the Board has looked at this question before, specifically in 1998, and this shows a summary of my interpretation of the recommendations made at that time, that soldiers that were going to receive primaquine in a malaria endemic area would be screened. This was presented by Maj. Littrell, and we recognize him as actually helping iwth this particular presentation.

(Slide)

Now the question has already been summarized for you by Col. DeFraites as to who should be screened -- if screening should occur and, if so, who should be screened, and the complicatoin here is that -- this is an Army-specific issue -- the good side of htat is we

actually have data from our sister services, so I'll show you what we've got. Currently, by U.S. Army regulatoin, the only people who are required to have G6PD deficiency screening are high-altitude parachutists and military divers.

(Slide)

Now, this is from teh United States Navy, and I would like to thank Cdr. Meg Ryan and the U.S. Naval Great Lakes Recruit Center for thse numbers.

Judging on what the Navy is seeing both then and currently, 2 percent of your recruit population being G6PD deficient is a pretty good estimate.

(Slide)

Now, we also looked at their deficiency breakdown by ethnicity. Now thse are the number deficient by the number screened. As is indicated, this is primarily a problem in people of African American heritage, but it does exist in the Asian and Caucasian population, and these people tend to be the B- variants that are at greater risk for severe hemolysis.

(Slide)

The Air Force. We'd like to thank Dr. Katerina Newhauser at Brooks Air Force Base for the recent data from Air Force recruits. There the numbers seem to be a little lower, but I think 2 percent is still a pretty good estimate of what your recruit population would have.

(Slide)

Now I'm going to do some cost analysis for you. I'll try and simply this both in terms of time and effort, but a lot depends, as you might imagine, on your assumptions.

Now, a vast majority of costs are not due to not screening your population, aare from the few severe reactions that you get -- people who massively hemolyze have to be put in the hospital, hemodialyzed or transfused.

How the other side of hte equation balances out in terms of the screening really heavily depends on how much you pay for it. This estimate of $3 per test is directly from what the United States Air Force is doing at Brooks Air Force Base, and the high end is just what happens

if you call up a commercial lab in the Washingotn, D.C. area and ask how much it is to do a single one.

In our hospital estimates, we had a bit of difficulty getting anyone to agree on a current value. This is the same figure that was used in the last analysis to the Board in 1998, adn I think is pretty conservative for someone with those sorts of severity.

Now, I would submit to you that the key question here in this analysis is what is the percentage of people who are actually G6PD deficient who, if you give them primaquine, will hemolyze.

(Slide)

Like most of the things in epidemiology, if you can tell me the attack rate, I can tell you the answer. Now, as you might see, we don't actualy know what the attack rate is, but let me try and guide you through what I think are some reasonable numbers.

This axis is the percent of people who are deficient, who will severely hemolyze once they

receive primaquine. That means here -- this is 1 in 1,000 of your total population receiving primaquine, and down at this end it's 2 per 10,000. We think these are pretty reasonable numbers. This is what you see in the entire Army. Now, that's ont the American Army, but it is a real life circumstance.

Now, let's lookat what you pay per test, that's the blue line, meaning that let's say if you have 3 percent of your deficients hemolyze, you can pay $7 per test and everything will break even. What I've been trying to graph here is where do all the assumed costs break even. In that situation with that attack rate, if you pay no more than $7 test at our assumed hospitalization cost, everything balances out.

Well, what happens if your hospitalization cost varies? Well, if you look at $3 per teset, $6 per test, and $12 per test, you see that as it becomes an increasingly rare phenomenon the costs necessary to break even quickly become astronomical than probably than anyone would actually spend in a real circumstance.

If you're like the Air Force and you're paying $3 a test, everything breaks even well below $10,000.

Before I go on, are there any questions aobut the graph?

(No response.)

(Slide)

Let me give you a round number example. Let's say we're going to prophylax a brigade of 10,000 soldiers coming back from a malarious area. Let's take a high cost estimate of $10 per test, assume that 2 percent of the people are deficient, and that the hospitalization cost would be about $10,000.

This gives you an estimate on the break-even point of, on the high end of that axis that I showed you, 5 percent. Again, this is 5 percent of those who are deficient, so roughly a hemolysis rate of 1 in 1,000.

(Slide)

Now there's another point that requires judgment becuase it's unknowable, but it's the question of how does one manage rare events? If

the U.S. Army uses considerably more primaquine than it has been doing in recent years due to its involvement in Central Asia or Iraq, then the opportunities for severe hemolytic cases will certainly increase. And besides the monetary cost which I just reviewed for you, there's the questoin of legal liability if a soldier dies or is seriously harmed when the U.S. Army orders him to take a drug which has a known adverse event without a known screening test to identify the persons at risk for that adverse event.

(Slide)

So let me try and restate the question. Does the risk of severe hemolytic event outweight the cost of the screening program? Can G6PD screening information actually inform the decision to use primaquine? This is not a trivial point. Just becuase you screen people on entry to service or at some distant point, that doesn't necessarily mean that that information is available when they are handing out primaquine en masse. And if the recruits are to be screened, should we be concerned about the rest of the population that's already in

the Army?

(Slide)

Now, I'll stop here for questoins, but I would note that my picture here is urine from two different people. One of them is me. The other one is a patient I gave innate immuno quinoline to, a woman, interestingly enough, who had an A-deficiency, who hemolyzed half her blood volume for me and certainly scared her physician thoroughly. She did well, but that's not blood, that's urine. That's what you see when someone hemolyzes.

Thank you, and I'll take your questions. Yes, please?

DR. OSTROFF: Thanks very much. Why don't we start --

COL. SHANKS: Oh, I'm sorry, I'm supposed to let you recognize them. All right.

DR. OSTROFF: Dr. Cattani?

DR. CATTANI: A couple of questions. You mentioned that some of the force that may have received medical attention would receive it outside of the military. I wonder if there is any kind of data on mortality and then a retrospective look at

G6PD status at all, would that be available?

COL. SHANKS: I think the simple answer is no. We have within the room most of the military's malaria experience, I think, and I don't think any of us has ever seen anyone die of this in the miliary. Now, that's not true in some of the out of the way places we've been in the Third World. The simple answer is no.

DR. CATTANI: And my other question is about the logistics of giving the test. Is it a test that can be given easily in the field or is it complicated?

COL. SHANKS: It's technically not a difficult test, the screening test. It can be done in micro-titer plates en masse, and that's why it fits so well into a recruit screening program when you're drawing blood on everyone and they're at a fixed position and you can set it up and do it en masse.

That being said, it's very hard to ship that out to the field, make sure your controls work right, especially any refrigerated reagents. And I think those of us who have been in the field or

returned from Southwest Asia recently would see that it would be very difficult -- not impossible, but difficult -- to get consistent data out in a very hot environment where your reagents may be in trouble.

That being said, you can do this off of filter papers. I mean, it can be transported and done at a central lab, but then you've got the problem of actually getting the data back to the person. The reason that person hemolyzed that I showed you there was a clerical error caused by the facts of the data from the central lab shifting, and moving the lines from the positive/negative so they didn't match exactly. So, I'm painfully aware of just how many things can go wrong even when you're screening nearby.

DR. OSTROFF: Dr. Shanahan.

DR. SHANAHAN: Dennis Shanahan. Do you know what the Air Force and the Navy do with their data?

COL. SHANKS: I think I should probably let one of them answer for themselves on that.

(Technical malfunctions prevented

adequate recording of discussion.)

LtCOL. GIBSON: Can I add a little bit to that. Having spent considerable time at Lackland Air Force Base with the recruits, those that are G6PD deficient are brought out of training for a short, relatively short -- 15 minutes -- discussion about G6PD deficient and what that means. And it's done within a day or two of knowing about their status which -- the blood is pulled on the first day of -- actually Day Zero before they start to train. So even though there is some education associated with it, you have to remember these are recruits in a training environment (inaudible).

DR. OSTROFF: I assume that they're told (inaudible).

LtCOL. GIBSON: Yes, sir.

CAPT. SCHOR: I guess I'll answer for the Navy. That is annotated in the medical record if they are deficient or not. The discussion is going on over in CENTCOM right now for the tens of thousands that are facing redeployment, and malaria prophylaxis with primaquine is to -- is really not

the issue of whether they are qualitatively deficient, but the issue I believe is only qualitative screenings on entry, and to issue a quantitative screening so you can give primaquine to more folks. So that fit the issue and that was not addressed here, so that the (inaudible words), wherever they are, the issue that we don't have a deployment health record (inaudible words).

DR. OSTROFF: Dr. Patrick.

DR. PATRICK: A follow-up question on (inaudible) sensitivity/specificity meant predicted values. I assume that might vary.

COL. SHANKS: Obviously, it varies. The typical screening test used is very sensitive and tends to pick up people who may be on the borderline or not have it, and that tends to be the way that you look at using a screening test. It picks up nearly everybody as far as we know. I don't have specific numbers.

My limited experience with the quantitative test is even working in a research lab, you better have your controls down very well because that can vary with the ambient temperature

in your lab. So we've really not had much practical experience with the quantitative assays.

DR. PATRICK: I'm not completely clear, the option on the table is to treat everybody at accession, or is the other option to select discrete people for (inaudible)?

COL. SHANKS: Well, again, it sort of depends on how you look at the Board's decision of 1998. The Army has not screened anybody really. We still give the drug without screening people. Part of the reason I think that this question is being presented to the Board now is to develop some consensus on the way forward so that we can do something.

DR. ATKINS: Just to follow up on that, the slide you had about the analysis of the 10,000 person cohort, those are all people who are going to an area where they would get prophylaxis.

COL. SHANKS: Yes.

DR. ATKINS: Do we have any sense -- you alluded to the fact -- of people currently being enlisted, what proportion of them are likely to end up being deployed to an area? Obviously,

you can't predict that, but --

COL. SHANKS: In some units, very high and repeated. The unit I quoted at Fort Benning actually -- our difficulty was they had been both in Afghanistan, around Pakistan, and in Iraq and some other places they didn't want to name. So, for the actual infantry, if they're in for even three years now, the likelihood of going to Southwest Asia is high.

That being said, the risk in Iraq is small, and in Kuwait essentially zero. So things change. We didn't expect to be in Somalia where we had a post-deployment outbreak. But I think the likelihood of an Infantryman during his career requiring primaquine is very high.

DR. PATRICK: In the deliberations of this, was there ever any consideration given to targeting by racial background? I notice Meg's data on San Diego, that almost 50 percent of people are of mixed race (inaudible) varied background. How is this handled in the services now in 2003 and going forward?

COL. DeFRAITES: I can probably answer

that because the issue came up with Sickle Cell Trait screening. It doesn't make any sense to ask people about their racial background because (inaudible words).

COL. SHANKS: My anecdotal experience is the Australian soldier that massively hemolyzed on me was blond, blue-eyed, had a Maltese mother.

CAPT. SCHOR: The racial demographics are self-reported racial demographics, so the Navy personnel system, and I'm sure the Marine Corps system, those are self-reported categories. And you can report anything you want to and it's never questioned.

DR. PATRICK: But there's no other (inaudible words).

DR. OSTROFF: Col. Fensom and then Col. DeFraites.

(Technical malfunctions prevented adequate recording of discussion.)

COL. DeFRAITES: This is Col. DeFraites. I just wanted to, just for purposes of refocusing the question, it's not really an issue of, I guess, the fact that screening is -- the

question we've had in the Army is the effectiveness of the screening programs, and just the knowledge that those -- even though we only have 5 inpatient admissions for what's considered to be (inaudible) related anemia over the last 10 years, none of them are Army people, none of those 5. So it's just curious that those cases showed up in personnel who theoretically were screened -- the Navy, Air Force and Marines -- it's just interesting, that's one of the things that sort of stuck in our craw, is the idea of how is the best way to do this. And, also, the type of screening, if you ever want to do qualitative screening. Now, of course, we're not talking about falciparum malaria, we're talking about vivax malaria, which is no fun to have, but it's not usually related to a more severe outcome. So there is a cost with screening people out who otherwise could take primaquine safely.

The experience in the Army has been pretty favorable. They maybe just were lucky because they haven't run across a really fatal case yet, and that's another issue, but just given the experience after Somalia where we did push

primaquine (inaudible) given on a massive basis, and we estimate about 8,000 soldiers received primaquine prior to screening. At the time there were 2 soldiers who had some evidence of hemolysis, one was very mild and the other soldier had malaria -- he was developing malaria. Those two never quite sorted out whether they had G6PD deficiency, but never required (inaudible).

So, really just to repose the question, what is the most effective way to do this screening to where it makes sense. Does it make sense to do quantitative screening for more focused time and place (inaudible), that's really what we need to know.

LtCOL. GIBSON: That's a nice segue because from a logistics standpoint under current DOD policy (inaudible words). So there is an opportunity from a logistics standpoint to (inaudible words).

DR. OSTROFF: (Inaudible.)

COL. SHANKS: Yes, mostly because of -- it depends on how many you're doing. Again, I didn't look at quantitative specifically in terms

of cost currently, but when I did it some years ago -- I mean, it was a factor of 5:10 more than just doing a screen. I can't tell you what it is now, but my suspicion would be it's a similar multiple.

DR. OSTROFF: The second question I have is do we actually have any data on (inaudible)?

COL. SHANKS: The amount of primaquine dispensed is certainly going up. Whether the amount of drug that is ingested is actually increasing is a separate issue.

DR. LeMASTERS: Just looking at the Navy statistics, if you are deploying 100,000 people and 25 percent of them are African American and you have 1,650 who are going to be deficient -- I mean, that seems like a very high number and a pretty high concern. I think action has to be taken based upon your susceptible population and you have a large number of potentially susceptible population. And that's just a comment. My real question is why wasn't the April 1998 recommendation put into place?

COL. SHANKS: A good question that I

have no answer for that would not be considered prejudicial to the Board.

COL. DeFRAITES: That's a good question. The reason we brought the question back to the Board again was the fact that the effectiveness of the screening just did not convince the Army to go forth with what policy (inaudible), at what cost, to what end, what we're really going to be accomplishing with what policy. That's the reason.

DR. CATTANI: Jackie Cattani. What do you do when someone is G6PD deficient and they have been exposed to malaria?

COL. SHANKS: You don't give them primaquine. In the Australian Army, which has much higher exposure in places like New Guinea and East Timor to vivax -- and many times chloroquine resistant vivax, if they are known to be deficient, you omit the primaquine, you talk to them, you try and let the medical officer know particularly that this man may come in with a fever because he hasn't received post-deployment primaquine. Once you get someone who has vivax and G6PD deficiency, that's

even more difficult. Generally, the attack rates for vivax relapses are such, a few percent usually, that we can work around the few people who have both.

DR. CAMPBELL: Let me ask maybe a naive question, but how much does cost run this decision because, if it does, I think your chart leaves out a lot of cost that would be very important, like what does it cost to bring somebody out of the (inaudible) and replace that person on the post, and I think that cost per case would be a lot higher than $12,000.

COL. SHANKS: Absolutely. This was purposefully meant to be a very conservative estimate.

DR. ATKINS: One last point. I mean, I think we can't be completely reassured by the fact that we haven't seen much in the past (inaudible), we're going to need to at least prescribe a lot more primaquine. And so I think we shouldn't rely on the fact that things have been okay so far, when we clearly have evidence that patients are being put at risk if they are taking something and are

G6PD deficient. How much risk may be hard to quantitate, but it's certainly --

DR. OSTROFF: It seems to me when I think about (inaudible words).

CAPT. PARISE: This gets a little bit into my talk, but the standard would be not to use primaquine prophylaxis in anybody who is G6PD deficient regardless of the severity. So really quantitative tests wouldn't be relevant in that situation. For those that, as Dennis mentioned, have vivax malaria and need primaquine for a radical cure, so the treatment mode our recommendations are for those with severe deficiency -- that is, less than 10 percent of enzyme activity -- we would not use primaquine, and for those who have a milder deficiency it could be considered to use a regimen -- probably would use a regimen of 45 mg once a week for 8 weeks. But those are the people who seeking it for a treatment. Basically, a decision between a provider and the patient (inaudible words).

DR. OSTROFF: But as far as the issue of using primaquine prophylaxis (inaudible words).

CAPT. PARISE: That's right. We usually recommend that a test has to be done before you induce primaquine in any situation.

COL. GARDNER: It might be useful to just, when you make a recommendation, discuss the logistics of how to manage that because when you're prophylaxing 10,000 people, they tend not to be one-on-one more invasive, they tend to be a mass prescription that is handed out as they get off the plane and so on, in a mass setting. And the logistics of making sure they check to see what the results were before they hand them the prescription becomes very important, and those types of issues need to be dealt with.

DR. CATTANI: I guess I don't understand why if there was a recommendation that it be on the dog tags, why it would be difficult to check that as prophylaxis would be handed out.

COL. GARDNER: Is that how it's done in the Air Force?

LtCOL. GIBSON: To my knowledge, the Air Force does not have (inaudible) on their dog tags.

CAPT. SCHOR: That's certainly something that is an optional thing, but I can assure you that there has been three weeks of effort in-theater to identify people who are G6PD deficient based on their medical records which are with the battalion and squadron surgeons. But we have the medical record. We don't have a scaled down deployment record that may or may not have the information. So the issue is might there be some clerical errors at accession where the results are improperly recorded? I suspect there is. It's a human system with the Marine Corps, 43,000 people coming in and being screened every year.

Might the test have a false-negative or false-positive rate? I guess that's very small, but that's possible. So did that account for the one or two Marines that got admitted over the last few years? Maybe. So this is a human system that, as was discussed, the population at risk we always make tremendous efforts ont to give primaquine to those that are G6PD deficient and provide those that are deficient the proper counseling. We monitor their fever, and they are followed up by

the battalion surgeon who certainly knows if you're G6PD deficient and, yes, we can control the (inaudible words), and that will be a very common scenario. But it's a very overt effort right now in here to educate those who are at risk and to avoid exposure to primaquine those who are at risk.

So, are there ways to improve the system? I suspect so. I really don't think it's an issue for us whether we give primaquine (inaudible words) because I think we're still going to do it.

CDR. LUDWIG: My question is in the civilian practice, are they tested for G6PD deficiency prior to when they have a relapse and they are being evaluated for treatment, and if that's so, it seems like, from our knowledge, doesn't seem like a relapse of vivax is necessarily (inaudible words), wouldn't that be a reasonable consideration (inaudible).

CAPT. PARISE: That is what's happening. I mean, at this point in the civilian sector, primaquine not only is used for treatment (inaudible words). On top of that, we are adding

primaquine for primary prophylaxis, so that will change the scenario for those people (inaudible).

COL. BRADSHAW: Dana Bradshaw. I just wanted to ask Bob and maybe Dennis if he recalls -- you mentioned a recent experience at least in Somalia was that the Army may have had one case that did that hemolysis (inaudible) primaquine. Do you recall if there's any papers published during the Vietnam Era or Korea before the recent resurgence of vivax, of the experience with hemolysis in primaquine use?

COL. DeFRAITES: Well, certainly the Vietnam Era, the combination of (inaudible words), but I'm not that familiar right off the top as to whether or not they'd done screening (inaudible words).

COL. SHANKS: Yes, it was a 45. That was just discovered during the Korean War. Actually, the question came up because some of the black soldiers were looking kind of bluish around the lips, and that's what sort of started off the whole inquiry that figured out glutathione metabolism and such. They were given daily on the

boat between Pusan and San Francisco, and that's where we got two weeks as a regimen, and generally it was well tolerated. Now, that experience informed the Vietnam experience where it was felt that by going to weekly, yes, some of them would hemolyze, but they would have a while to recover before you gave them another dose.

Again, one of the key issues here is the ethnic composition of the military over the last generation has evolved. Now, it's not completely different, but we certainly have more people from Middle Eastern and Eastern European background now, and those people genetically are at risk.

LtCOL. EDMONDSON: LtCol. Mauhee Edmondson, I'm the Liaison Officer and Action Officer for the (inaudible words). I would just ask, keep in mind that the (inaudible) across the country test or screen on an average of 400,000 -- 60,000 applicants a year to bring in 250,000 a year (inaudible words). The Navy at Great Lakes and the Air Force do the screening at a training site after the applicants are already entered into a service.

The Army (inaudible) that they have five training sites, not just one or two and, of course, the Marine Corps only has two --

CAPT. SCHOR: Three, including officers only.

LtCOL. EDMONDSON: So just when you come back with your recommendation, I would ask you to keep that in mind because currently this screening (inaudible words) comes out of specific budgets. (Inaudible) budget would then cut any screening to come out of your budget, which comes out of (inaudible words). But you would have a large group of individuals who would be perhaps screened who would never enter into the military.

COL. DeFRAITES: I didn't think (inaudible) screened for any condition that was not disqualifying, medically disqualifying (inaudible words).

LtCOL. EDMONDSON: I may have misunderstood, but aren't the (inaudible words).

COL. SHANKS: Recruits.

COL. DeFRAITES: (Inaudible words), but it required upon arrival of recruits at a station,

not as a process because it is not medically disqualifying.

DR. OSTROFF: Other comments or questions?

(Technical malfunctions prevented adequate recording of discussion.)

DR. RUNYAN: I was just wondering if there's not screening, is there a process by which people are informed of the risk when they are given the primaquine, is that an issue worthy of consideration?

COL. SHANKS: I don't think I can really answer that. As has been already mentioned, primaquine tends to be given en masse when the troops are thinking about something else, i.e., going home.

COL. DeFRAITES: We do have information (inaudible words), and we dispense it, so that is issued when we're giving any (inaudible). So implementation of that policy and that intent, I don't have any data to say how well that is being done, but on that information sheet is given with the primaquine so that soldiers can have the

information about G6PD deficiency. So if someone knew that they were G6PD deficient and knew what that was and the read the paper -- when they got the paper and they read it (inaudible words).

DR. OSTROFF: Thank you very much. Why don't we -- we're a little bit ahead of schedule, but we have a tendency to run over towards the end of the agenda. So let's take a ten-minute break, and according to the clock that's on the wall it's ten after, so let's come back at 20 after 9:00 and start with the second question for the Board.

(Whereupon, a short recess was taken.)

DR. OSTROFF: Let's bring the meeting back to order.

COL. DeFRAITES: I'm going to yield my time to Col. Shanks to present the question.

DR. OSTROFF: Dennis, take it away.

COL. SHANKS: Again, we would like, as has been stated, to continue to talk about malaria, but this time a different drug and a different issue.

(Slide)

For the first time in a long time we

actually have a new drug to consider, and that's known as atovaquone/proguanil, its trade name being Malarone. The question before the Board basically is now should we use this.

Now, this is a combination drug. It is formulated as a combination. You get both drugs in the same pill. It kills both liver stages and blood stages. Now, let me qualify the part about the blood stage. It kills blood parasites that are metabolically active. It does not kill the stay-behind forms in the liver which cause late relapses that we were just recently discussing.

Atovaquone/proguanil is really quite well tolerated. Taken on an empty stomach in a treatment dose, some people will vomit, but that really is the major issue. For most people taking a common prophylactic dose, it's very well tolerated.

Its efficacy against falciparum malaria both in treatment and in prophylaxis is quite good -- in almost all studies, in excess of 90 percent. I feel I should -- I'm going to comment just very briefly that the vivax data is more limited, but

our Navy colleagues have been trying their best to resolve that, and it does work against vivax malaria. The changing of the product insert has not been done yet. And, again, I mentioned that its issue with vivax malaria is not that it doesn't work against it, it's that it doesn't work against the liver stage -- the relapsing stage.

(Slide)

This drug combination was licensed in 2000. It's being widely used in the civilian population, particularly in travel clinics in Europe and in the United States. This came about particularly when studies done in large travel clinics showed that the combination, which is proguanil/atovaquone was better tolerated than proguanil/chloroquine which many people in Britain were using.

The dosage is 250 mg of atovaquone, 100 mg of proguanil. It's given daily. It can be started basically when you start to travel and 7 days after return. There are human challenge studies to show that that's quite sufficient to prevent falciparum malaria. Even if you are bitten

on the last day when you leave, 7 days is enough to stop it.

One issue, as with all new drugs, is the Malarone is relatively expensive compared to other prophylaxis options. That being said, not too surprisingly the company priced it such that a cost of two weeks of Lariam and two weeks of Malarone are essentially equivalent to the short-term traveler to Africa.

(Slide)

Now, the question to the Board is how do we use atovaquone/proguanil, if at all. And I would suggest that there are three gradations generally that the Board could make. Either "this is a good thing to have, but we don't need to be using it currently because mefloquine daily and doxycycline daily work"; "atovaquone/proguanil could be used in certain niches where a well-tolerated, highly effective drug is particularly important, such as aircrew or special operations"; or "it could be formally entered as a third option for use along with weekly mefloquine or daily doxycycline". Thank you.

DR. OSTROFF: Thanks very much. Let me ask if there are any questions before we move on to the next presentation.

LtCOL. GIBSON: I'd just kind of comment on the aircrew issue, has there been research on that guideline for aircrew members?

COL. SHANKS: It has not been formally cleared, so it could not be used today. However, I think just because my powers of persuasion with the Air Force have been insufficient doesn't mean that at some point it won't eventually be cleared. Its side-effect profile was really a success that it was very likely to be well-tolerated in them.

LtCOL. GIBSON: Thank you.

DR. OSTROFF: Thank you. Let's move on to the next presentation. We have Dr. Monica Parise, from the Division of Parasitic Diseases at CDC, who is going to be talking about evidence-based review of malaria chemoprophylactic drugs.

CAPT. PARISE: Thank you to the AFEB and to especially Rick Riddle and his office for inviting me and helping me to get here.

DR. OSTROFF: Before you go on, let me

point out that your slides are at Tab 7.

(Slide)

CAPT. PARISE: CDC malaria prophylaxis recommendations are made by the Malaria Epidemiology Branch in our Division of Parasitic Diseases with input from the Division of Global Migration and Quarantine, both in the National Center for Infectious Diseases.

Informally, we have sought external input on our recommendations, for example, through the American Society of Tropical Medicine and Hygiene, through comments that we've gotten from providers along the way, but we held an expert motion on Malaria Chemoprophylaxis at CDC in January of this year as a way to have a more formal mechanism to elicit expert opinion on some of our malaria prevention specifically prophylaxis policies and recommendations.

There was DODO representation at that meeting. Allen MacGill, Cameron Richie and Phil Coyne were there.

(Slide)

In preparation for that meeting, we

performed an extensive literature review and created evidence-based documents on the six drugs that we recommend for malaria prevention. I'll get to those six shortly. Each of those documents are fairly extensive, probably ranging from 10 to 40 or 50 pages and are highly referenced. And then we took those documents and summarized the main points in two- to three-page guideline documents. And in those shorter documents, basically we pulled out points that we saw as potentially unclear or controversial from the literature or in discussions we've had with travel medicine providers, and raised them specifically as discussion points at the meeting to ask the experts about.

(Slide)

The documents that we put together covered a variety of components on the drugs that I will list in the next couple of slides, on the recommended dosing, on the efficacy as well as the effectiveness, and listed state from studies on efficacy and effectiveness in a table format. The documents covered pharmacokinetics, adherence data if there is data available, safety information also

listed in table format, and looked at both severe as well as mild/moderate adverse reactions.

(Slide)

Other components covered were contraindications, data on safety with regard to duration of use, therapeutic index and overdosage, drug interactions, use in special populations including children, pregnant women, or people with pre-existing medical conditions such as renal or hepatic disease, for example, and cost.

(Slide)

The next three slides cover the topics that were discussed at this two-day meeting, and basically the bottom line was we wanted to get input on our current recommendations for malaria chemoprophylaxis for civilians, which are that in areas where there is only chloroquine-sensitive Plasmodium falciparum, that chloroquine is the drug of choice with hydroxy chloroquine as an alternative, and that there are three options for prophylaxis in areas where there has also been reported chloroquine-resistant Plasmodium falciparum, which includes mefloquine, doxycycline,

and atovaquone/proguanil.

(Slide)

And then we covered in individual sessions the six drugs as listed here that we recommend for prevention. Basically, prior to going into this meeting, primaquine was basically for prevention use for terminal prophylaxis, as we've been discussing its use this morning.

(Slide)

We had a few additional sessions to elicit input on these topics that were structured a little less formally, specifically on our health communications and on self-treatment issues and people traveling to very low-risk areas.

(Slide)

I'm going to give you just an example of the points that were raised, for example, in one of these sessions so that you can see what some of the sorts of questions we asked the experts were. Under mefloquine dosing, for example, how long should that be started before travel; is one to two weeks adequate; should CDC be recommending a loading dose regimen for mefloquine, which we have

not been recommending to-date.

Another issue that we've been asked about a lot because there have been problems with mefloquine tolerance are can a split-dose, a twice-weekly regimen be an alternative? A lot of focus on mefloquine adverse drug reactions. How can CDC better communicate these to the public? What about the long-term neuropsychiatric adverse drug reactions that have been reported? What do the experts think of that? There's been some note in the literature that women may tolerate this drug less well than me, should we be communicating that to people? Is there data in the literature that people should avoid alcohol while on mefloquine? And what about a need to monitor people that are on mefloquine long-term with tests, such as liver function tests or ophthalmologic exams?

We raise these questions because as we look at the literature and drug labels, they are there, and some of these recommendations come out, and is there an evidence base for that?

(Slide)

Another big question, we don't

recommend people use mefloquine if they have a history of seizures, but when you talk about pediatric use, febrile seizures are common, and can mefloquine be used in that subcategory?

What about precautions in people with cardiovascular disease and specific cardiovascular conditions? What about use in pilots and divers? And then there has been data in the literature on concerns over use in pregnancy, with possible reports of an increased rate of spontaneous abortions and stillbirths, and what do the experts think about that?

We gave out -- and needless to say there's a lot of issues here -- we gave out packets with all these documents about a month before the meeting so that people could prepare themselves before coming.

(Slide)

I can't really give a summary on all these six drugs in the next half-hour, so basically I've chosen to sort of focus on sort of the bottom line that came out of the meeting, and then on some of the answers we got to some of the discussion

points that were raised, if there were specific questions on the data related to Malarone or anything else, I'm happy to answer questions afterward.

So, here is the bottom line. Basically our use of chloroquine in areas where chloroquine-sensitive falciparum was confirmed, there is much less data on hydroxychloroquine, so it's seen basically as clearly a second-line alternative, but an acceptable one if there are situations when it is the best drug -- for example, someone already on it.

In areas with chloroquine-resistant falciparum, it was recommended that we not have a drug of choice, that to avoid the perception that we preferred certain drugs over others, that they be listed alphabetically by generic name in our health communications material, and also that primaquine -- now this would be in a primary prophylaxis for primaquine as opposed to using it in a terminal prophylaxis mode for the last two weeks, this would be used during your whole trip -- and that was recommended to be added as a second-

line agent at 30 mg a day as a choice for prophylaxis for people traveling to areas with chloroquine-resistant falciparum. Second-line mainly because of concerns about G6PD and the need for civilian providers to be testing for G6PD before sending travelers on this, and concerns that that might not always happen and we could have problems.

(Slide)

We had proposed the elimination of this, but we actually had done it and we asked the experts what do they think about this, and it was affirmed that because we have three effective drugs for areas with chloroquine-resistant falciparum to eliminate chloroquine/proguanil as a recommended option.

Other recommendations we were given was to be more explicit in our recommendations that in areas with chloroquine-sensitive falciparum, if you can't take chloroquine or hydroxychloroquine, you still should use one of the other drugs that are used in resistant areas.

To add a specific statement for people

that are -- I mean, there are increasing public and providers that are concerned about the safety of these drugs, and if there are concerns about that, to start even earlier, such as three to four weeks before travel.

And then to add specific warnings, for example, to the Yellow Book, to avoid purchase of basically chemoprophylactic or treatment drugs overseas, if possible, especially prophylaxis you have more control because they may be of suboptimal quality.

(Slide)

It was recommended that we disseminate more information on adverse drug reactions. We also held -- as part of a larger risk communication strategy related to mefloquine, we held focus groups with a number of different kinds of travelers before this meeting. And basically what we heard both from the experts at the meeting and in the focus groups is that people want more information to be able to make with their provider a more informed decision. At the meeting it was recommended we try to better lay out advantages and

disadvantages of the various options in a table, and to try to give people rates of adverse reactions, which sounds simple but given the different methodologies in the studies, it is not all that easy, and to also provide discontinuation of the drug due to adverse reaction. And, basically, the last point overall was to -- there are a few points that we really need to get across better, such as the risk of malaria, that it can kill you and that we, for this disease, do have prevention strategies that work, inducing a drug.

(Slide)

So now I'm going to basically go through some of the points on each of the drugs that came up. This is really icing on the cake, and some of these are really not things that come up commonly, but if you're dealing with provision of malaria prevention advice to the 27 million civilians that go to malarious areas every year, these points come up.

As I mentioned, chloroquine over hydroxychloroquine was based on a review of the literature that -- because some bodies do recommend

this -- that eye exams are not needed even for long-term malaria prophylaxis. Even though there was no data, the experts recommended that we do leave in the option that we've had, that twice-weekly dosing with chloroquine if people would like to do that for tolerance reasons is okay; that no G6PD screening is needed prior to use with this drug. The reason for this is that there is some data in the literature -- not a lot of it -- that there can be hemolysis after chloroquine use. It's fairly weak data.

And then there a number of points I'm not going to get into, I mainly just list them on a slide, that we either did not have time to address at the meeting, or that we need to go back to the literature and look at specific aspects to really be able to answer these questions as we finalize these documents and put them out in our health communications.

(Slide)

Doxycycline -- these again were questions that we asked -- no good evidence that doxycycline interferes with the effectiveness of

oral contraceptives. We get asked about the use of minocycline for malaria prophylaxis, and basically the recommendation was that there's so much more data on doxy that if at all possible people should be changed to doxycycline. And then a few other issues such as use during breastfeeding and long-term use that still need to be revisited.

(Slide)

We asked the experts if the dose of primaquine for terminal prophylaxis should be increased -- the usual dose is 15 mg a day for 14 days -- whether in certain geographic areas -- for example, in the South Pacific, where there are frequently relapses even after this routine dose -- if we should be increasing the recommendation for terminal prophylaxis. This actually sort of surprised me. The experts pretty strongly recommended that what they were doing in their practice was using 30 mg pretty routinely for anybody, so that we've changed this in this year's Yellow Book that just came out.

We asked do people have better ideas about who we can recommend get terminal prophylaxis

because, basically, the recommendations at this point are fairly vague. People that are in areas with substantial exposure to vivax malaria, and that can depend on the time that you're in that area as well as an estimate of the intensity of vivax transmission in the area, but there's no quantitative recommendations on this, and we really didn't come out of the meeting with anything better quantitative, I'll have to say.

In terms of people with G6PD deficiency, as I briefly mentioned before, where it may be considered for radical cure in people with mild G6PD deficiency, it was recommended to be just completely avoided for prophylaxis in persons with any degree of G6PD deficiency.

(Slide)

Moving on Malarone, the drug has been out, as Dennis mentioned, for about three years now. We looked at the efficacy data and basically the experts agree that there is adequate efficacy data -- as you can imagine, there are less trials with this drug than for drugs that have been out for the last 20 years -- to be a first line in non-

immune persons as well as that its efficacy for Plasmodium vivax, even though it's more limited, is sufficient to recommend this drug for use in areas with substantial vivax transmission.

As Dennis also mentioned, there is some evidence that this drug may not prevent the establishment of hypnozoites, and so for people who would get terminal prophylaxis with primaquine, they should still get that if they are on a Malarone regimen.

(Slide)

Mefloquine -- as you can imagine, this took up fairly lengthy discussions, and one of the comments we got from providers out there is this is getting harder and harder to prescribe. We asked the panel what did they think about these reports of longlasting neuropsychiatric reactions after mefloquine, and I guess I have to say I don't think we came up with a good recommendation for that, a good idea of what that is. There was a fair amount of discussion that there is neuropsychiatric illness at baseline in a population, how do we separate this out after mefloquine. There's no

necessarily biologic explanation that we may have at this point for these longlasting effects, but we really don't know.

The group felt that we should include some information at least for people that there are some studies that have indicated some gender differences in ability to tolerate mefloquine, not to say we don't want to recommend this drug for basically half of the population who might use it, women, but just that we should make people aware of that, that up front people should know this drug has a long half-life, and so the adverse drug reactions can last for weeks, for us to be more clear about that.

It was felt that it was okay because the pathology in those with febrile seizures is different from those with a seizure disorder, that this drug could be used in those persons.

(Slide)

The data did not support a precautionary statement planned on the concomitant use of alcohol and mefloquine. Based on the data, it was felt that the data don't support that people

who use tests that define fine motor coordination, such as pilots, necessarily need to avoid this drug based on the data, but that it may be prudent to suggest that if they are going to use it to start early.

We'll be adding permissive language for using a loading dose, and then, again, various topics that we still need to revisit.

(Slide)

That moves off the use of the drugs for prevention. Probably the main things that came out of the self-treatment and treatment session was that because sulfadoxine-pyrimethamine resistance is worsening and worsening in various areas of the world now spread to Africa, especially East Africa, that this is really not a drug we should be recommending for non-immunes for self-treatment anymore. And so really what that leaves us with is Malarone for a self-treatment regimen.

And they suggested that stronger language go in on avoiding halofantrine because people are often prescribed this, or may be prescribed this overseas and there are concerns

about the safety because of cardiac complications.

(Slide)

So, basically, what are our next steps? This has gotten slowed down a bit basically because of details to other diseases that we've had at CDC. We have minutes from the report. Once we edit those somewhat, that will be reviewed by the panel. We will revise the evidence-based documents. We still need, as I mentioned, to go back to some specific areas, probably pull more literature, and then taking that we will revise our overall and drug-specific recommendations and add in the level of evidence for each recommendation, which we haven't done so far but we have all the literature so we can do that, circulate that to the group and have discussion with them, and then have final review at CDC, and then basically once we're happy with those recommendations, update all of our health communications materials, such as Yellow Book, our Website, brochures for travelers with those.

So that we can best disseminate this, we also plan peer review publication of these

documents as well as possible publication in the MMWR. And that's really all I have to say. I'd be happy to answer questions.

DR. OSTROFF: Thank you very much. Why don't we take a couple questions first, and then we have another presentation from Col. DeFraites.

COL. ENGLER: I have a question on mefloquine in regards to (inaudible). Have any studies been done (inaudible) a person feels okay, it doesn't affect their function, and now much more sophisticated data suggests a long impairment of performance to drive a car even when the person thinks they are unimpaired. Is there any data with mefloquine (inaudible words).

CAPT. PARISE: There's not data that's looked at people who have been on it long-term, but there have been fairly sophisticated testing both in flight simulators and in driving situations where it's been looked at. And it really hasn't come out that it's impaired coordination. One caveat to that is that in one of the studies, a person who didn't tolerate mefloquine was taken out, so we don't know everything there is to know

about people that didn't tolerate it, how well they would have been, so you would have to stop it. So that's where we are now.

DR. OSTROFF: Dr. Blazer.

DR. BLAZER: Can you give a little more detail about the neuropsychiatric problems, and specifically in the long-term?

CAPT. PARISE: Well, basically, in short -- not the long-term -- but we think that the severe reactions are pretty rare. We estimate that they are at about a rate of 1 in 10,000, although that varies depending on the methodology of the study, from 1 in 200 or so up to 1 in 10,000 of seizures or major psychiatric problems.

And then there are a host of other more acute less severe neuropsychiatric issues that occur short-term, such as insomnia, strange dreams, fatigue, lack of energy, inability to concentrate, and some people have reported that those effects have lasted a very long time. Now, the half-life of the drug is three weeks, so it can take three, four or five months to really wash the drug out of your system if you are at steady state, but some of

the reports have been after that, months later to years later, up to ten years later. I've heard cases that this has just ruined people's lives. I don't if anybody -- I had heard that there may be some data in DOD about how some of the studies that might shed light on that, but I've not seen anything in terms of effect on the brain. But I don't really think we have a good explanation of what that is. I mean, as I mentioned, at the meeting there was discussion -- and we did have a psychiatrist there -- of, well, are people susceptible, are they susceptible to these problems and this drug has brought that out? But I really don't think we understand it.

DR. BLAZER:

CAPT. PARISE: Yes. If you look at the neuropsychiatric effects and compare, say, mefloquine to chloroquine proguanil, and these will be just in short-term studies. Yes, they definitely are higher.

DR. OSTROFF: Dr. Haywood.

DR. HAYWOOD: One of your recommendations is to provide data on rates of mild

and moderate adverse reactions. What database are you going to use?

CAPT. PARISE: We'll take these evidence-based documents that we've created that I've mentioned -- I mean, for mefloquine it's probably about 40 or 50 pages long, and there are -- I mean, it's unbelievable how many studies there have been on mefloquine with placebo or comparater. So we would have take that and we'll have to summarize that in a way that's understandable to even the public.

One of the recommendations we got at the meeting -- because you will get different rates if you look at trial, for example, versus an observational study -- was to really focus on randomized controlled trials as providing the best level of evidence. So we'll definitely show that, you know, show what comes out of the trials, and then possibly have some information that's come out of observational studies as well. Certainly in the very technical documents that will be posted on the Website that will be available will have all the data there, but those will be geared at a fairly

high level of healthcare providers, and we have to also get something that the public can understand, or providers who don't deal with this every day can understand.

COL. BRADSHAW: Dana Bradshaw. I don't know if Alan Magill is here or not, but he gives a very good comprehensive lecture of the review of literature of neuropsychiatric (inaudible), and if you're interested in that I'm sure we can get him to provide it, or we can make it available to the AFEB.

DR. OSTROFF: Other comments or questions?

(No response.)

Why don't we go ahead to the next presentation, which is Col. DeFraites, and then we'll open it up for discussion.

COL. DeFRAITES: Thank you. The objective of this presentation is to give sort of a military spin on some of the considerations that go into decisionmaking in terms of malaria prophylaxis for U.S. military. I want to acknowledge up front that I collaborated for this presentation with Col.

Dennis Shanks and also with Capt. Kevin Hanson, in the back, and this presentation was originally supposed to be given by Dr. Magill, but because he had this excuse that he was in Kuwait until last week that I was nominated to give the talk, but we got a chance to chat before I went and gave his material. Let's go to the next slide.

(Slide)

This in a nutshell are the major factors that go into decisionmaking, so I'm finished. Just read the slide and that's all we need to know. But I broke them down into three areas having to do with the parasite itself, having to do with, sort of broadly written, as the environment of the host, so some soldier factors and some military situational factors, and then, finally, those factors related strictly to the medication. So I'll go into each one of these.

(Slide)

First of all, in terms of the parasite, in all situations the U.S. military is a non-immune -- from a malaria perspective -- a non-immune population, so we're always inserting this non-

immune population into malarious areas. And the situation of malaria may vary depending on what's going on. We could be in an endemic area of malaria that's not experiencing a particular outbreak, or may insert into an epidemic situation where we have large numbers of non-immune similar to ourselves flooding an area, and also with unstable or very favorable environmental conditions for epidemic malaria with mosquito breeding and a large number of exposed infected persons in the area that our troops are co-located with. These are factors that can really change or affect how seriously, first of all, we take the malaria threat in terms of assessing the risk and, secondly, what other considerations we may take in terms of prophylaxis.

(Slide)

Secondly, of course, in terms of the parasite is what type of malaria is found in this area, and to that degree we depend a lot on our risk assessment, the Armed Forces Medical Intelligence Center, and a lot of the information that we can get from the existing sources in the

countries or the areas where we're going. From our perspective -- and it's germane for the discussion this morning, and certainly from the overall large military problem if you look back over the last ten years, most of our cases have been relapsing malaria, about 80 percent of the total burden in the military. And for the most part, these cases can be traced to failure of compliance with medication.

(Slide)

Though I will tell you in the case of the Army in Somalia in 1993, it was a case of not assessing the threat -- and I'll get into that and some of the characteristics of the environment later on -- but in terms of assessing a particular threat in a particular focal area of a country.

Certainly, falciparum malaria is the greatest threat to life, that's certainly the life-threatening form of malaria for the most part, the issue of drug resistance and the geographical spread of resistance is important.

Treatment drugs, when we talk about if we don't do prophylaxis right we have to resort to

treatment, and in case of falciparum you need to treat correctly, you need to treat promptly, and you need to treat completely. And so the treatment arm having to depend on a deployed military to employ prompt treatment sometimes is mistaken, or it can complicate our plans. And certainly the complications of falciparum malaria as I alluded to with the life-threatening complications of cerebral malaria, renal failure, et cetera.

I will say even though relapsing malaria is our most common from the numbers perspective, we have had at least one death of a soldier who had falciparum malaria -- he actually died from a pulmonary embolism -- he had falciparum malaria at the time. He had just traveled from Africa to Ascension Island and then on to Puerto Rico, and it just completed along the airplane flight, however, he did have falciparum malaria.

We had at the same time falciparum that was acquired also in West Africa, and the soldier experienced cerebral malaria and renal failure, however, he recovered. That was a year and a half ago. In the current situation in Iraq and

Afghanistan, the cases that we're aware of have all been vivax malaria when speciated.

(Slide)

Next, I want to get into some of the environmental issues, and clearly the type of miliary mission varies quite a bit, and I have here the spectrum from combat going through peace-keeping and humanitarian assistance type operations, to the type of repeated insertion and extraction from a malarious area that might be experienced, for example, by a Marine expeditionary force that's on a deployment around the world that lasts nine months, and during that nine months they may go to Thailand for several weeks, then they may get back on the ships and go to South America, go to Africa, go to Persian Gulf, go home, and so they go in and out of malarious areas. And that's when you're considering your prophylaxis approach, you need to consider this type of repeated insertions and extractions.

The point of bringing up the spectrum of military operations brings to mind the idea that commanders, unit commanders not the medical --

well, medical folks, too, but unit commanders in particular have a lot of risks to the soldiers and to the mission that they need to be balancing the entire time. And so when you're in combat, there's a different set of risks than there are, for example, in a peace-keeping or humanitarian assistance, or an uninterrupted long-term occupation. And so the perception of the risk of malaria in balance with these other risks is one important consideration that we need to make when talking about protecting soldiers against malaria.

(Slide)

The military population itself. We're not a homogeneous population, the troops vary greatly in the need for and response for prophylaxis. We have I think, from an operational perspective, probably the best situation is a cohesive unit that's under discipline, that has a single leader, that are present for duty every day at the same location and that there's constant communication and discipline is good.

We have another type of unit that might be these more combat support units, like the

transportation units, the truck drivers, the logisticians of supply, signal units and whatnot, that might be scattered with small detachments of five or six, or two soldiers that their commanders is a couple hundred miles away and they are on a detachment, that might be strung along a road or at a distant base.

We have with our combat engineer units construction engineers building roads as part of humanitarian assistance operations. They may have small detachments that might be in very remote locations under intense pressure from malaria and other vector-borne diseases that might be remotely located.

And, finally, a characteristic of the military population are the older, more experienced troops that often believe themselves to be above, that they are tough or they are immune or they don't need to take this stuff, or they've never gotten malaria before so they don't need to take it now.

And, finally, not to -- well, the aviators in the room know exactly what I'm talking

about. In terms of attitude, No. 1, but secondly, also because of aviation medicine concerns about their high performance and that they are very special people, we know, and so they deserve special consideration in terms of malaria prophylaxis.

(Slide)

The command climate, as I already alluded to, certainly for us in the military this is probably the key to success or failure of malaria prophylaxis, and that is the command climate, and I talk about attitude, awareness, and training. Attitude in terms of -- again, it gets back to these experienced soldiers and their attitude toward their susceptibility to malaria -- certainly a leadership/command emphasis is crucial to achieving compliance. And many of us in this room have had personal experience where leadership has been there and leadership has not been there and we've seen the consequences of both.

The awareness, and this gets to the risk communication to the troops and their commanders of do they perceive the threat. And,

again, balanced against these other threats, as I mentioned -- the spectrum of military operations from combat to occupation to humanitarian assistance -- how do they judge that threat in balance to other threats to the troops.

And training is have they actually ever done this before? Have they actually ever taken chemoprophylaxis. The other thing I'm not going to talk about too much, but certainly is part of our protective posture toward vector-borne diseases, is the use is the use of repellents, bednetting, and other barriers to biting mosquitos. I may get to it a little bit later, but I just wanted to mention that. That's another key armamentarium in addition to chemoprophylactic drug, but since we're talking about chemoprophylaxis, I'm not going to say anything more about that.

U.S. Geological Survey.

(Slide)

The duration of exposure also varies greatly, and that's another consideration that we have. I f you're going into an area, certainly the risk is cumulative the longer you stay, in general,

you know, the greater the risk. And also there is some data on compliance rates in military units, not necessarily U.S. military, but certainly there's a fairly extensive literature of other military, worldwide militaries and their compliance. And it looks like the longer you stay and are exposed to malaria -- and, again, maybe this is part of the risk diminishing with time -- but with daily medications that were studied, in one study after five months the compliance had dropped to about 40 percent taking the daily med. I couldn't find any specific data -- somebody in the room may have it -- on compliance with weekly medication.

Certainly long deployments, the longer the deployment if you have seasonal transmission of malaria, you may go from a low-transmission season to a high-transmission season, but the longer you stay the more likely you're going to bump across the high-transmission season.

(Slide)

And talking about seasonality, certainly one of the problems I alluded to before

in terms of assessing the threat is we have the additional complication of the seasonality which varies by geography. Even in Africa, malaria is seasonal. You can have your guard lowered by going into an area at low season, not seeing any cases, and then not realizing at what point it goes from low-risk to high-risk.

I mentioned the highest transmission season and the rainy season. Again, the troops can be lulled into a sense of complacency if they don't see people getting sick.

Then the other problem -- especially this was true in Somalia -- is that the geographical distribution of malaria is focal and local -- that is, it can change with various locations and the type of malaria can be very specific to a particular subregion that your intelligence might not be finely tuned with enough resolution to give you that specific threat information. And, also, the mission changes and troops that thought they were going in one location then get diverted someplace else, and you really need to reconsider your malaria prophylaxis for the

entire force.

(Slide)

In terms of -- again, this is another host factor, but it gets to sort of a cross-over with the medication issue -- and that is the troops' perception. It gets to this attitude of the command and also the soldiers, but in general soldiers, like most adults I guess, don't like to take pills -- especially if they don't feel sick, they don't like taking pills -- and that's not to say they don't take some pills they shouldn't take, but in general they don't like to take pills that we tell them to take -- I want to caveat that.

And, also, that's especially true if that pill that you're telling them to take makes them feel ill. And so if that pill makes them feel funny or just does anything to them that's adverse, especially if they're not ill in the first place, compliance is an issue, as you can understand.

When I say perception is reality as a subtitle, I mean the third bullet, that the reputation of the medication can achieve legendary, mythic status with troops. And we ran into the same

issue with asking troops -- Col. Sanchez I know was in the room before, but he led the study we did of tick-borne diseases and use of personal protective measures by troops going to Fort Chaffey, Arkansas, which is "tick capital" of the United States. They don't call it that, that's my term. They don't advertise themselves as that. But it's very interesting to hear of the types of procedures and practices that the soldiers adopt, and use of sulfur -- even eating matchheads off the kitchen matches with the little tip -- they would eat that because that gave them protective power against ticks, and to powder sulfur in a ring around where they had to lay down on the ground -- well, we didn't think it worked. We looked at that, and we didn't have any evidence that showed that any of that was efficacious.

But it's interesting because this will get -- what this gets ingrained is in the culture of the unit, and the same thing is true of the attitude and the reputation of these medications.

Troops are also very well-informed. They are on the Internet. They read the newspapers.

They listen to each other especially, and they are very well aware of adverse publicity of medications. In particular, I guess Lariam is the one -- mefloquine, that is -- that's been on our radar screen recently, and certainly a lot of troops out there are very concerned about that.

Finally, the compliance with the terminal prophylaxis -- now I use this term not quite right because I meant to say that part of prophylaxis, all of it, including the blood stage medication that you use as well as primaquine -- but that amount of prophylaxis that's given after you depart from the malarious area, there's a big problem with compliance with that part of it because once you remove -- you know, out of sight, out of mind -- you remove the soldier from the malarious area and all of a sudden malaria drops off as one of his concerns. If it was even on there before, it's really dropped low now.

Certainly, our experience is that the command emphasis evaporates. If it was there before, it very soon dissipates because commanders have other things on their minds. And I mentioned

that the perception of the disease threat wanes, and the side effects from the medication may persist, so it's an uphill battle with some of these medications.

(Slide)

In terms of the dosing regimen itself -- in other words, for the most part we're talking about daily versus weekly dosing for the most part. Certainly, a short-course medication that we could give one single dose of before exposure would be great, and I guess tafenoquine on the horizon here has the potential for being this sort of "fire and forget" type of medication that would be potentially very useful in our armamentarium.

Daily medication, especially unsupervised -- and I mentioned, you know, some of these missions and some of these units that are off, a little detachment all by themselves -- expecting soldiers to take a daily medication sometimes is -- well, it can be problematic to remember to take a medication daily. Certainly, you know, use of doxycycline daily -- and I guess Malarone would be a daily medication -- does

require supervision for troops to really be compliant.

Weekly regimen is generally thought to be -- and a little truth in advertising here -- the data aren't really all that clear. However, I guess the impression that I have, and also a lot of my collaborators on this, is that our experience is that with commanders able to focus on malaria once a week and make a big deal of malaria medicine once a week is doable. Asking them to do that every single day, every day, without fail, is harder to do. But you can make like a "Malaria Monday", or Sunday is the day across the theater, and the commander at the top says "Sunday we're going to take our medicine", and 1st Sergeants and everybody runs around Sunday morning making sure everybody takes their medication -- that can work.

Now, it's not exactly always directly observe therapy, but it's one baby step short of that, it's not bad, it's pretty good. However, of course, that emphasis -- as I mentioned, when you leave theater sometimes that emphasis falls off. But in general, a weekly drug is better than a

daily drug for the military, I think, in general.

(Slide)

Complexity -- and this is true -- it's a general principle of working with GIs -- and it's the "keep it simple, stupid" principle -- the simpler we can make this understandable and executable, the better it is. And that;'s why coordinating among the services and among the components on a particular operation, and having an agreement or consensus on a malaria approach is very, very helpful, if you can achieve that. We can't always achieve that because of differing -- as I mentioned, some of these differences in subpopulations. Certainly, simpler is better, and a single drug -- again, for simplicity purposes -- is better than two.

Again, a medication administered before we deploy would be best, then we don't have to carry it along and have to worry about any of this. And I mentioned the consistent policy among joint and combined forces is ideal, but not always achievable. And when I say "joint", I mean like the four U.S. services, and coalition and combined

is when we bring other countries like are present today with us, or we go with them.

(Slide)

Of course, and I'll finish here, if we had our dream, I think most of us who deal with malaria in the military in terms of chemoprophylaxis, the ultimate would be a single-dose med or a shot that we could give during basic training that would be 100 percent efficacious and has no adverse effects. So that's all we need. So if the Board would just recommend that, then I think we'd be done, so I would appreciate it. I'll take any questions. Do we have time for questions?

DR. OSTROFF: Yes. Thank you, Bob, that was very helpful. I think that's what we'll recommend.

COL. DeFRAITES: Okay, thank you.

(Laughter.)

DR. OSTROFF: Can I ask one thing, in looking through the briefing (inaudible words).

COL. DeFRAITES: Ken, do you want to start?

CAPT. SCHOR: I'll jump in here

(inaudible). Those decisions are usually left at the task force level (inaudible). Some might disagree that the need for a consistent policy, that theater-level policy would be helpful, there are a lot of differences between services and differences are okay, unless there's some huge difference in outcome, i.e., in treating malaria. For instance, in CENTCOM -- (inaudible) the Marines there is using not mefloquine, they are using doxycycline. I was a little surprised at that at first, but remember that they are thinking about they were in the river valleys (inaudible), and there was a BW threat that doxycycline kind of nicely helped mitigate, too, (inaudible). And, oh, by the way, malaria season is not always in (inaudible). Now, obviously, compliance is going to be an interesting feature. I think it's clear that the drug seemed to work pretty doggone well, but we'll see what compliance and outcome show with time. I think it's a bit early at this time based on the type of malaria.

So I think one of the most difficult issues here is that it's very difficult to

prescribe malaria medications and regimens one-on-one in the tropical medicine study. It's really hard for all those reasons to try to put together task force level recommendations -- in fact, that's why I went into preventive medicine, trying to do that sort of stuff, because the risks are very differential. And there's a discussion (inaudible), but the issue of travelers from non-endemic countries in the CENTCOM RAR to an endemic area when -- it may be a day, two days, three days, four days -- when do they start taking malaria prophylaxis. So these are very difficult questions, and we're trying to risk stratify to the extent possible, we always try to simplify and take it down to the battalion and squadron level if there is a (inaudible) mission.

(Technical malfunctions prevented adequate recording of discussion.)

COL. DeFRAITES: I just wanted to say, just for Operation Enduring Freedom, most of the operations -- not all of them, but most of the operations that you've read about -- have been in the CENTCOM RAR, CENTCOM Regional Area

Responsibility. CENTCOM has published sort of an overarching general policy about those countries where prophylaxis is indicated, but leave it really up to the component services to make additional policy.

As Ken mentioned, the Marines in Iraq were using doxycycline, and that actually was a decision at the level of what's called the Coalition Forces Land Component Commander, which combines the British Army, British -- all the land forces -- British, Marine, U.S. Army, and that doxycycline prophylaxis policy was made at that level. CENTCOM Surgeon basically deferred to the land commander in CJTF180, which is mostly the Afghanistan/Pakistan area, the prophylaxis procedure TF180 is mefloquine for the most part. Again, it's hard, going back and looking at the decisionmaking process, it's difficult to see what the difference is between those two areas.

I'll tell you, there was a lot of discussion about Iraq and how much chloroquine resistance there may or may not be because if you look at the Yellow Book and CDC recommendations, it

recommends chloroquine with primaquine because there's a lot of relapsing malaria.

So we, from our standpoint, I think fairly -- at least at the Army level, we influenced CENTCOM and the CFLC folks to at least consider the risk of chloroquine resistant malaria. I think these other factors have led to (inaudible) prophylaxis, that's really a different regimen, but anyway, who knows, it may work. I don't know what went into the final decisionmaking.

In general, for the Army, we still consider, I think, similar to what CDC put out in terms of the first line drugs, but for chloroquine resistant areas we recommend either mefloquine and usually we favor that because of the reasons -- for the usual troops, again, individual missions need to be tailored individually, but generally we consider mefloquine and doxycycline being sort of co-equals in terms of the drugs of choice for chloroquine resistant malaria.

We haven't really haven't addressed -- and one of the reasons for asking the Board to look at Malarone is we really haven't factored Malarone

-- we don't know where it fits right now in our recommendations, whether it's going to be a co-equal. Certainly, the cost is a big factor for Malarone, but I'll stop there.

LtCOL. WOODWARD: LtCol. Woodward for the Air Force. Just by policy, we do mandate (inaudible) done by the local unit or (inaudible), and then after that our policy is to follow (inaudible) recommendations or other guidance on which malarial drug to use -- which pretty much follows what Col. DeFraites described for the Army.

I would like to emphasize and point out (inaudible) aircrew is -- and just so you know, in the Air Force our use of pharmaceuticals for aircrew, the process is that once we have a drug that's approved for use in aircrews, unless there is a compelling reason to entertain approval of new medications for aircrew, industry is not going to pursue that, unless there is a compelling reason to switch from the medications that are approved for aircrew for malaria. Doxycycline is the approved medication. So when you consider a nw medication for aircrews, there would have to be a very strong

reason to suggest that we substitute (inaudible). Of course, it's nice to have because the testing process is very long and there are not specific tests for all new products in aircrews.

LtCOL. GIBSON: I just wanted to add from a Health Affairs standpoint, we put out a letter or memo to the Surgeons last year reminding them to remind their physicians that there are (inaudible) of the entire regimen and (inaudible), and it's a risk-based threat-based decision on which medication is used, and prescribing the medication (inaudible).

LtCOL. PETRUCELLI: Bruno Petrucelli. I wanted to comment on (inaudible words) Col. Woodward pointed out the process is really determinative more than anything else (inaudible words) almost 15 years ago for a licensed product. And I'm always intrigued and even (inaudible words) by the fact that we put so much emphasis on people who fly aircraft or even just fly in them. I want to just remind everyone that virtually every person in uniform carries weapons, and that's a significant fact right there in terms of (inaudible

words). And more importantly than that, a lot of people in the military -- Navy, Army, Marines, every service -- control weapons defined weapons of mass destruction as simply weapons that mass destruct or destroy. There are many people who are not pilots or not aircrew who control these systems with very fine ordered skills (inaudible words).

DR. OSTROFF: Sharon.

CDR. LUDWIG: I want to comment on what happens in the Coast Guard because we have (inaudible) going to Latin America (inaudible words).

(Technical malfunctions prevented adequate recording of discussion.)

DR. OSTROFF: Let me ask a couple of other questions. One of them is being that we have doxycycline being primarily used as (inaudible words), there's an actual experiment being done. And I'm wondering if anybody is looking at or trying to -- I mean, I realize (inaudible words) to try to compare what the (inaudible words).

COL. DeFRAITES: Not formally, but as we -- if you don't get any cases, it's hard to know

if you didn't get cases because you aren't exposed. What it comes down to for us is there's not uniform exposure. So a lot of times it's difficult to make these judgments of who was actually exposed in terms of your denominator. That's always been a challenge for us for malaria.

So, as I mentioned, the cases in the Rangers yesterday and I think Dennis mentioned it this morning, that's vivax malaria that probably was acquired somewhere in Afghanistan or Pakistan.

DR. OSTROFF: I'm not talking about efficacy (inaudible), I'm talking about once they're added to the falciparum (inaudible) who is taking it.

COL. DeFRAITES: Oh, no, no one is doing a study of actually looking at compliance rates. No.

DR. OSTROFF: The other question that I would have is nobody has really talked about what (inaudible words) how much malaria is actually occurring in military population on the bases. I know we collect at least some data on (inaudible) military populations (inaudible words).

COL. DeFRAITES: I'm sorry, was that directed to me? How many cases in the military --

DR. OSTROFF: (Inaudible words.)

COL. DeFRAITES: I don't have the figures.

COL. SHANKS: Twenty or 30 a year has been an average in the Army, almost all vivax, practically all (inaudible words) .

CDR. LUDWIG: I have a similar question, and that is we were not aware of data that indicate how many people who are infected with vivax have already -- untreated and non-immune, will have a relapse?

COL. SHANKS: I think that one is mine. It depends on how many times you've been -- prisoners of war from the Philippines who have relapsed 10 or 15 years if they have been kept under those conditions for a very long time. Our soldiers under more likely infected situations depends on how lucky or unlucky they were, where his unit was and what time of the year. We've seen up to 30 percent rates in company-size units in Somalia. I know that we don't put soldiers into

the island of New Guinea very often, but the Australians do, and having a 30 percent attack rate afterwards is bad, but it does happen. I don't know if Dave would like to say anything about vivax after exposure.

CDR. FRYVATT: I can't say, Dennis.

CDR. LUDWIG: Let me clarify. I'm talking -- I don't you'd be able to tell the answer from the military, and my question to the military, I'm asking of people who are infected and not treated will have a relapse.

COL. SHANKS: Depends on where he got it. The (inaudible words) type vivax is famous for (inaudible) multiple times. Korean vivax is famous for coming in a year afterwards, but not terribly frequently thereafter. Probably as we understand these organisms better, there are probably many vivax that have their own (inaudible), but especially for tropical vivax your risk of relapse if you have initial disease is quite high.

COL. DeFRAITES: Sharon, I'll need to get back to you, but we did a study of a unit in Somalia in -- that was that unit that I think had

30 percent attack rate -- and we did get antibodies, I just can't remember -- I'll have to get back to you on the specifics of whether we found antibodies in soldiers who did not present with clinical illness. That might help clear it up. But that particular company unit was the one, and essentially because the unit did not get primaquine prophylaxis essentially, you know, basically had their blood stage covered with mefloquine, but did not get primaquine prophylaxis. So pretty much that's sort of a marker for what the attack rate for those who came out of Somalia with hypnozoites that then later became manifest was about 30 percent. But we have some antibody data, too, and I'll have to see if we found antibodies in significant number that didn't have disease. Trouble with that approach -- no, it would be okay because -- no, it would be hard to say because we then introduced primaquine, so we may have wiped out some people who would have later become ill, we may have cut it short.

Some to think of it, I've talked myself out of it -- I don't think I can help you. Sorry

about that.

(Laughter.)

COL. MAGILL: Alan Magill, from Walter Reed. Just a comment, this looks like some of my most recent experience in the current area of operations. This whole business of risk assessment -- and we went round and round about this (inaudible). If you're going to a conference in Canada, there's no risk, you don't have an issue. If you're going to deploy a force to Central Africa, you know right away that malaria is a clear and present danger, that you really have to institute a full array of personal protections, prophylaxis, et cetera, across the board. Also having the appropriate diagnostics and therapeutics to take care of these issues. So, in a way it's almost easier if we deploy to Central Africa because we know it's a problem and everybody gets onboard.

Unfortunately, guys in travel medicine, a lot of our travel is to areas in which there is zero risk or very small risk or maybe occasionally some measurable risk for malaria. I think that's

exactly what we've seen in Afghanistan. Your typical person going to (inaudible) for three months it is zero risk. However, a special forces group can go for a couple of weeks in a river valley and have a measurable risk. How do we target for interventions with groups that may need it most.

Look at Iraq. If you're in a travel clinic and a tourist who is going to Baghdad for one night or two months, you wouldn't give a prophylaxis because there is zero risk. Probably 95 percent of our troops are in Baghdad and for them there's zero risk. You have to have a simple message. So if you go across the (inaudible) in mid Iraq, the current policy is for one night, you get whatever it is, 7 weeks (inaudible words) or 6 weeks of doxycycline, and of course this is way over-kill. We're probably giving (inaudible) drug to people who don't need it, certainly don't want it. And I think one of our drivers here is our reluctance to have any case of malaria in the military -- and I agree, we don't want any cases -- but we don't have a really good feel for the cost

of doing business that way, which is the adverse being associated with these drugs. We don't have a system designed to capture it in-theater, and I frankly don't think we will, but currently with doxycycline, if you give 10,000 people doxycycline, you're going to (inaudible words). They're out in the desert, 110 degrees, not a drop of water in sight, and they're taking a pill for malaria? They understand this very quickly, and compliance goes way, way, way down.

So, I don't have a good solution, but it seems like, especially as we shift from a wartime setting to more of a peacetime setting -- or in this case something in between -- we might do a little bit better job of targeting our troops that may need these interventions.

DR. OSTROFF: Thanks.

CDR. FRYVATT: I'll just comment that the people with real-world experience in relapsing malaria, vivax malaria, are the Australian military, and they're the ones that are still so strongly behind (inaudible). One other thing is that the rule of thumb that tropical vivax is

short-term relapsing is not the rule of thumb, it's a fallacy. You can have very, very late relapsing tropical malaria as well as very early.

LtCOL. GIBSON: I just wanted to add to that, you mentioned the side effects of doxy, mefloquine, et cetera. Now we're on it's not without risk itself. It has an adverse event or adverse reaction profile as well that should be taken into consideration in the decision.

DR. ATKINS: Has there been head-to-head comparison to Malarone versus doxy because the ones in the slide refer to Malarone versus mefloquine.

COL. SHANKS: You didn't do a doxy (inaudible)?

CDR. FRYVATT: No.

DR. PATRICK: What's the status of (Slide)

COL. SHANKS: In advanced Phase 3 testing, but realistically could not be licensed within the foreseeable future, meaning the next three or four years.

DR. OSTROFF: Can you tell us why not?

COL. SHANKS: Not without compromising

some confidentiality agreements and giving at least an hour lecture.

(Laughter.)

COL. VEAZEY: Possible (inaudible), negligible risk inherently and probably not going to (inaudible). It's something that has to be investigated very carefully, and they are just about to begin a six-month dosing trial and the Uniform Services University Health Sciences (inaudible words).

DR. OSTROFF: Further comments or questions?

CAPT. SCHOR: I would just like to emphasize that I think that the key here is the fact that as good as the Yellow Book is (inaudible words). There are very few decisionmaking tools that are distributed to the users that allow folks that have the experience and the different factors, decisionmaking factors presented (inaudible words), so the practice guideline sort of thing is tremendously needed. (Inaudible words) military medicine kind of needs to get on with, so they need to weigh the different factors. And then have to

take into account the fact that you get (inaudible words), and so the issue of pre-exposure (inaudible words) you don't have three weeks most of the time, you only have a few days most of the time.

The fact that the Board needs to realize that in small theaters of operation there's a lot of movement through that for various and sundry reasons, whether it's logistics, whether it's emergency leave, whether it's press coming in, all of those sorts of things, and it goes beyond just the (inaudible words). There's a huge number of complicating variables so that decisionmaking tools are -- you know, I would strongly support providing them.

MR. BLICKLEY: Thanks. Can I ask one other question? There seems to be (inaudible words), what do we know about compliance with some of the other potential prophylaxis (inaudible words) insect repellent and other types of modalities that might also (inaudible words).

DR. OSTROFF: I'd have to get the specific figures, but almost every time we've put that on units that have been deployed (inaudible

words).

(Technical malfunctions prevented adequate recording of discussion.)

CAPT. SCHOR: The only other thing I would add is that human nature is a (inaudible words). It's very difficult, if you could get (inaudible) improvements on uniforms, that would be a good thing. The Marine Corps (inaudible words), and nobody thought about treating that with (inaudible words), flea and tick collars are still purchased as a (inaudible) thing, (inaudible words) applications with Deet. Every Marine is given a mosquito net, whether they use it properly is a problem of education. They certainly don't share with anybody (inaudible words) because they are responsible for that piece of gear. So this is a constant challenge, but it's one of the most important things (inaudible).

DR. OSTROFF: I assume you wear your dog tags along with your flea and tick collar.

CAPT. SCHOR: Maybe we should treat those.

DR. OSTROFF: Monica, did you have a

comment?

CAPT. PARISE: This wasn't on the personal protection (inaudible), in response to a question a little while ago, there actually is a study that's not out yet, that did compare (inaudible), that included mefloquine, doxycycline, Malarone and chloroquine proguanil (inaudible words). And what was recommended was Malarone and doxy, although overall in their abstract, it looked like Malarone is just a little better, but (inaudible words). Doxy did very, very well compared to Malarone, is my understanding from that.

DR. OSTROFF: Thanks. Are there other questions or comments?

MS. EMBREY: In terms of (inaudible), there was a study from the Gulf War -- the first one -- about pesticide use (inaudible words) that prophylaxis may not be the perfect solution (inaudible words).

DR. OSTROFF: I think that's a good point. I know certainly in the (inaudible) data we've done a lot of work looking at Deet and

potential adverse events associated with Deet and (inaudible) in terms of the concentrations that are used in those products which are probably safe materials given to people who use it more than they should. So I think a lot of that is probably (inaudible).

(Technical malfunctions prevented adequate recording of discussion.)

DR. OSTROFF: Thanks very much. If there are no further comments, let me just ask the members of the Board who may be writing up reports on the questions before us, are they relatively clear on what they are going to be doing in terms of the questions, before we move along?

DR. CATTANI: Dr. Cattani. I just have one question. I think it was Monica who mentioned that the cost of two weeks of Lariam was similar to the cost of Malarone, is that correct?

COL. SHANKS: That's me, and it -- well, again, it depends on where you buy it, but six weeks of Lariam, which is what you're supposed to take for an exposure, and two weeks plus 7 days of atovaquone/proguanil were very carefully -- it

cost almost exactly the same in different markets because that was the competition, and most people who go to tropical countries go on vacation for one or two weeks.

DR. CATTANI: My other question -- and I don't know if you want to comment on this -- what would you think the tradeoff is vis-a-vis the response or the fear of taking Lariam or mefloquine versus taking prophylaxis? In other words, there's an argument could be made that taking prophylaxis is better, but is that outweighed by compliance issues that if the armed services feel that this is a drug that or course they don't want to take it, does anyone -- I realize it's speculation, but I think it's an issue that's going to have to be addressed (inaudible words).

COL. DeFRAITES: When we use mefloquine -- this is the Army -- in deployments, really don't -- have not gotten the impression that there's been noncompliance in-theater, it's been generally once the commanders are onboard, "This is what you're going to do", and they do it. This has worked very well, we felt we got good compliance in Somalia,

not having gotten reports from Afghanistan that troops were refusing to take it or anything like that. Really, I think it brings in terms of risk communication a challenge more than fear that people will throw the pill away on a large scale, one drug versus another.

And, again, it tells a little story about how individual soldiers' experiences can become legendary, the same thing is true of doxycycline, as many of these medicines, that he took it and had all sorts of upper GI problems, and learned when not to take it or when to take it (inaudible words), who had the same thing -- effect occurs (inaudible words) widespread views of drug testing side effects (inaudible words). So I would say that it would favor something that you can (inaudible words).

(Technical malfunctions prevented adequate recording of discussion.)

DR. ATKINS: I guess I'm feeling I don't have enough information to make a decision on Malarone because I think the (inaudible) are very (inaudible) with doxycycline, and it sounds like

there's some information that may be becoming available, and I don't know if it's possible to recommend that we collect more information on it in terms of (inaudible words).

COL. SHANKS: It's a lot less fragile. If you take your doxycycline every day, it's compliance will be very similar to Malarone. However, if you miss a day on Malarone it probably doesn't make much difference. With doxycycline, your efficacy rate is approximately equal to your compliance rate. Now, obviously, we don't like to build in things for noncompliance, but as you can tell from the discussion around the table noncompliance is a factor, and it's one way to deal with it.

There's also a demand for it, particularly from (inaudible) and other high-ranking officers who know that that's what travel clinics give. Now, that's not a reason for the Board to weigh its decision one way or another, but it is a question that comes up.

COL. MAGILL: If I could just add one comment to Dennis' there, I think one of the big

advantages of Malarone is that it's a causal prophylactic if you take it for seven days after your last exposure whereas doxycycline is a suppressant prophylaxis and you are supposed to take it for 28 days after your last exposure. And this is the area at greatest risk for noncompliance. For a healthy person who does not perceive himself at risk, nobody is going to take 28 days. Somebody in that same setting for 7 days, he might take 3 or 4, maybe even 7, so there is a distinct advantage there. I think the initiative to reach the civilian market has moved very strongly towards Malarone is your basic -- you know, short-term their focus is on numbers. I think many of us see that as the niche also for Malarone in the military -- relatively small numbers, a few hundred numbers deploying -- say, a special forces group training in West Africa for two weeks and then leave the area -- so small numbers, short duration, Malarone is clearly as effective, probably as cost-effective as well. For a few hundred thousand troops in Iraq (inaudible words).

DR. OSTROFF: Thanks. What I'd like to do is, if it's agreeable to the Board -- we're a bit ahead of schedule, which is never a bad thing, particularly when we get to the Preventive Medicine updates where we tend to bog down a little bit -- is that we go ahead and have one or two of the Preventive Medicine updates before we break for lunch, since we do have the award ceremony in the afternoon which is likely to disrupt things, and that way we can see how the updates go, and try to get through those quickly. And why don't we start with Col. Gibson, who will give us the update from Health Affairs.

LtCOL. GIBSON: Thank you. I was looking forward to doing this at 1:00 o'clock. Instead, thanks to the efficiency of Dr. Ostroff and Dr. Riddle, I get a group that's not only awake, but hungry. So, thank you.

(Slide)

Since the last meeting of the AFEB, the world has seen the emergence of a new pathogen that has had a global impact, to say the least, and we've also seen an unprecedented effort, Preventive

Medicine Public Health and clinical effort, to characterize the disease, write the genomic code for it, develop diagnostic tests, and implement control measures, public health control measures across the globe.

While CDC has had the lead on this in the United States and arguably in the world, the Department of Defense took several actions to be proactive in helping to control this within our population. Very shortly after the outbreak was recognized, there were a series of policy documents, situational reports throughout the Department of Defense, to increase the situational awareness, to ramp up surveillance, and to provide information, risk communication information across MHS. We also did situational reports on a daily basis for the Secretary of Defense on this, those continue to this day, although as of last week we backed off to -- as of this week we backed off to three times a week rather than a daily situation report.

We coordinated very, very closely with Department of Health and Human Services and CDC,

put a liaison, a DOD Liaison in the Emergency Center at CDC so we could have the most up-to-date information we possibly could. DOD GEIS was collecting samples and monitoring for respiratory disease across the globe. We had samples, and we continue to have samples coming in through our Global Respiratory Surveillance Program.

The commands, the combatant commands, and in particular Pacific Command, issued guidance and travel restrictions to SARS-affected areas -- issued two of those -- one early on that impacted the original affected areas, and then just recently added Taiwan to that list.

The Department of Defense plays a role in emergency MEDEVAC when all other agencies or all other venues aren't available, and even though it took us a little bit of time to coordinate it, we did help out in removing an American citizen from Ho Chi Minh City, who had SARS. USAMRIID right here was deeply involved from the very beginning, continues to be involved in testing antivirals for the corona virus, and we stood up Websites and did various other things. One of the other products,

the one I want to talk about today, was a tabletop exercise that we conducted on the 1st of May, and it was involving an outbreak -- the scenario we used was an outbreak of SARS in a theater of operation. Brought in a number of senior policymakers to discuss the policy implications of this. So I'd like to discuss a little bit about what we term the "SARS Wars Exercise".

(Slide)

The problem that we presented them with was how to develop a proactive strategy to manage SARS before it presents in a theater of operations, and got the best minds together across the Department of Defense and including Centers for Disease Control, Veterans Affairs, and the Surgeon General of the United States, the Office of the Surgeon General -- the Deputy Surgeon General attended the meeting.

The products that we were looking for were strategic products, products at the strategic level -- primarily a Policy Memorandum to start to direct this process of attacking an outbreak in a theater of operations, which you can imagine have a

major impact not only on operations, but because of the way we do business in a theater of operations, communicable disease control can be problematic in some cases, and there are also some political implications when military people become the source of infection for civilians in a host nation. So we wanted to discuss those.

Also as part of this, we're looking at the opportunity to develop DOD Directives which would give us an approach to outbreaks in a theater of operation not just for SARS, but could we come up with a template for doing that that we could operationalize for other types of outbreaks.

(Slide)

The basic outcome that came out of here, and that makes a lot of logical sense, was a tiered, risk-based framework to it, where we apply risk reduction measures appropriate to the level of risk both in time and space within a theater of operations. This fits within a NATO Medical chemical/biological/radiation framework that combatant commanders are somewhat familiar with in how they approach these issues, with these sort of

headings.

(Slide)

The basic template that we came up with based on the decisions from the senior leaders was, if you look at the matrix across the top, the various impact Tiers 1 through 5 depend on the situations of SARS with respect to the theater of operations. We're actually in Tier 1 at the time -- no SARS in the world. SARS is really with us at the present time, so we really move from Impact Level 0 to 1, and the various things to sustain transmission within the theater to an uncontrolled outbreak -- you know, the "Omigosh" syndrome -- and then these capabilities that we discussed from the standpoint of this NATO template with the various operational capabilities laid out there to -- strategic capabilities and operational capabilities laid out beside them. We're filling in those squares as we speak. We have a draft of this document that's ready to go into coordination at the present time. It will require a lot more heads and more than the last three weeks of time to fill in all of the information on each of these Impact

Tiers, but that's where we're headed at the present time.

(Slide)

Some of the implications and considerations is a phased approach -- in other words, we take the SARS issue, the types of operational measures taken would depend on time and location even within the theater of operations, the risk onboard ship is different than it would be on the shore. It would be different if you had SARS cases in Baghdad versus in some other location within the theater of operations. So what commanders do within those locations would be dependent on that risk.

Uniform protection against all of the populations at risk, to include military, the Coalition Forces, and the civilian populations, understanding that preventive measures need to be in place at all of the echelons of care from Level 1 right through definitive care. One of the -- and I'll talk about this a little bit more -- but we talked about MEDEVACing only by exception -- in other words, leaving our cases in theater if

entirely possible. And then operational management of the cases -- in other words using good clinical guidance on how we do things from a risk management standpoint at that specific location, and making decisions that can withstand scrutiny later on.

And, finally, coordination with the other players. This won't be in a vacuum, it won't be just military folks. Within our current theater of operations certainly there will be an Iraqi government within a short period of time. We have GMO (phonetic) that are out there as well that we'll be working with as well as the Coalition Forces.

(Slide)

Very strong recommendation from the senior leaders was to move the laboratory assets to theater. We have, as you know, CDC has developed a PCR test that does allow at least from a surveillance standpoint for rapid identification or rapid confirmation of cases. The sensitivity and specificity, of course, is still being worked out. Since one of the primers for this product will fit into a lifecycler and we have a product called

RAPIDS (phonetic) which basically uses the lifecycle technology to be able to do PCR work, the goal is to move that as close as we can to the theater of operations for detection.

MEDEVAC by exception -- what we're talking about here is moving assets to the theater, if needed, to take care of any cases. The vast majority of peoples, particularly in our age group of cases, would not be at great risk for mortality -- the mortality risk is certainly age-dependent -- and we could potentially take care of most of these cases in theater. The exceptions would be those cases that are uncontrollable or who have concomitant problems -- the sucking chest wound as well as being infected with SARS -- and providing personal protective equipment, ensuring that that is available in accordance with CDC guidelines. And then, of course, risk communication.

(Slide)

So, in conclusion, we feel as though the SARS could have an adverse effect in a theater of operations. We wanted to put together some sort of policy document or an approach that would allow

us to do this. We felt as though this tiered risk-based approach is the optimal way of helping to prevent and control SARS. That's it.

DR. OSTROFF: Thanks very much. Let me open it up to questions from the group. John?

DR. HERBOLD: How would you interact with the Department of State and other nonmilitary personnel in theater (inaudible)?

LtCOL. GIBSON: We've already been interacting with the Department of State not in this theater -- actually, we have in this theater, but most of our interactions with the Department of State has been in Southwest Asia at the present time, and collaborating at the table, sharing information, and supporting as needed and as required.

DR. GRAY: Roger, I'm reminded again that frequently military personnel have been held liable in the sense of importing a number of infectious agents, not only our personnel but military personnel from other countries, and that threat, of course, is a tremendous one, particularly if we were to import this agent into a

crowded retreat facility.

I want to commend you for getting involved with the CDC nerve center, but I'm wondering if the CDC is fully sharing with you some of their reagent -- for instance, their monoclonal antibodies (inaudible), and the very latest, because I think certainly that the DOD deserves to have that capability.

LtCOL. GIBSON: I'm not sure about the monoclonal antibodies at this moment. I know that USAMRIID has been working on a daily basis with CDC on these issues. So I'm not sure that that specific diagnostic test is available at this moment, but I will tell you that we have also provided a couple of things. With respect to screening going into an operational theater, we implemented that back in I believe March, end of March the services implemented screening procedures for our troops going into an operational theater, to reduce the risk of bringing something in.

We also have recommendations that are at the Personnel and Readiness, the Under Secretary of Defense for Personnel Readiness, with respect to

training environments and what needs to be done in training environments to reduce the risk of introduction of infection -- simple, logical, straightforward good public health practice which we've seen to be effective in controlling this agent, and those things are being implemented.

MS. EMBREY: I wanted to comment first on the question about our support with the State Department (inaudible words). The situation there is such that additional guidance has been issued to ensure that while there is no (inaudible), that DOD would work (inaudible words), and to also, to the largest degree possible, provide for (inaudible words).

(Technical malfunctions prevented adequate recording of discussion.)

DR. OSTROFF: Let me make just a couple of comments. One is I'm not aware of (inaudible words) it wasn't when I left the other day.

(Technical malfunctions prevented adequate recording of discussion.)

LtCOL. GIBSON: We, as guests normally -- we're talking here in a theater of operations,

but as guests normally in those host nations we tend to comply with their wishes as much as possible. Keep in mind that most places where we would have a SARS case from one of our folks there, they probably already have SARS and they probably already have people in their hospitals. We would be most likely to move out an individual where we could not provide appropriate levels of care without bringing in an air transportable hospital or something like this, which we obviously wouldn't do. We would move the patient before we would do that.

LtCOL. WOODWARD: I just wanted to share that if we do need to transport a patient, U.S. Transportation Command has very carefully considered the safest way to transport a patient, and procedure for receiving the patient (inaudible) are in place, but U.S. Transportation Command does have a protocol for how they do a transport -- what type of aircraft, what would the aircrew (inaudible), that sort of thing.

LtCOL. GIBSON: To add to what Kelly said, TRANSCOM's recommendations for moving

patients was actually used by CDC. It was a template for CDC's product, their recommendations. So we were out front on that issue.

We also -- just to give you a status report on where we are with SARS within the Department of Defense, we have one suspect case. We've had several cases, about a dozen -- or several cases that were brought to our attention -- this shows that our surveillance system was working pretty well -- brought to our attention, and only one of those, an individual in Utah, a retiree, met the case definition for a suspected case, and only after a slight change in the CDC case definition where you didn't have to have objective fever but reports of fever, and that allowed that case to be a suspect case. We've had no other cases across the Department of Defense at the present time.

DR. LeMASTERS: My question goes back to early detection, and it lists the movement of the military, sort of constant movement, coming from like Canada -- I just heard of two cases up in (inaudible) Toronto, and from the Asian countries. Are we doing -- I know we're doing screening

(inaudible) come back into the States?

LtCOL. GIBSON: We follow CDC's lead on this. CDC at the present time is meeting aircraft as they come back to the States, handing out health alerts, and they are made aware of people who are symptomatic at that time. The individuals are informed of their risk for -- since they've been in a SARS-affected area, their risk of having the disease over the next ten days and to report for health care. We're following exactly the same procedures.

DR. LeMASTERS: I was just thinking about it's too easy just to take the temperature when people don't (inaudible). It seems like that the military wouldn't have to perhaps even have a higher standard to early detection of forces coming in from particularly high risk affected areas.

LtCOL. GIBSON: At the present time, we're still following CDC. There were those discussions. The number of folks that we have in these areas tend to be relatively small, and certainly the situational awareness of SARS is quite high, particularly in military members. And

at the present time we do not plan, by policy, to be taking temperatures of people when they arrive or ten days afterward, it's a matter of informing and making sure that they monitor their health.

CAPT. SCHOR: Just a quick thing. This has been tremendously (inaudible) because of level of cooperation and information sharing with CDC, with WHO. We have Preventive Medicine Liaison Officers with WHO. We have, thanks to the support from GEIS, we've had consistent presence -- I think Col. Shanks has been down there most recently since he signs the daily update that we all get. So we have somebody down in Atlanta. And that sharing of information has allowed PAC Fleet to try not to send folks into the highly desirable Port of Hong Kong, and making difficult decisions of going into Singapore because that's where your big ships are at. It's been a win-win for (inaudible) which is ongoing right now in Thailand. As you know, Thailand was very -- a Fort Apache of the Bronx kind of an approach to folks coming into their borders, and everybody got screened, was screened for symptoms and fever -- Marine Corps, Army, Air

Force -- anybody going into Thailand got screened. And the win-win is the support from GEIS and the Tabletop Research Center and with and (inaudible). The project (inaudible) we are doing (inaudible) has never been done before, and the sensitivity of screening for this has the highest command attention, and it's all thanks to the information sharing and making those hard calls where you don't go into ports, there's a lot of off-limit travel. You don't go to China now unless you absolutely have to. So the level of travel internationally is kind of astounding, as we have found out with this, and the military has been forward in reducing the risk of exposure by eliminating travel or severely curtailing it.

DR. OSTROFF: Again, that's the point that I would emphasize, that has been one of our primary strategies as well, is to try to stress and recommend that individuals not make what we consider as nonessential travel to SARS-affected areas, and there are generally two reasons to do that. One is because it reduces your risk of getting SARS, but also reduces your likelihood of

coming back with some other respiratory infection (inaudible words). And so it's been a fairly successful strategy for us to do that.

As far as the issue of what to do about person coming from those areas, we have in general defaulted to the WHO recommendation, which is probably a better strategy than screening individuals when they arrive, is screening those individuals before they embark. And that's been WHO's position, and that's a position which we also support. And WHO has made recommendations that all SARS-affected areas, that all individuals traveling out of those areas should be screened prior to departure. And how exactly that's done varies somewhat from country to country to country, and some locations actually are taking temperatures of individuals before they get on planes or get on ships or get on trains or whatever it happens to be, and others order a questionnaire and overall just visual checkers and things of that nature. But that's probably a better way (inaudible words).

DR. LeMASTERS: Just one final comment. I've just come from the (inaudible) in Seattle,

and talking to a couple of (inaudible), who were asked about what kind of screening they went through, if any, when they left China, and they had not done anything. There was no screening when they left China.

DR. OSTROFF: And to a certain degree, it depends on where they're coming from as far as (inaudible words).

DR. SHOPE: Bob Shope. Just wondering if DOD has identified quarantine facilities in the overseas sites. (Inaudible words.)

LtCOL. GIBSON: At the present time, with the number of SARS cases and the distribution of military members across the world, we haven't identified specific quarantine locations within each of our facilities. Part of this within an operational theater, part of this template we're working on is to be able to do that if necessary. We have a DOD regulation or DOD Directive right now on emergency powers for commanders that plays into this issue of quarantine. Quarantine is an awfully big step. Other than that, no, we haven't identified -- on a onesy-twosy basis, we haven't

identified quarantine in-theater. We do have, as we talked about with respect to individuals in one location where we don't have a strong DOD presence, the ability to MEDEVAC those cases and designated hospitals for MEDEVAC.

COL. SHANKS: 18th MEDCOM has actually built a separate isolation facility, with 8 ICU beds and 8 ward beds, partly because of its perceived threat being in Asia, so at least in one case in Seoul, Korea they've done that.

LtCOL. GIBSON: That's a good point. The Korean commander has taken some very, very effective measures.

COL. MAGILL: Just a comment. This whole SARS thing really sprung up, of course, in mid to late March right at the time of Operation Iraqi Freedom as we were preparing to go to war. So, it's very interesting to see that access to the Internet and the WorldWideWeb was absolutely essential to stay abreast on developments. And most of our forward deployed forces in Kuwait were literally in a just-in-time environment, and they were setting up tents while this was going on, and

very limited and very intermittent access to the Internet. A few of us in more rear areas had good access, and the Kuwaiti government had a scare the first part of April with a reported suspect case, and very quickly they realized that the U.S. military (inaudible) on a daily basis 110-115 percent of the population of Kuwait. And they instituted through the American Ambassador a very pointed query to us because they wanted to make sure that the military, our military, was not a backdoor to introduce SARS into their country. And this stimulated a tremendous amount of activity (inaudible) which obviously people had other things to deal with. So we had a very few weeks during that period in Kuwait.

DR. OSTROFF: Let me ask this last question, and then we probably have to break for lunch, but while a lot of your thinking and a lot of your planning has been around the situation with Iraq -- and I think it's very appropriate -- but I'm just curious -- and you may not be able to answer this -- have you thought through what you might do with Korea? We've been relatively

surprised so far that Korea has been spared from SARS, but it might not last.

LtCOL. GIBSON: I would defer that to the combatant commander of the Joint Force in Korea. I will say this, I have seen some of the documentation on the steps that he has taken, and they are extensive. Let me just put it this way. It has been considered and well thought out.

LtC. JONES: I really don't have much to add to that other than the fact that in Korea the measures (inaudible words) than what is being recommended by the Pacific Command there. (Inaudible words.) So I believe they are taking it very seriously and (inaudible words) relationship with their leadership. So I think they're monitoring it very, very closely and preparing for it.

DR. OSTROFF: We'll take one more question.

DR. GRAY: It strikes me that the international samples that Project (inaudible) is working now are much more of a threat to the (inaudible) than they were, say, six months ago.

What sort of precautions has that group taken?

LtCOL. GIBSON: Dr. Neville will handle that one, I'm quite sure, it's his lab.

(Technical malfunctions prevented adequate recording of discussion.)

DR. OSTROFF: Rick, do you want to give us some instructions for lunch?

COL. RIDDLE: What we're going to do is we're going to have a working lunch here in the conference room. The conference room will open back up at 12:45. It will be just for the Board members, the Preventive Medicine Liaisons, the speakers from this afternoon and this morning. Everybody else has the NIH cafeteria, or there are multiple places to eat off-base. But we'll open back up here at 12:45 and the meeting will start again at 1:00. I did want to remind everybody that this afternoon Dr. Winkenwerder will be here at 2:00 o'clock, so what we're going to do in the afternoon session, as quick as his Aide calls we'll go ahead and shut down and get things ready to do the presentation. We'll have a break after the presentation, and then we'll finish up with the

speakers this afternoon.

DR. OSTROFF: Thanks. We'll adjourn. (Whereu

AFTERNOON SESSION

1:00 (p.m.)

DR. OSTROFF: Col. Jones has been very quietly standing up there quite a while, so I'm going to rap the gavel and let us start at least by my watch about 50 seconds early because everyone seems to be back. So, let's get started.

LtC. JONES: Thank you, sir. I very much appreciate the opportunity to provide a Preventive Medicine update from the Joint Staff perspective. Obviously, this will be a very brief update, but what I wanted to do was focus on some of the preventive medicine issues related to Operation Iraqi Freedom. Of course, a lot of things are still going on with regard to Operation Iraqi Freedom, very much still underway, and there's a lot of effort already ongoing with regard to capturing lessons learned with regard to that operation. The Joint Staff has already begun to do that. Also, the Combatant Command Surgeons will be meeting next week, and the key focus will be

lessons learned, so that should be very interesting.

Beyond that, I know ASD Health Affairs is planning something that, although not called lessons learned, will have some of that aspect to it, later on this summer. And in addition to that, of course, Joint Forces Command has the responsibility for developing Joint Unified lessons learned. So there will be a lot going on, and it's very preliminary at this point, so there's not a lot I'm going to be able to tell you in terms of lessons learned. But what I wanted to do was focus on some of the key new capabilities that have been developed -- either new capabilities or maybe enhancing some capabilities to try to fill some gaps or improve our posture with regard to force health protection.

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This is the outline I'm going to cover.

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First, I'd like to start talking a little bit about DNBI monitoring. We've really increased our capabilities with regard to detection

for chemical and biological agents. Our detection capability continues to improve there. But it's recognized that really the only full-spectrum capability that we have to detect chemical and biological attacks is still our health surveillance system.

The Theater Functional Steering Committee recognized that there was a need to field some additional capability that we didn't already have, and in looking at what we could field rather quickly, the Pacific Command had developed a technology demonstration project that was implemented prior to the actual beginning of ground and air operations for Operation Iraqi Freedom. The solution that was used was the Joint Medical Work Station. It's a Web-based system, and the idea is it's much more than just a DNBI surveillance system, it's a command and control system for deployed medical facilities. Really, the idea was to provide the Medical Commands with a common operational picture from the battle space, so although the services had their own individual systems, the Navy had a system, the Air Force had a

system. The Army prior to this had not really fielded a Web-based type system, so they were still using, I think, mostly spreadsheet type analysis of data. But there was a desire to really bring all that data together to provide one common operational picture, and to do that in very short order, I might add. So, again, a lot of these things were done very much on the fly or on the run.

The system again does a lot of things, but one of the things specifically that I wanted to focus on is the disease reporting aspect of it, and the epidemiological analysis tools that go with it. So this did give us a new capability. It also accepts patient encounter module input from the service systems, which obviously where you eventually want to go, is to be able to have the patient encounter data logged in from the beginning, almost on a near real-time basis fed into a system where you can do some very much real-time analysis, and that kind of piggybacking on that was the idea that obviously waiting for weekly DNBI data is really not adequate with regard to

determining if you want to be able to pick up a chemical or biological attack and be able to implement countermeausres and interventions in a timely way, our weekly DNBI monitoring that was previously required by Joint Staff guidance wasn't adequate for that purpose.

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So, what we did was, in January the Joint Staff sent out a message that directed that daily DNBI reporting would be implemented. This requirement was taken on by U.S. Army Central Command. They decided rather than using the normal weekly reporting categories, to come up with five special surveillance categories that would particularly apply to this idea of what we needed to find out right away, and the five categories are shown on this slide -- dermatologic illness, infectious GI illness, lower respiratory, and systemic fever illness. And also they added another category which was unexplained neurologic symptoms. So this was again a CENTCOM decision as to which categories that they would do. They felt that this was something that could be done in the field at an

operational level even down to their Level 1 facility, so at the lowest level what they were hoping to capture with this kind of approach. Again, the purpose was enhanced surveillance and identification of health events -- I specifically talked about the chemical and biological type events, but also for naturally occurring events obviously they would be useful as well.

Now, this did not supersede the weekly DNBI reporting, as I mentioned, this was a smaller subset of the overall reporting that was required, so the weekly reporting continued to be done in accordance with the JCS memo. The Air Force Institute for Operational Health did a yeoman's job with regard to analyzing this data, the weekly and the daily data. It's a huge job to do that, and they continue to play that role and we're grateful for their efforts with regard to that.

And I did ask AFIOH -- I hope I'm pronouncing that right -- LtCol. Kenneth Cox, who has been instrumental in pulling all this together for something that I could present to the Board in an unclassified fashion. Obviously, we always get

into those issues of some of the data is classified, and we're still working those issues of how we can declassify data at the appropriate point to make it useful for a number of purposes. And I realize LtCol. Cox, when he sent me this slide, pointed out all the potential problems with making these kind of comparisons and certainly this body is very much aware of those kind of limitations, but given all that, when we look at Operation Iraqi Freedom and compare to some of the other recent operations, our DNBI rates seem to compare fairly favorably in that regard. You have the slide in your books, so I'm not going to spend a lot of time on that.

(Slide)

Now, the next topic I wanted to cover was occupational and environmental monitoring. I think this is one area in particular where we -- sir, do you have a question?

DR. OSTROFF: I would just ask could you clarify for me what were Operation Joint Endeavor and Operation Joint Guard?

LtC. JONES: The operations in Bosnia

and Kosovo. So those are some of the more recent major operations that we've had.

Just transitioning to occupational and environmental monitoring, this is something, if we really look back to Operation Desert Storm, we've made tremendous strides with regard to this area. I think this is one of the areas we've made probably the most progress, and it really starts as a full-spectrum type of approach with regard to the continuum of surveillance is the way I would describe it.

First, it starts with the intelligence preparation of the battlefield. Before anybody deploys anywhere, there's really a quite extensive intelligence gathering and assessment that's done. The Armed Forces Medical -- AFMIC (phonetic) of course plays a key role in that. CHPPM plays a role in working with them. And it was very interesting, on the CiproNet they post these pre-deployment occupational and environmental health risk assessments, and there were I think on the order of 50 -- maybe I'm getting the number wrong -- but around 50 for very specific locations within

Iraq and Kuwait where we were expected to have personnel deploy, 40 to 50 pages of detailed summary along that kind of order, so really a lot of detailed information that was prepared in terms of assessing the threat before anybody even deployed.

Once personnel were deployed and were in base camps, then teams were brought in to do baseline assessments from an occupational and environmental assessment. After those baseline assessments were done, of course, we also had -- Preventive Medicine teams from all the services were equipped with in addition to their organic equipment, the Center for Health Promotion and Preventive Medicine provided them backpacks for occupational and environmental health monitoring for all the services, so they had that capability as well.

Of course, Preventive Medicine units are going to do their typical operational environmental health surveillance, the routine kind of things, the preventive medicine sanitary surveys and inspections that you would be familiar with

that they would normally do, so that's an ongoing thing on a weekly/monthly basis for various things.

Then there's the issues of event tracking when certain specific events come up. A good example would be the Iraqi oilwell fires, which was anticipated again that Saddam Hussein would likely set fire to various oilwells and the potential health risks associated with that. So CENTCOM actually did a tab to their appendix in the Annex Q that dealt specifically with oil fires and the risks associated with that. So that was something that they were planning for before there was actually any oilwell fires set. So, again, anticipating, thinking head, and teams were sent in to assess that risk as soon as they were able to get into the theater and get close enough where they could assess that threat.

In terms of health risk communication, obviously that's always key with regard to this. We not only need to collect the data, but we need to communicate it to unit commanders, to individual troops, and throughout we need to communicate also to our Preventive Medicine personnel who can then

train-the-trainer type approach and get this information down to the lowest level.

And a key aspect also, of course, are deployable laboratory assets. We had the theater medical surveillance team, the theater Army Medical Laboratory, the Navy had shipboard assets, and the Air Force has deployable medical assets, so a wide range of deployable lab capability was deployed in support of the operation. And, of course, they have reachback capability to the U.S. for specialized capabilities and confirmatory type analysis, things like that.

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The next topic I wanted to briefly mention is the use of investigational new drugs. The combatant commands requested use of three products for BOTTOX. They requested the use of BOT toxoid, BOT immunoglobulin, and BOT antitoxin. And, again, some of the limitations with regard to those I think were brought up in earlier sessions. Also, Special Operations Command requested us of the fibrin bandage.

So, how did things go with regard to

implementation of those? Really, we're still waiting for data and assessment, lessons learned. A key part of that, though, was that U.S. Army Medical Research and Materiel Command deployed IND assistance teams, which I think, as you all know, INDs are very difficult to implement under any circumstances. Under an operational situation, extremely difficult to implement. And so the idea of sending out IND assistance teams I think was very critical to at least trying to make that work. I have not gotten the official lessons learned or after-action reports yet from that, but in talking to Col. Magill, who is in the audience, from WRAIR, there are some very interesting things that he had in terms of comments, and it will be interesting to see what the assessment is of the viability of these things.

Part of the idea, of course, is that -- in the short-term anyway, as was mentioned -- we have anthrax and smallpox as licensed products, and we have antibiotics for certain threats, but there are a number of threats we don't have vaccines for. So for the foreseeable future, we may be relying on

IND type products and how to do that as smart and as efficiently as we can to support the combatant commands is very important.

You probably know that the combatant command actually has to request the use of an investigational new drug. The decision is with the Secretary of Defense. And even if the Secretary of Defense makes the decision to use an IND, they still have to be given with informed consent unless the President of the United States decides to waive that requirement. So very detailed reporting requirements and health risk assessment type requirements required to be given to the individuals.

Just a few notes of things that we think would need to be improved in terms of seeing this process unfold recently in OIF is that we certainly believe that we can improve the process even based on the limited experience that we've had recently.

One of the things that we really think is important is that investigational new drug use needs to be planned just like the use of other

countermeasures. It really needs to be included in the planning process in the Annex Q health service support. We need to deal with INDs, what is needed, when they are going to be requested, use of implementation teams, and it really needs to be just part of the overall planning process. In the case of these INDs, they often require special equipment like freezers and things that would not necessarily already be in-theater. So there's a logistical piece that really needs to be dealt with, and so we certainly are going to try to champion, from the Joint Staff perspective, making that as part of the normal planning process for the Annex Q.

Also, I guess I would just like to mention that obviously putting the information as much -- we tried to use some of the tools that were available. The Military Vaccine Office had developed some draft documentation with regard to IND implementation for combatant commanders and down to the unit level leaders. Those were in draft form, but we went ahead and sent those to the combatant commands anyway. We think it's really

important that we use the ability of the CiproNet and the ability to use the force health portal to provide information that combatant commands can readily get for themselves as part of their planning process.

And I would just like to mention, obviously, that everybody is kind of looking for a silver bullet with regard to these INDs. There are clearly some -- they aren't silver bullets, they are very difficult to implement, and we really have to look at what the limitations are, but yet figure out how we can best use them.

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Vaccinations is something that, as Col. Riddle mentioned he spent about half of his time working vaccinations, I spent probably, I don't know, 75 percent of my time working vaccinations in the past year. Overall, as has been mentioned -- I'm going to cover this very briefly -- I think the implementation was relatively successful especially considering the tight timeline that we were under. However, I think the goal would have been to have all of our personnel, before they deployed,

vaccinated for smallpox and with at least the first three vaccinations for anthrax. We didn't achieve that goal. And, of course, if in fact there had been a preemptive strike, that was a serious concern. So, although we had a large number of our personnel that were protected in-theater, when they arrived in-theater, there were still a fair number that were not. And, of course, I know from our own leadership on the Joint Staff perspective, they are looking at it from the standpoint not of what has been done, but what hasn't been done in terms of protecting our troops.

I've briefly mentioned that Bot Tox products were provided. They had to, again, be given under informed consent. And with regard to the way ahead, we certainly, from a supply standpoint, had been limited on what we were able to do, and this has been discussed. I would only just like to mention quickly that there was a difference in approach between smallpox -- as we I think gathered from the briefing, smallpox is a real threat, yet it's somewhat of an indeterminant threat, and in dealing with an indeterminant threat

that has potentially very major strategic consequences, we felt that the best approach was to use a capabilities-based approach where we would protect certain capabilities that we could not afford to have impacted in the event of a smallpox attack.

In offering ideas with regard to expansion of the program not only looking at higher-threat areas, but also certain capabilities that would need to be protected again. The DEPSECDEF has already directed the vaccination for continuity of operation personnel, and in the Pentagon within the National Capital Region, so that we would continue to be able to operate in the event of a smallpox attack. That's already been directed, and the services and the Joint Staff are planning to implement that, as well as the OSD staff. So that is ongoing.

Now the idea that maybe we need to expand that to combatant commands, maybe even to service field headquarters, because again we have to think about what the vulnerabilities are there. Also, the need to be able to respond in a homeland

defense situation, Northern Command and Pacific Command have both requested the authority to vaccinate certain forces that would respond in terms of homeland defense -- example, quick reaction forces and other forces that would be needed to go right into the attack would be prepared to. And so that's something that needs to be considered as we look at potentially expanding the program.

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And the last topic that I wanted to briefly mention was post-deployment health assessment. Dr. Chu recently directs, actually on the 22nd of April, that the services would implement certain enhancements to the post-deployment health assessment process. Needless to say, that came the 22nd of April. Implementation is supposed to begin tomorrow, so it's a very tight timeline.

I wanted to quickly cover just some of the highlights of some of the differences between our existing post-deployment health assessment process and what's been directed in terms of

enhancements from Dr. Chu.

First of all, sea-based personnel are now included. In the past, if sea-based personnel had not gone ashore, they would not have been mandated to go through this process, now they would. All health assessments now have to be conducted face-to-face with a trained health care provider.

Blood samples now will be obtained from all returning personnel. In the past, when HIV samples were taken, those samples would also be part of the repository, but now for all personnel.

The questionnaire, DD Form 2796, has been significantly expanded from 2 pages to 4 pages, and the key things that were added to it in terms of questions deal with mental health issues, specific medications taken during deployment, and personal concerns about environmental and occupational exposures, just to give you a very kind of thumbnail overview.

The services were directed to prepare implementation plans. The Marine Corps and the Army I know have already published their plans. I

know that the Navy and the Air Force have theirs at the very top levels of their organizations, so I expect they will be signed out soon as well.

Implementation, again, is supposed to begin tomorrow. Now, changing a program like this in the midst of the biggest deployment in 12 years -- we're talking, of course, about a half a million people that have deployed -- so it's a huge undertaking, particularly to be doing this with less than 30 days from notice to implementation. And as always, I believe that the services are, my impression is, stepping up and doing everything they can to meet that challenge.

That's all I wanted to cover, and I'm ready to take any questions, sir.

DR. OSTROFF: Thanks. Why don't we open it up before I ask my questions.

DR. RUNYAN: I wonder if you could give a little more detail about the injuries that were shown on the table that you presented. They appear to be at a rate of 2 to 7 times of all the other (inaudible). I just wonder what some of the circumstances are, what some of the countermeasures

are that are being put in place, and the priority?

LtC. JONES: Ma'am, that's a wonderful question, and I wish that I was prepared to give you a detailed analysis of what's behind those injuries. We actually don't just capture that one category of injuries. If I recall correctly, there are four categories with regard to injuries that we separately break out so that we have some specification of what those injuries are. But for the purposes of this presentation, because of the short nature of the time, and also somewhat with regard to the classification of the data because I believe that if we go below a certain level we have to begin to worry about some classification issues. So I'm sorry I'm not prepared to give you a detailed breakdown, but that data certainly is collected and it is analyzed. And I don't have any summary lessons learned to give you on that right now, I'm sorry.

DR. OSTROFF: Dr. Patrick.

DR. PATRICK: The Form 2796 has gone from 2 to 4 pages. The questions on personal concerns about environmental and occupational

exposures, are those both force choice and open-ended?

LtC. JONES: I'm going to let my colleagues chime in here because they are aware of the process as well, so feel free if you would like to add to it. There are some very specific -- a number of specific things that they're asked about. Were they exposed to dust? Were they exposed to JP8 fuel? It's a lot of tic-and-flick kind of thing. So there is a lot of that. I believe that there's still some room for the open-ended kind of answer as well.

DR. PATRICK: I would think there would be great value in having open-end, so it sounds like there are various chances to describe your experience and sort of things that could be evaluated later.

LtCOL. WOODWARD: I don't remember the exact wording, but are there other exposures that you (inaudible words).

LtC. JONES: And I might just mention, in the past the questions have mostly been more open-ended, and this is providing I guess some more

specific questions to supplement that.

LtCOL. PETRUCELLI: The four pages is really the full -- essentially old 2 pages plus 2. So, like you just said, the open-ended part is still there. It's a two-edged sword when you ask about exposure, this got a lot of attention among the services because if you answer that -- as was alluded to this morning -- you ask about substances that were used because we're trying to protect them, like Deet, you also don't want to embed in their minds that there's a problem with these, so it's one of these -- it can be argued either way.

Another comment I want to make is in response to the question about injuries. If you add up all the medical categories, they are about the same -- all the types of injuries, all the types of medical, they are about the same. If you break down the injuries, particularly in places like Bosnia where there is almost a fixed facility type of environment now, you have almost a garrison type environment, a lot of work going on, but there's no hard floors, they fall and they hurt themselves, and a lot of those hard floor injuries,

create injuries, and those are training related injuries, not necessarily accident type injuries or clumsy things get in the way, but just day-to-day stuff that you'll see if you follow the same type in garrisons.

DR. GRAY: In anticipation of a multi-symptom condition arising from this latest deployment, do you think you might be able to share some of those post-deployment data with us at the next meeting?

LtC. JONES: Sir, we certainly can look into what we're able to share. I know we had a classified environment for the earlier presentations at the beginning of this week, so we certainly will talk to the folks from AFIOH and see what we can put together that would be appropriate.

COL. DeFRAITES: The actual data from the post-deployment questionnaire?

DR. GRAY: Yes.

COL. DeFRAITES: As they come in, so far haven't had that many 4-page forms come in yet. (Inaudible words.)

DR. GRAY: I think those data will be

very interesting.

DR. CAMPBELL: Can you talk about the detail of the operational surveillance you did, what kinds of data you got on exposures, occupational environmental exposures?

LtC. JONES: Yes, sir. A lot of the data -- the last time I asked for it, a lot of the data was still being sent back to the Center for Health Promotion and Preventive Medicine for assessment. They are going to do a report on that, but I don't believe that the report has been prepared at this point. They haven't finished preparing the report. So that would deal with not only the Iraqi oilwell fires, but other exposures in terms of the air monitoring and water and soil data that was used. From my recollection, there was nothing particularly unusual that had been seen in the early samples that had been brought back. Obviously, there's a lot of particulate matter with regard to just the dust that's in that theater. You're going to have, of course, a high ambient rate of dust there as well. But they did do a number of things with regard to water, soil and

air. I can't really give you a good breakdown of that yet because a lot of the data is still being summarized in reports.

DR. POLAND: Do you have some way of linking individual exposures to environmental exposures, track units or individuals to see what they were actually exposed to?

LtC. JONES: Yes, sir. They are using a geographic information system now to track the unit as the units move. We still aren't at the point yet where we can track individual personnel, all their movements, because our personnel system thus far does not support that kind of capability. That's certainly what we believe in the medical community that we need, to be able to track individual movement. So, yes, we'll have all -- the environmental data is put in one database, a GEIS system where you can see what the exposures are at various locations. To the extent that we have units, where their locations were, we have that in there. The problem is at this point if you were to ask about a particular individual and where they were at a particular time and what they might

have been exposed to, unfortunately, at this point our personnel system still doesn't support that, but we keep trying to work that issue with the personnel side of things.

DR. POLAND: This is something that we've asked for and wanted for years, so I commend you on the implementation of it. My question that relates actually to Gulf War 1 and future deployments if on this 2796 Form. Are there questions specifically about vaccines, or open-ended questions that relate to that? If so, can you kind tell me what the character of those questions is?

LtC. JONES: There are certainly questions with regard not only to vaccines, but with regard to other medical countermeasures like PB and other things that folks might take. So, yes, there are specific questions. It's more "Did you receive such-and-such vaccination?" It's sort of a yes or no kind of an answer format. And, again, there is some room for some open-ended questions as well, so if you want to fill in other things as well, you could do that.

But I think there's been an attempt to -- I mean, I don't know that you could come up with a totally comprehensive list, but I think with regard to the things that were most likely for people to use as medications in terms of medical countermeasures, those are on the list.

DR. POLAND: Including IND vaccines?

LtC. JONES: They probably do not list every product, sir, but -- you all may be able to help me, is BotTox on there, for instance, specifically?

CAPT. SCHOR: I carry this around in my hip pocket, it's such a near and dear thing. Question 4 asks the vaccination of smallpox, anthrax, botulism and says "Did you receive: typhoid, meningococcal, other blank? No, No, None". Of course, many times they respond and they say no, they didn't, they could probably be courtmartialled for failure to report (inaudible).

LtCOL. GIBSON: I would add that the IND process will identify those folks who (inaudible words).

MS. EMBREY: Just to re-emphasize that

this new form is not a self-assessment form, it is a form that an individual fills out and then sits down with a provider and goes over those, how they answered those questions, and then there is a dialogue between the provider and the individual, for the provider to make a determination on what issues this individual needs further followup. So this isn't a complete change from the previous form.

LtC. JONES: Also, we sought to document the medical records, and we have service reporting systems for vaccinations and things like that by individual, so there is still that piece of it behind it.

DR. OSTROFF: Dana.

COL. BRADSHAW: I wasn't with the Preventive Medicine Officers, I guess, when they were commenting on the form, but I was just wondering if we eliminate what's behind the self-reported vaccination and how any discrepancies are going to be handled between that and what's actually in immunization registries because there's two ways to gather this supposed exposure

information, and there has been some additional literature -- obviously, the difference in what's report -- (inaudible) from the U.K. just recently had a letter to the (inaudible) that talked about the lack of validity of self-reported immunizations (inaudible).

MS. EMBREY: I think that the fact that this is a provider (inaudible) the individual provider should have the medical record on each individual deployment record, and he will have access to the immunization records on that individual. And if the individual reports that he has received a vaccination or some kind of medication that's not in his records, then that is something that that provider is going to have to resolve, that he did and he didn't record it, that can be corrected at the time.

DR. OSTROFF: Col. Gibson.

LtCOL. GIBSON: I just wanted to say there are also reports about the validity of self-reporting environmental exposures, and to a great degree these questions help (inaudible words). This identifies those other issues that we need to

focus on (inaudible).

DR. OSTROFF: Other comments or questions?

(No response.)

I'd like to really congratulate (inaudible) for tremendous amount of work to address many of the concerns and issues that we've had with (inaudible words), and the assessments. So I think you're to be congratulated for all the (inaudible) been able to accomplish. I will say I'm a little I'll use the term "dismayed". Over the years these issues that are being talked about are issues that the Board has spent an inordinate amount of time addressing, unfortunately, usually after-the-fact, and I think when you hear some of the questions from us about the way questions are being asked on the form, et cetera, is probably a little bit as a result of not having an opportunity to review some of those materials (inaudible words). I mean, we are an official advisory board, and I'd like to at least put in a plug that we're always here and available to be able to assist you as you work on validating these types of

instruments, although very often after-the-fact, we'll come back to you a year or two later and say we wish you had asked this particular question and we would have given this particular guidance. So I'm just going to put my little dig in that from our perspective this is what we're here for, and you're always free to call upon us to participate in the process (inaudible words). So that's my little (inaudible), I had to get one in at least.

Col. DeFraites.

COL. DeFRAITES: Thank you. I'm Col. DeFraites. I'll be giving the Army report. What I'm going to focus o this time is exactly this medical screening requirements for re-deploying soldiers, so I appreciate LtCol. Jones basically stealing my thunder, and we can skip directly to slide -- well, let's just go through them quickly. First slide, please.

(Slide)

This shows you -- and you've got this in your folder so I don't need to read all of these, but basically this is a lineup of all the guidance that's out there providing policy guidance

for the Army in executing re-deployment medical screening, and at the bottom is this memorandum that he's mentioning, that Dr. Chu, the Under Secretary of Defense for Personnel Readiness, signed a month ago on the enhanced post-deployment health assessments that I'll be talking about. Next slide, please.

(Slide)

Here is the goals of the program for the Army and, again, these are all laudable goals. Down at the bottom I think is where we really get to where we hope in terms of what's called a center of gravity, is trust and confidence of those who we are responsible for taking care of, that we can earn through these other efforts -- not only take care of them, but also get their trust and confidence. Next slide, please.

(Slide)

I'm going to use the next slide to kind of illustrate these. These are sort of the way the Army has posed to try to conduct this redeployment screening, and it might be a little bit better just to go to the next slide.

(Slide)

What we're planning to do right now, as of today, is to try to initiate this process of redeployment screening. Now, again, this applies to those soldiers who are forward deployed in the CENTCOM theater that are going to be redeploying, is to right now get some type of medical threat briefing before the soldier completes the DD Form 2796. Because of the expanded form and the time that it takes, really we are going to be limited in providing a lot of the face-to-face encounter in-theater, so a lot of the face-to-face encounter is going to occur after the soldier redeploys and gets back, for the Active Component back to their home station, for the Reserve Component to the station, their mobilization station where they'll be demobilized -- not their home station, but their mobilization station. And this will be where there is this visit to the provider, will use the DD Form 2796, goes over the soldier's concerns and also, most importantly, starts the trail of what type of referrals might be needed. Also, at that time, a tuberculosis skin test will be placed and a blood

specimen will be drawn, a post-deployment blood specimen. We're using the HIV mechanism, the contracting mechanism through which we get HIV blood in order to get a good chain of custody on these specimens, with the labeling and the data entry, so that we can associate this particular specimen on this date with a particular soldier, with confidence.

Then I have here what the next step is what's called the clinical practice guideline, which is the -- some of you I guess will be familiar with the deployment health clinical practice guideline, which is initiated to a large degree by what is considered to be one of the vital signs now -- do you have a health problem that you think is related to your deployment -- and what i have divided up here is the Reserve Component soldiers versus the Active Component. This referral for active duty of Tricare Direct Care system will absorb these referrals. For the Reserve Component, if need be, the service member, the Reserve Component service member is retained on active duty -- that's what ADME is, active duty

medical extension -- if he has unresolved medical problems that require additional care, he stays on active duty.

After he is released from active duty -- and in this 90 days, we have a followup skin test 90 days later, TB skin test -- there's a program certainly for National Guardsmen, Feds Heal, which is part of -- they can provide immunizations and they can do TB skin tests. So after the solder reverts from active duty, then any followup, including followup skin test, will be performed through that mechanism.

(Slide)

In terms of the issues that we have and some of the things we're working on right now, of course, as I mentioned, we have intense congressional, OSD and Army command interest in full compliance as best we can. And as Dave mentioned, having new requirements laid on while we're in the midst of planning complicates things a bit. However, we are working with the in-theater elements to try to accomplish a smooth and 100 percent accountability for soldiers coming out of

theater.

We also have -- we have been working quite a while on an automated pre- and post-deployment questionnaire. We had just done the two-page 2796 when we have a four-page, and so that's delayed this somewhat. Now, according to my calendar, 19 May was two days ago, we still don't have -- I have not seen that new expanded form in the automated format yet, that I've been able to navigate. So I think we're maybe a couple of days behind there. The idea here is that what this allows -- and, again, it addresses the requirement that this form not only is filled out by the soldier, reviewed in a face-to-face encounter with a health care provider, kept in his medical record, but there's also a copy -- the data from that form need to be transmitted to our central database as part of the defense medical surveillance system maintained by Army Medical Surveillance Activity. So right now, with a paper copy, you need to make a copy of this thing and mail it in after -- and I can present data next time, if you like, on how we're doing with the pre-deployment forms. The

post-deployment -- and we thought the automation would at least allow the transmission of digital information from a form that's filled out online or on an automated way, we could at least eliminate the need to do xeroxing and mailing, but we don't have that capability just yet.

And then, finally, the final part of this was to allow health care providers to have "read only" access to automated forms 2796 through Tricare Online, through this Internet base -- and it's role-based accessed, so health care providers only -- so type in a soldier's Social Security Number and have access to all of their pre- and post-deployment questionnaires that they've ever filled out. Right now, we've got -- they just cut the cake at the Army Medical Surveillance Activity last week, that they processed their 1 millionth pre- or post-deployment form, so we have over 1 million forms that are in this database that are available for review. Right now, even with the paper forms, the process is the image of the form when it's mailed in gets scanned, so the Pdf version image of the form is available for review

in an automated way. You can call it up. Then the data form the form are also hand-entered, and that's where the holdup is going to be for this additional two pages with a lot more data on it, lot more data entries. Data entry is going to be held up. That's why it's even more important this automated system needs to come online. But for the first time, even if the soldier has no form in his medical record for whatever reason, the health care provider can still get access to those particular forms. If they've been completed and mailed in, at least he'll be able to call those up and see them.

The only other thing I wanted to touch briefly on -- I know we've mentioned it several times -- has been the malaria cluster that's occurring in Army Rangers. Army Rangers is a regiment of Rangers that are stationed at three posts around the United States, one battalion at each post, and the Headquarters of the regiment are at Fort Benning, Georgia. We have reports of a cluster of 10 cases among Rangers since late April. All cases of malaria have been vivax malaria. Talking to the Regimental Surgeon, they have a

total of 23 cases that they've accumulated since roughly last fall. All the soldiers that have had malaria can be traced to a deployment to Afghanistan or Pakistan in the fall time frame. Interestingly enough, and the thing that sort of distracted us for a bit, was that a subset of that group also went to the Iraqi Freedom Operation. I'm not exactly sure where all they deployed during that time. However, these cases, the 10 recent cases occurred shortly after they finished. They were on doxycycline prophylaxis for Iraq, and then just stopped it abruptly because they didn't think they had any malaria exposure.

So it suggest to us that there may have been some exposure, but then they make the case that all of these soldiers were at a place where other soldiers who didn't go to Iraq have come down with malaria, and so they feel it's all related to this earlier deployment. Again, it speaks to compliance because they feel that each of those cases has specific compliance issues, especially with primaquine terminal prophylaxis.

That's all we have at least on that,

unless there are specific questions.

DR. OSTROFF: Thanks. Let me open it up to questions or comments from the group.

LtCOL. GIBSON: I'd like to add on this issue of the clinical practice guideline, the issue of Guard and Reserve personnel, that when they come off of active duty, if they've served in a combat environment, they are authorized two years of VA health care without having to prove service connectivity. So they basically can get medical care for a two-year period. The VA is also using the same clinical practice of post-deployment clinical practice guideline.

MS. EMBREY: I think from a policy perspective there are some other changes that weren't highlighted that I think are important for you to know. One is that there is a re-emphasis (inaudible) on making sure that these forms enter the institution permanent record on that individual as opposed to the individual hand-carried record. So that the DMSS data collection as a central point is not the institution's individual data record on the individual, that that individual's medical

record maintain's this data as well.

Secondly, I think it's also important to know that this new policy required the services to develop an implementation plan to identify specifically how they would execute quality assurance on the program which is a requirement as well. (Inaudible words) which means it probably will not be as successful for future redeployments, but I think everybody in the services especially are (inaudible) and trying to do the best they can, but this could change at the (inaudible).

DR. OSTROFF: Thanks. Now that I've had a chance to take a look at the form, there are a lot of certainly interesting and potentially problematic questions on this form, and I'm wondering how geared up the services are in terms of handling what some of the responses may be to some of these questions. I mean, a lot of people said yes to some of these very sensitive clinical health questions, I mean, at least they would have to be in the system to be able to address those concerns. This doesn't mean that 50,000 people actually (inaudible words).

COL. DeFRAITES: The consensus in the Army at least in the behavioral health community felt that these questions fell within the scope of a provider which could handle at least the initial (inaudible words). That is not to say that 50,000 (inaudible words). They felt from previous experience with similar type questions that there was a reasonable expectation that for the most part (inaudible words).

DR. OSTROFF: I'll just point out that some of these questions (inaudible) psychiatric intervention and hopefully there won't be a lot of --

COL. DeFRAITES: I think that was their plan actually because (inaudible) --

(Technical malfunctions prevented adequate recording of discussion.)

LtCOL. WOODWARD: The Air Force, in our preparation, that very potentiality is that we have the knowledge and we have folded up in our (inaudible) of what the impact would be on this, that this will be obviously a priority of care for our redeploying personnel doesn't push other care

into the civilian network. In other words, we would (inaudible words).

(Technical malfunctions prevented adequate recording of discussion.)

CAPT. SCHOR: I would just say that like Col. Woodward said, the Marine Corps realizes that many of the Marine Corps bases there's not much in the way of medical support is with them, so they did improve the combat stress and all that sort of stuff, combat stress and deployment stress are equal opportunity threat. The medical folks (inaudible words), so they're doing screening.

(Technical malfunctions prevented adequate recording of discussion.)

MS. EMBREY: I would just comment that if you don't know you have a problem with limited resources until (inaudible), and if you don't know, you don't know. So I think that we're all going to be learning from experience. I think that, again, this post-deployment assessment (inaudible words) and we do have specialists in the Reserves that we could call upon if we need it, and that we have other specialists that we can refer to (inaudible

words), but it's a matter of resourcing. And I think that (inaudible words).

DR. GRAY: Let's be optimistic and say that the data that you summarize is very favorable in the sense that there are not a lot of evidence or morbidity. As Roger suggested, it would be very strategic to get that information out to the public as quickly as possible that is the case.

DR. OSTROFF: Other comments? Dana.

COL. BRADSHAW: Just as we looked at deployment questionnaires in the past, we did have a much more generic short kind of mental health screening, and there were deferrals from every deployment. And when we've looked at those in the past, most of them -- it was over 90 percent -- got followup. Most of them were in the primary care clinics, and there were secondary referrals to the specialist. In the mental health arena it's about at the same rate that they normally get referrals from primary care clinics (inaudible). We have that data. It may be more from this, with more violent combat and so on.

COL. GARDNER: Just two quick points.

One is you have to recognize the setting that these are being filled out, and they are people who are on their way home after being gone a long time, and anything that they admit to at that point may result in delaying their getting home to their families. And so unless they've had serious problems, they're probably not going to be picked up at this point in our process. They'll be picked up later on through our clinical practice guideline process.

And, secondly, the intent is not to go from this screening directly to a specialist unless there is a really severe problem because the mental health community is very sensitive to the issue of mental health referrals affecting your security clearance and your deployability and so on. So the intent is that these referrals be handled in almost every case at least first by their primary care system.

DR. OSTROFF: Thanks. As you can tell by the fact that the (inaudible words) we'll save the last Preventive Medicine updates until after the ceremony is finished.

Col. Riddle, are we ready to get started?

COL. RIDDLE: Yes. I'm pleased to introduce The Honorable William Winkenwerder, Jr., M.D., Assistant Secretary of Defense for Health Affairs, who will present the Secretary of Defense Medal for Outstanding Public Service to members of the Armed Forces Epidemiological Board.

Other distinguished visitors in attendance for today's presentation are Ms. Ellen Embrey, Assistant Secretary of Defense for Health Affairs; MG Lester Martinez-Lopez, Commanding General, Medical Materiel and Research Command; RADM Robert Hufstader, the Medical Officer of the Marine Corps; Col. James A. Poland, U.S. Marine Corps, Retired; Katelyn Marie Sheeley; Karen Poland Sheeley; Kim Lea Holden; Jean Marie Poland, and Alex Runyan. Please be seated. Dr. Winkenwerder.

DR. WINKENWERDER: Great, Col. Riddle, thank you. Thanks to all of you for being here. I'm delighted to be here today. Boy, this is a big group. I hope you are having a good meeting. And this is a nice time for us to come together and to

celebrate something that represents our appreciation for the great work that you've been doing, certainly for your entire history, but more particularly within the last year or two.

I need not tell you, though, my prepared remarks tell me that I should say this, I probably don't need to tell you about the history of AFEB, but I will just say a word or two about it. Conceived at the beginning of World War II, established formally by what was then the Secretary of War -- not the Secretary of Defense -- January 11, 1941. And under its initial charter, the AFEB advised the Surgeons General and the Department of War, but also conducted and directed specific research programs through AFEB commissions. And the history of this institution, of this august body, is filled with some of the leading names in the United States history of public health, people like Kenneth Maxie, Dr. John Enders, Albert Sabin, Theodore Woodward, Abram Beninson, Dr. Richard Shope, father of Robert Shope, a current Board member -- where is Bob Shope? You sure know the history, I should not be saying anything to you.

Dr. Gustav Damon, Anna Betcher, and Scott Halstead, just to name a few.

So today we are here to recognize the current members of the AFEB in the following way. The Secretary of Defense Medal for Outstanding Public Service is the second highest award by the Secretary of Defense to private citizens whose superior accomplishments and contributions to DOD merit that special recognition.

During the period of January 1, 2002 through December 31, 2002, that two-year period, the AFEB was asked to consider and make recommendations on 31 emergent and complex health policy issues. This is more than double the number of issues from the previous two-year period and significantly greater than any other two-year period in the history of the Board. I knew you were working hard, but I didn't know you were working that hard. But that is really truly impressive.

I need not tell you, but your work is done without compensation. It is done in a way that requires a considerable amount of time,

roughly 30-person days of work per year, 240 hours of consultant time per recommendation, and a cost if you were to add all this up of many millions of dollars, and so that is truly outstanding work.

The accomplishments of AFEB are realized through the selfless dedication of each of you, motivated -- it could only be without getting compensated for all this time and work that you put into it -- by your patriotism, your good citizenship, and your sense of public responsibility to the health and welfare of our service members, and for that I am deeply appreciative.

You operate under intense media scrutiny, congressional scrutiny, and so it's a unique set of requirements. You understand the unique requirements of the military and the things that we do and ways that frankly just very few others, if any, really understand that, and so that is very, very important.

The distinctive accomplishments of the current AFEB members and their volunteer service to our nation and commitment to the health of the

military service members are appropriately recognized at this time with the award of the Secretary of Defense Medal for Outstanding Public Service. The members of the AFEB bestow great credibility upon our military medical programs, and they do so by preserving their independence. Our successes in military medicine are greatly supported through the individual personal and professional integrity of AFEB members, and I'm honored to preside over today's ceremony.

And with that, Col. Riddle, if I could ask you to provide the orders.

COL. RIDDLE: Please stand.

Attention to Orders: Citation to accompany the Secretary of Defense Medal for Outstanding Public Service to members of the Armed Forces Epidemiological Board for exceptionally outstanding public service, Office of the Assistant Secretary of Defense for Health Affairs from January 2001 to December 2002.

The AFEB's understanding of the unique military environment and requirements, as well as the needs of the Soldier, Sailor, Marine, and

Airman resulted in strong and effective medical research in preventive medicine programs for individuals who served in the Armed Forces. The ability to seek timely independent scientific advice from a committee of experts has been and will continue to be critical to the Department's ability to meet its obligation to safeguard and conserve the health of military members worldwide. The many accomplishments of the AFEB are realized through each member's selfless dedication, unparalleled patriotism, and shared sense of public responsibility for the health, welfare and readiness of the men and women of the United States Armed Forces.

For these and many other contributions, I take great pleasure in presenting members of the AFEB the Secretary of Defense Medal for Outstanding Public Service. Signed, Donald H. Rumsfeld, Secretary of Defense.

Please be seated.

DR. WINKENWERDER: Ellen Embry, would you please join me. Ellen is the Designated Federal Official for the Board.

Dr. Steve Ostroff. Steve will join us in accepting the award. Steve is the current President, and obviously is a person of great skill and experience, and just knowledge and appreciation both for public health and the unique needs of the military, and I've really enjoyed working together with you, Steve, this time during your tenure.

(Whereupon, the awards were presented to Dr. Ostroff.)

(Applause.)

COL. RIDDLE: When I call your name, please come to the stage for pinning of the medal, and please remain on the stage for a group photograph.

Dr. Linda Alexander.

(Whereupon, the medal was presented to Dr. Alexander.)

(Applause.)

Dr. David Atkins.

(Whereupon, the medal was presented to Dr. Atkins.)

(Applause.)

Dr. Douglas Campbell.

(Whereupon, the medal was presented to Dr. Campbell.)

(Applause.)

Dr. Jacqueline Cattani.

(Whereupon, the medal was presented to Dr. Cattani.)

(Applause.)

Dr. Barnett Cline.

(Whereupon, the medal was presented to Dr. Cline.)

(Applause.)

Dr. Jean Forester.

(Whereupon, the medal was presented to Dr. Forester.)

(Applause.)

Dr. Gregory Gray.

(Whereupon, the medal was presented to Dr. Gray.)

(Applause.)

Dr. Julian Haywood.

(Whereupon, the medal was presented to Dr. Haywood.)

(Applause.)

Dr. John Herbold.

(Whereupon, the medal was presented to Dr. Herbold..)

(Applause.)

Dr. Grace LeMasters.

(Whereupon, the medal was presented to Dr. LeMasters..)

(Applause.)

Dr. Leon Malmud.

(Whereupon, the medal was presented to Dr. Malmud.)

(Applause.)

Dr. Kevin Patrick.

(Whereupon, the medal was presented to Dr. Patrick.)

(Applause.)

Dr. Gregory Poland.

(Whereupon, the medal was presented to Dr. Poland..)

(Applause.)

Dr. Carol Runyan.

(Whereupon, the medal was presented to Dr. Runyan.)

(Applause.)

Dr. Dennis Shanahan.

(Whereupon, the medal was presented to Dr. Shanahan.)

(Applause.)

Dr. Robert Shope.

(Whereupon, the medal was presented to Dr. Shope.)

(Applause.)

Unable to attend this afternoon but also receiving the Secretary of Defense Medal for Outstanding Public Service are Dr. William Berg, Dr. John Glen Morris, Dr. Elizabeth Barrett Conner, Dr. William Moore, Dr. Philip Landrigan, Dr. Pierce Gardner.

Please join us in congratulating the members of the Board.

(Applause.)

We're going to take some group photos, and then please join us outside for refreshments.

(Whereupon, a short recess was taken.)

DR. OSTROFF: Capt. Yund, the Board would absolutely love to thank you for all the

great assistance and support we've had from the Preventive Medicine Liaison from the Navy. We will definitely miss you, and we're looking forward to your last update.

CAPT. YUND: Okay, great. Thanks. And I don't see any reason why we can't have one of these in Sicily.

DR. OSTROFF: I'll second that motion. Just tell us when.

(Laughter.)

CAPT. YUND: I've been asked to talk a little bit about individual medical readiness. I think that you heard a little bit about individual medical readiness at the last meeting, but things have moved forward a bit and I want to give you an update.

I have been working on a working group that Ms. Embrey organized under her Force Health Protection Council. All services have had representatives on this working group, and I'll brag a little bit that we actually came to not just consensus, but unanimous consensus on what we wanted to do, what we thought was a good thing to

do as far as individual medical readiness, and I'll just tell yo a little bit about what all that is.

(Slide)

First of all, medical readiness is medical readiness to deploy, but I want to make a distinction here between medical readiness to deploy and deployability. Deployability is more a decision that's made by the line warfighter, am I going to take this person on deployment or not. That's not our bailiwick, but certainly it is our bailiwick to make a determination about whether someone is medically ready to deploy.

Whatever scheme you use for individual medical readiness, it has to be based on certain criteria, and I'll share those with you in a bit. There's been a lot of visibility on individual medical readiness to very high levels in DOD, and it's an item on the military health care system balanced scorecard, so it's reported out at a fairly -- well, it will be reported out at a fairly high level when we get all of it organized.

(Slide)

So, who really needs this information

about whether people are individually medically ready, and the answer is really people at all different levels within DOD, within the services. Certainly, this kind of information is going to be useful to the front line warfighter so that he knows how medically ready his folks are to head off into the hinterlands and do good work. Headquarters at a number of different levels, including service headquarters and also DOD, OSD -- this is an item that Mr. Rumsfeld asks questions about regularly. So that adds a little bit of additional motivation for us.

(Slide)

This is jut a quick list of the six what we determined were the most essential elements of individual medical readiness. I'm not going to read them down here because I have a slide on each one of them, and we'll just move into those slides.

(Slide)

First is the periodic health assessment. We talked quite a bit about that yesterday. This criterion or category is something that obviously the services have, for now anyway,

different policies and procedures about. For the Navy active component, it looks like we'll be reporting on the active duty periodic physical exam, which is every five years or every two years or every one year, depending on your age, and we'll also be reporting on the preventive health assessment.

(Slide)

Deployment limiting conditions, again, as specified by service policies. This is just a few examples that you can see up there. I won't elaborate on that any further.

(Slide)

Third category, dental readiness. This is kind of a shining star in our little constellation of individual medical readiness because this is something that for quite a few years now all of the services have been doing exactly the same way. The classification is the same. The definitions are the same. So this is something that was very easy to import into the IMR classification scheme.

(Slide)

Immunizations, again, to a degree, according to service policy. There are certain immunizations that are handled uniformly across the services. I have those listed there. And there are other immunizations that are not handled exactly the same way across the services. We may be moving toward more uniformity among those ones that aren't uniform right now, but there still are some significant differences among the services.

(Slide)

Again, there are some differences in what we refer to as medical readiness laboratories, things like HIV, DNA on file. Some services do G6PD and/or Sickle trait, some don't. At this point, though, it's these readiness labs will be reported according to each service's policy.

(Slide)

Individual medical equipment is the last category. Simple things such as eyeglasses, two pairs of eyeglasses -- simple, but very important. If somebody who doesn't have 20/20 vision or perhaps doesn't have anywhere near 20/20 vision heads off across the world on an important

mission and doesn't have a spare pair of glasses or doesn't have current glasses, that can clearly have -- even though it's a sort of pedestrian item, it can have an impact on that person's ability to accomplish their little piece of the mission.

(Slide)

So now the IMR classification, each individual, each person who is reported on, fits into one of these four categories -- one and only one. So a person is fully medically ready if they are current in everything, and dental Class I or II. Dental Class II allows fully medically ready. Someone is partially medically ready if they need simple things that can be acquired or taken care of in a short amount of time. Someone is not medically ready if they have a deployment limiting condition or if they are Dental Class III. And they are in this unknown or indeterminant category if their health assessment is overdue or if their records are missing, or something like that.

Now, there's the possibility that somebody could appear to fit into more than one of these, but it's a business rule of ours as far as

IMR that they are only in one category. So if someone has a missing health record -- well, that's a bad example because -- if someone has a deployment limiting condition, but other than the deployment limiting condition they simply need a couple of minor things -- immunizations, whatever -- the deployment limiting condition trumps and they end up in the not medically ready category.

(Slide)

How will this be reported? It's already being reported quarterly to Health Affairs through the balanced scorecard, and our initial metric is the percentage of personnel across the service who are fully medically ready. There are lots of ways to slice-and-dice this. You can look at the people who are in -- you could look at the percentages of people who are in all four of the categories, but this we think is the baseline most important, most significant way to look at individual medical readiness.

The services owe their implementation plans and timelines for how long it's going to take to be able to do this, to have their reporting

system online and be able to report against all six categories by the 2nd of June. The Health Affairs Policy Memorandum was signed out on the 2nd of May.

(Slide)

So how are the different services actually going to accomplish this as far as retrieving the data that will be used to calculate how many people are in the fully medically ready status. The Air Force is far and away above the rest of us with their PIMR system. The IMR is individual medical readiness, but the "P" is preventive health assessment individual medical readiness.

The Air Force has been working on this system for a number of years now, and it is currently reporting on 5 out of the 6 categories. The one that they are still working on is the individual medical equipment.

The Army's in pretty good shape, too. The Army has a system called MEDPROS, which probably is a little bit behind the Air Force as far as the number of categories that they are able to report, but MEDPROS is a system that's been

around for a while and has good capabilities for collecting the data that are needed to report individual medical readiness.

The Navy and Marine Corps have SAMS, and there is some individual medical readiness data in SAMS, but we have very little central visibility of that data at this point, and so we have a long road ahead of us to develop the capabilities that are needed to report this the way we want to in the future.

As far as Reserve Components, actually the Navy Reserve is way out in front of Navy Active Component with a system called RAMIS that is not quite as capable as PIMR, but moving along pretty well in that direction.

The Army Reserve I understand uses MEDPROS, but the Army National Guard does not for some reason. And Air Force Reserve and Air National Guard use PIMR for several of the categories, but they don't make quite as full a use of it as Active Component Air Force does.

(Slide)

I wanted to mention just a few of the

sort of stumbling block issues that we've been dealing with as we create this system, and we've been trying to move it along pretty fast. One issue that we've discussed a number of times is in any one category does a service report against its full spectrum of policy items in that category, or should we be reporting against common elements that all services have in common. For example, with immunizations, does it make sense for us to be reporting -- for all of us to be reporting those 4 or 5 immunizations that we all have an identical requirement for, or should each service be reporting those things in addition that it has additional requirements for? And as you've seen through the slides, right now the status is that we are going with service policy, but there's still some discussion about how that's going to be in the final picture.

Next issue, retrieval from existing data sources versus data entry into a new database. It would be very difficult for us to hand-enter all of this information into a new dedicated database for individual medical readiness. It's

really important for us to be able to retrieve the data from existing databases so that it minimizes the amount of labor and person-hours that are chewed up collecting this data. That's our goal, but that's also a problem because not all of the databases exist yet. Some of them exist, but don't have good connections to a central reporting site, central visibility, and that's where this timeline comes from. We need to accelerate that process and make the changes that are necessary so that we can access all this information from databases that already contain the data rather than hand-entering it from the health record into a Website or whatever.

Next issue, system immaturity and how to report in the interim. This is really another aspect of the same issue. If it's going to take the Navy six months to get to the full capability of being able to report all 6 criteria, how do we display the data in the meantime? The two reports that we've given so far, the only thing that we have central visibility on currently is dental information. We have excellent dental information,

and we can show that 95 percent of all people in the Navy and Marine Corps are Dental Class I or Class II. We don't have data for the other items. So it's a little misleading, although it's the way we've been showing the data. Our overall score is 95 percent because that's the only item we have to report, but there are 5 other categories that we are not able to report on. It's probably not fair to the Navy and Marine Corps for us to report an overall individual medical readiness of zero because we don't have visibility of the data in the 5 categories, but it's certainly an over-estimate that we are 95 percent well on individual medical readiness.

So the same working group is devising a mechanism to report what we have, but yet make it clear where there are holes and where there are data gaps.

(Slide)

And there's the e-mail if you want to come to Siganella.

(Laughter.)

DR. OSTROFF: Thanks very much, Jeff,

once again for all of your help. Let me open it up to just a couple of questions. Let me point out that we're now actually behind schedule, so we'll have to try to pick up the pace a little bit.

I just have one very quick question, which is are there measurable outcome objectives as to what performance is supposed to be? Obviously, we want 100 percent of personnel to be medically ready, but (inaudible words). I assume you have some milestones you want to try to attain.

CAPT. YUND: We need a target. If we can continue to report the percent of personnel who are fully medically ready, if that remains our metric, clearly we need something to aim for so that we sort of encourage ourselves to make progress. And I don't think that it's been identified exactly what that target or that threshold needs to be. We're never going to get to 100 percent because there are always going to be people who are on limited duty or for one of the multiple reasons are not deployable. So the compromise level of the metric I'm not aware that we've settled on, but Ms. Embrey --

MS. EMBREY: The balanced scorecard actually has targets -- I can't remember what they are off the top of my head. I think we have for the next three years different -- increasing percentages of the force in each service to be fully medically ready, and I think it starts at like 60 or 70, and I'm not sure -- I think our optimum is like 85 to 90 percent is where we're trying to go as a target.

DR. HERBOLD: The level of readiness sounds like a (inaudible) or operational readiness discussion criteria. Is there a history to why the CNO (inaudible) at the Navy level because I would think that operational commanders have some sense of the readiness of their force under their command.

CAPT. YUND: Yes, sir, operational commanders do have a good sense, and in the Marine Corps an excellent sense, of what their level of individual medical readiness is. The situation is that there are multiple homegrown systems spread around throughout the Army and Navy and Air Force and Marine Corps that do this sort of thing, and

they are not compatible with each other.

So, part of the push here was to come up with something that would allow a similar scheme of measuring similar metrics so that we could look -- so that OSD could look across all of the services at once. But I think what will happen will be that this standardized IMR metric will be the system that the individual services, of course, and the line commanders and ship skippers end up using because the data is going to be there for them to look at, and they will all be able to look at the same sort of data.

COL. DeFRAITES: This is Col. DeFraites. I think from the Army perspective, it's quite a bit different. Army readiness is based on (inaudible), and from a personnel standpoint, in general, if you've got manning persons assigned to authorization in your unit, there is this -- my perception is it's always been a presumption that you never ask the question of, "Yeah, you've got somebody in that slot, but are they medically ready to go?" And it's only now that we're starting to get into the details about there's more to

readiness than just getting the person assigned to that slot. The Army readiness reporting, I believe, has been limited just to that. It's never been Army-wide kind of individual level medical reporting that says what percent of the force is medically ready to go. I don't think the Army has ever asked that question, or if they have asked the question, they never got a good enough answer and (inaudible words).

MS. EMBREY: And to give them the credit, they've been the workhorse in developing this for us, and suggesting that I think that most importantly it is a way to inform the commanders on the demands that we are now going to put on them to assure that these (inaudible) are met, not just for forward deployment, but as a regular part of the health maintenance (inaudible words).

DR. LAUDER: I don't want to confuse the issue here, I think I understand it, but I'm trying to put it in the perspective of what the question was yesterday about (inaudible words), and all the services don't have, for example, a pre-deployment physical exam component -- for example,

the Army does their physical exam every five years (inaudible) four and a half years. The Navy is saying as part of readiness not to be a physical exam within the requirements of the Navy, and I'm trying to put the two in the same (inaudible) and come up with some sort of a consensus as to what (inaudible) says and put it in context to the original question about physical exams.

DR. OSTROFF: I guess the way that I looked at it is, for instance, the (inaudible words). I actually like this mechanism to begin the process of some uniformity because (inaudible words).

(Technical malfunctions prevented adequate recording of discussion.)

CAPT. YUND: Let me just say in response to Ms. Embrey's comment that the GPPM/PG may have been the workhorse out there in the field, but there was somebody behind the GPPM/PG with the reins and the whip to crack.

DR. OSTROFF: Jeff, thanks very much. Another individual that we'll be saying our goodbyes to, Capt. Schor is going to give us the

Marine Corps update. Ken, we'll miss you as well.

CAPT. SCHOR: Well, thank you. It's certainly good to be here. It seems like we're going to have some amphibious operations, if that was rain on the roof here.

(Slide)

I just have two main topics on my slides, but let's just hold it on this slide for just a second. There was an interest in some of the early look information on Operation Iraqi Freedom, with some great concern about putting a lot of caveats to this from my boss, Adm. Hufstader, who was here earlier for the presentation.

We have a database that is using TRACES. TRACES is the system that gives folks a ticket out-of-theater for MEDEVAC, so when they are beyond the level of care that could be provided in-theater -- be it at a field hospital, at the hospital ship, that sort of thing -- then they are entered into TRACES and they are MEDEVAC'd out-of-theater, as you know, to (inaudible) and then on to the D.C. area. This is a tool that was used by the

Commandant and the Assistant Commandant of the Marine Corps to track bodies to actually personally greet everybody that was MEDEVAC'd out-of-theater.

So we use this as a proxy for acuity. If you were sick enough to get MEDEVAC'd out-of-theater, we're hoping it was kind of significant and it couldn't have been handled in-theater. Now, we realize that there's a whole lot of issues. The policy and the strategy is to MEDEVAC out-of-theater and not to hold them in-theater like we used to, so theater evacuation policy plays a role and expectations for casualties play a role.

So our data suggests, after some cleanup from some Reserve Medical Corps officers that were helping us, that about 650-ish Marines were MEDEVAC'd out-of-theater. About two-thirds of those were for battle injuries. Approximately 25 percent were for disease, and about 100 of those were MEDEVAC'd out for non-battle injuries, whatever those may be.

Interestingly -- and some of this was already initially reported in the Washington Post for the Army. I think our general epidemiology is

going to look somewhat similar. But looking at battle casualties, battle injuries of those 400, more than 50 percent were extremities, about 30 percent were torso and head injuries, and then there's a very small collection of unknown. These is based on ICD9 level coding that was put in this TRACES system, which is essentially a ticketing system for getting you on a flight.

I find it rather interesting that approximately 21 percent of the MEDEVACs were due to illness, not injury. I don't know what that means. I don't know if that was driven by smallpox concerns -- you know, we were giving smallpox inoculations and side effects and need for evacuation. That will certainly be something that we need to look at and compare to active duty and Reserve Component. There were approximately 72,000 Marines deployed into theater. About 20,000 of them were Marine Corps Reservists. So that gives you a sense of where things are. That's about all the further I can get with that data, but we have a database -- I have a Preventive Medicine Resident coming next week, and we're going to let him chew

on this just a bit and see what we can find. But recognize that that was a proxy for severity, getting visibility on those that were not MEDEVAC'd out is going to be a major effort, and it will be a very difficult effort for us to get that whole casualty and injury pyramid.

DR. OSTROFF: Do you have any comparative information as to how that compares to previous conflicts in terms of (inaudible words)?

CAPT. SCHOR: Well, the typical teaching is that it's about 3 disease non-battle injuries at least to every battle injury, but that is whether they are MEDEVAC'd out-of-theater or not. So this may skew some of those proportions, and I don't have comparative data at this time. I don't know if anybody else has any comments.

(No response.)

Next slide, please.

(Slide)

Just an update on this sports medicine injury prevention initiative. That is basically on-target, on-track. It's about 8 months into a 27-month pilot effort. We're looking to get funding

in the budget at FY06 level because that's the only budget that we can really influence. We have been very grateful for the Commandant discretionary reserve which has been significant. It's approximately $950,000 over two years that he has contributed. He didn't have a whole lot of money to spend, and he's put a lot of that money against this effort.

We are developing the health and safety reporting module that is glued onto the personnel tracking system as recruits come in, so that wherever that recruit is, whatever platoon they're in, and when they complete training the Marine Corps knows where they are, the DIs know where they are. So this module is appended to that. It's designed not to be a medical database, that's why we call it a health and safety module, so we've been very concerned about HPPA and are trying to just collect non-medical data like what do you think hurts, or where do you think you got your injury, if it was acute. Obviously, stress fractures are not acute, and there are a lot of those. And that will be difficult to ascribe an

event or a training cycle or evolution to.

My analogy is that we're building a ladder, an information ladder. One rail of the ladder is this data system that the Marine Corps is building on an Oracle database, and it's a Web-based system. And it will be role-password protected, so not everybody can see all the stuff -- that basic level of approach. But that's one rail. And, of course, the medical data is the other rail, and at appropriate levels and with appropriate attention to HPPA regulations, we're going to have to be able to put those medical databases and those administrative databases together.

So, looking at how long a recruit stays in training, and how do we appropriately minimize that or optimize that training, get them back to training and through the pipeline quicker -- it's an industrial issue, but it costs us all a lot of money when you're dealing with 40,000 enlisted and 3,000 officers per year. So we're very excited about that, and we have some very competent folks that are making that happen despite the Marine

Corps firewall issues that many of you have had to deal with me on.

The first athletic trainer of the 6 is starting today at Quantico where we train officers, and we're building some new ground. Those are our primary prevention keystones. They're going to be out and about trying to find better ways to train, trying to keep the DIs from perhaps asking the recruits to do things that may not be appropriate. And they will be providing that athletic trainer approach to life.

And when we were out in Southern California at the School of Infantry West, and at the Weapons and Field Training Battalion up at Pendleton, our athletic directors, the commanders, the colonels out there know how to use their athletic trainers. They are anxious to have them and anxious to use them very appropriately. They are walking the talk.

We realize that the operating forces, that the warfighters are very different than the training pipeline, and we're going to do some pilots and maybe put the athletic trainers in gyms.

Navy BUMED is a key partner to this. They have SMART clinics. They bring sports medicine, and we have a continuum of care approach there, and they are a great partner with this whole effort.

Our biggest concern is our potential for success, that the demand outstrips our ability to implement the program, and how do you measure effectiveness when everybody is trying to make the system better, so multiple inputs.

(Slide)

This is somewhat of an eye chart. We're actually in Phase II right now. We're finalizing the database collection which is Phase I, or the database building, and we're fielding that. We're putting the athletic trainers in place, and then we're going to move along from there. So I won't spend anymore time on that. The timeline is not a hard and fixed timeline, but it's based on getting those capabilities and those metrics done. Next slide.

(Slide)

This is just maybe a segue for my successor. I'm been somewhat peripherally involved with this whole issue. This relates to an off-base drycleaner who was tainting the well water for base housing down in beautiful Camp Swampy -- Camp Lejeune. And you can see the timeline there. They discovered it in the '80s. They closed the wells off. Standards were put for these solvents shortly thereafter, and ATSDR has been very much involved in this issue. I guess it comes under CIRCLA. Those of you that are CIRCLA experts, I'll have to defer to your knowledge on that. But they did a public health assessment and felt that there were no adverse health effects to be expected amongst the adults. And then I believe it was ATSDR that realized that we had a unique opportunity to follow birth outcomes, and so they were concerned about the potential effects of these solvents on births at Naval Hospital Camp Lejeune, among Navy and Marine Corps dependents. And os the Navy and Marine Corps helped identify about 12,500 folks who could have been drinking that water in those housing developments, and they are limited to not all

housing developments, but just a few geographically select ones. And they've honed that down to about 150 cases of interest. These are birth defects and cancers. And they are trying to get the medical records out of St. Louis right now. And my understanding is that the comparison group is going to be the Metro Atlanta Birth Defects Database. We don't know too much about that. And the bottom line is we don't know anything about the outcomes, although they have told us that in this area of small numbers that they may note in this survey some elevated rates compared to the Atlanta Registry. They will not tell us what they are until about nine days before this is released. This will be released in the summer. If anybody is interested, I can speak off the record. I know the date, but I'm prohibited from putting that in public record as this is.

There's a lot of lawsuits that are already on file from everybody that had any adverse outcome, whether they were born there or not. This is a classic sort of Love Canal kind of scenario. There are millions of dollars of lawsuits. Some of

them will meet validity criteria, some will not. So there's a very concerted effort by the Marine Corps to bring the lawyers together, to bring the public affairs folks together, and to work on the messages and the risk communication with ATSDR. And so we're very much a partner with ATSDR. And you can see where the future is, that they are going to propose a case control study. The next slide will take care of that.

(Slide)

So this is where I think my concern has been, that perhaps AFEB may play a role in this. It turns out that it may be a little bit less than I perhaps had thought, but we think that perhaps reviewing the case control study design may be a value-added input to this study design. This has gone up through some very strange channels in terms of looking at it, and the whole issue of human use and all that has really not been done to this point, even on the current survey. So it's sort of an interesting issue that we have been trying to support the ATSDR, and I'm not quite sure we shouldn't be a more equal partner in this whole

process because we bear the burden of the tail of this with trying to explain what the current study doesn't tell you, and trying to manage the over-inflated expectations at this point that this survey that's coming out this summer will provide all the answers in the world to all the adverse birth outcomes that are going to be ascribed to it, so the causality issue comes again. And there is, of course, congressional interest in this. So that's on the horizon, and we may need to ask for an off-cycle review by the subcommittee at least of the study, to get some comment on it, and I think that my successor will be able to provide an update, an early update in September.

(Slide)

And that's about all I have to present. My successor is Cdr. Dave McMillan. He is an occupational environmental medicine physician, currently working with the submarine base down in Georgia, and I'm headed to do things over in Stability Operations with HIV/AIDS, and they did the stability parts for Gen. Gardner in Iraq, which will hopefully go to some other federal agency

before I get there. So thank you for your support and help and the camaraderie. Any questions?

(Applause.)

DR. OSTROFF: Thanks, Ken, very, very much for your service, and I know I maybe kiddingly say that we could refer to the sports medicine initiative as (inaudible), for those Board members (inaudible words), we're very much looking forward to visiting at some point (inaudible words).

CAPT. SCHOR: Less people hopefully, absolutely. Thank you.

DR. OSTROFF: Questions?

(No response.)

If not, thanks again, Ken. Good luck with the new assignment. Our next update will be from Kelly Woodward, and I don't have to say goodbye to Kelly because he'll be here at the next meeting.

LtCOL. WOODWARD: Thank you. Well, while we're getting the slides up, I would like to make two comments. First is that I very much appreciate the opportunity to attend that wonderful award ceremony this afternoon, that was truly a

moving event.

Secondly, just for the record, based on our discussion earlier this morning about malaria prevention, I wanted to make sure everybody was clear, we don't promote, endorse -- and, in fact, we do discourage -- the use of flea and tick collars for humans.

(Laughter.)

COL. DeFRAITES: Same for us.

LtCOL. WOODWARD: Yes, I believe all the services do. All kidding aside, it is interesting, we know our people have actually chosen to do that, and some legends, as Col. DeFraites described, have arisen about that, and that's a very troublesome thing.

(Slide)

What I want to do this afternoon just very briefly is talk to you about the recent past and current steps we're taking in the Air Force on a journey toward precision use of our preventive countermeasures in our various prevention programs, and I'm going to talk about some policy actions we are taken and have taken in these couple of areas.

One is regarding vaccines, some policy changes for Yellow fever vaccination and Typhoid vaccination, and then some changes we are working currently for our TB, latent tuberculosis screening program, and I do want to note that the May of 2003 recommendation, AFEB recommendations on Quantefuron (phonetic) included a recommendation that the services update the Board on changes to TB screening policy, so here you'll hear what the Air Force is preparing and planning to do.

In the Air Force, because of the way we organize and the way we deploy personnel, we have what I would consider an increasing ability to assess risk for various diseases down to the individual level and down to the very specific location and conditions in which they might be when they deploy, and an ability to easily track down to the individual level what countermeasures we recommend and whether or not they've received them.

And then, finally, and most importantly perhaps, the ability to actually execute specific countermeasures down to the individual level, even if several individuals in a unit have a mixture of

differing recommendations.

(Slide)

The first issue is regarding Yellow Fever and Typhoid vaccines. What we have in practice had in the Air Force over the last many years is a rather widespread of Yellow Fever and Typhoid vaccine on a routine basis for personnel who were in positions that would be considered mobility positions or positions that would be supporting deployments. This arose from what we had called "alert forces", and in practice rose into being, "well, everybody could deploy, therefore, everybody must be alert forces", and so in practice we have vaccinated -- and I'll show you in a couple of slides the numbers -- we been vaccinating large numbers of people with Yellow Fever vaccine and Typhoid vaccine, many of whom never left the Continental United States.

So we see an opportunity here to, again, enhance our precision in using these vaccinations, and our new policy which we have in effect right now has done, has sent out very explicit guidance to the field to dramatically

downscale the use of both Yellow Fever and Typhoid vaccine, to use either or both of those vaccines, as necessary, in people who have an immediate and substantive risk, and that really meaning who are truly about to travel to an area where there is risk, with the exception of recognizing there are very few personnel in special units who may truly not have enough time to be vaccinated ahead of time, who would be routinely vaccinated, but otherwise we are discouraging routine vaccination with Yellow Fever vaccine and Typhoid vaccine. We think this is very consistent with national recommendations and, again, we feel like we can execute this.

The benefits that we anticipate are that we will have better protection certainly because we will be vaccinating more proximate to when people deploy, and run less risk that they will be in some period of perhaps waning immunity and, of course, minimizing unnecessary vaccinations and their potential adverse events. This is consistent with some directions from combatant commands.

I know specifically CENTCOM no longer has a theater requirement for Yellow Fever vaccine. They recognize that much of their theater is not a risk area for Yellow Fever, and that they ought to be able to know that if people are going to those few parts of their theater that truly where Yellow Fever is a risk, those people can be vaccinated accordingly. They also remove their requirement for meningococcal vaccine except for people traveling to the (inaudible) which is consistent with recommendations, so there are other movements to downscale, if you will, the use of some of these vaccines and eliminate unnecessary blanket requirements.

And just, by the way, what I didn't say earlier about this issue is that in practice more than half of the Air Force, that's half of the total Active and Reserve Component, had fallen into this program of being on mobility and requiring some regular vaccinations when far fewer than that actually went to the locations of risk.

(Slide)

The second one is targeting our

tuberculosis screening program. Again, another program where we have had both a combination of policy and practice that drove a very widespread use of tuberculin skin testing to the point where even as recently as last week I heard about one of the people in the Surgeon General's office going to the clinic and he was told that he was due for a tuberculin skin test. He said why? And they said, well, because you are a health care worker. And he said, well, no, I'm not actually working in the clinic, I'm at headquarters. I am not in any situation where I would be around patients. And they said, okay, then you're required because we think you need one and we can't figure out any other reason, but it's just easier to give it to you than to discuss it. And we think we're moving beyond that.

We think we now have the ability to give people the tools to make more risk-based decisions, and to target, again, our screening for latent tuberculosis infection, and what we are in the process of working right now is a policy that eliminates the need for routine tuberculin skin

testing for our force in general except a baseline at accession, and then only test people who fall into a risk category, and we're trying to align that as close as possible with what CDC's criteria are for determining risk of exposure to tuberculosis.

We think that this will greatly improve the interpretation of the tuberculin skin test because we'll be mostly testing people at risk, not testing people who are not at risk. And, of course, it will decrease unnecessary treatment, and what we have found is that we spend a huge amount of time in our Public Health offices chasing down people who had a tuberculin skin test, who never come back to have the test read, or at least are reluctant to come back and have it read, and we think we will actually be able to focus on people who we really do need to know their status, and not spend so much time focusing on the other whatever percent it is that actually probably didn't need the test in the first place.

So we're charging this hill and, so far, from our field, the drafts we've sent out have

been very well received. Our Public Health people are very eager to implement this policy because they recognize that they can do this, and they can do the risk stratification, people at the Air Force Institute for Operational Health are going to be helping us to support the field in making that risk assessment even down to the individual level, if necessary.

(Slide)

This will give you an idea of where we see some potential for change with these three different interventions. With Yellow Fever vaccine, we have over the last three years administered about 63,000 vaccinations per year. We have had no cases of Yellow Fever in the past three years. Typhoid, about 160,00 vaccinations per year. We had two cases of Typhoid Fever in the last three years, both of those people had been vaccinated, interestingly enough.

TB screening, over 300,000 tests per year. Fairly low positivity rate. We've had seven cases in active duty of active tuberculosis, and we know for sure five of those seven cases had

identifiable exposure risk to tuberculosis.

(Slide)

So we feel like we're really able to move along and getting very precise use of these preventive countermeasures. We aren't convinced that this will be a perfect journey, but we will be watching over the coming years, of course, for the impact of these policy changes both on operations in terms of our ability to meet the needs of our deploying and traveling troops, as well as watching, of course, for changes in disease rates, fully recognizing that having no Yellow Fever cases in the last three years isn't a reason to abandon vaccination. We very much believe in the importance of Yellow Fever vaccine, but not for people who never left the Continental United States. Thank you.

DR. OSTROFF: Thanks very much. Let me open it up for any questions or comments from the Board?

COL. DeFRAITES: Col. DeFraites. Just a question. You say that you can trace down to the individual, if necessary. The Army does things in

sort of big lots (inaudible words). The risk of delaying the decision until the last minute, then all of a sudden you've got to give the service guys immunization. If anything, our tendency has been to try to go the other way, to avoid the last-minute immunization of a bunch of (inaudible words). In a way, that's just the opposite of what you're proposing. I don't know if the Air Force may be better (inaudible) deliver this service on an as-needed basis, and maybe we in the Army might be (inaudible words), and Navy and Marines, too, about (inaudible), I think it's got a lot of merit. Certainly, Yellow Fever is not without adverse effects (inaudible words). It's interesting (inaudible words), however, as I said, we've almost from an operational standpoint gone the other way and said let's see how much of this we can get done ahead of time, without waiting to the last minute (inaudible) at Polk Air Force Base giving people shots (inaudible).

LtCOL. WOODWARD: And just to address that, why we think this is executable, if you will, in the Air Force is that the way the air

expeditionary force prepares to deploy is we have a period of time that is really designated as a preparation period of time before the forces who are designated to deploy are expected to go, and that is about a three-month period of time, at which point there is a series of steps in assessing where people are going, what their readiness status is, and what things they might need. And our field is feeling fairly confident that they can make in time these decisions, fully recognizing, for example, with Yellow Fever, I mean we want a good two-weeks lead time before somebody deploys to give them Yellow Fever vaccine so that they can develop immunity. But another example of where we are in the Air Force is we got calls from our component command in support of CENTCOM about TB risk, and they reminded us that the majority of Air Force people who deployed in support of current operations never left the Air Force installation where they deployed to, and had essentially no exposure to people who would have tuberculosis, and we don't want to have to chase positive tests for people who have no risk, or treat those people if

they have no risk for tuberculosis. So we're working it.

DR. OSTROFF: Thanks very much. Why don't we keep moving along. The next presentation is from the Coast Guard, Cdr. Ludwig.

CDR. LUDWIG: Good afternoon. I just want to say it's an exciting time to be the only operational Preventive Medicine Officer in the Coast Guard. There's a lot going on --

DR. OSTROFF: Possibly in homeland security.

CDR. LUDWIG: Well, I'm not sure about the, possibly. Fortunately, right now I'm able to focus just on Coast Guard, and that's enough because we are, as you know, a multi-mission service.

(Slide)

Actually, there are two things mainly that I want to talk about today. One is the impact of SARS on the Coast Guard, and the second thing will be the Coast Guard smallpox vaccination program, a little bit about it.

The Coast Guard, as I said, is a multi-

mission service, and there were a lot of questions when the issue of SARS came up, whether Coast Guard may be at increased risk because of some of the things that they do, such as boarding virtually every vessel that comes into a U.S. port, including some with people from all different parts of the country and, as you probably know, some of them with illegal immigrants from China and other such places where SARS is a great concern.

The other thing is that -- another area that the Coast Guard is concerned about was their search and rescue mission in which they will attend to any call for help off U.S. navigable waters, regardless of what the person may be sick from, and usually not knowing until they go to do the MEDEVAC or the search or the rescue, what's going on.

And, finally, as related to all this is what role the Coast Guard might have to play in quarantine of people who might be of concern. So we made a lot of contact and did a lot of talking, and I learned some things that I never knew before. One is that Federal law compels every vessel that comes into a U.S. port to call ahead if they have

passengers or crew who are suffering from certain infectious diseases or if they have a dead person aboard, and that although this is Federal law, as you can imagine, it is very, very difficult to enforce. The Coast Guard has not, at least in recent history, had any part to play in all this, but because of their concerns about SARS, we decided they needed a way to check ahead of time what vessels might be bringing in people that might have SARS.

(Slide)

So we developed a policy, and actually it's fairly simple. Before boarding or rescuing, they were to radio ahead and ask -- we had a list of questions basically that determined whether someone aboard fit the case definition for SARS, and anyone who was going to have direct contact with anyone who had suspected SARS, was to follow infectious control guidelines, including hand hygiene, N-95 masks, goggles and gloves, et cetera, that they were to put a mask if at all possible on the person who was suspected of having SARS, if they could tolerate it and, if not, hopefully they

could put on some oxygen and that would serve the same infection control process.

There were some specific concerns that had to do with the aviation community, as I said, with the search and rescue missions and any kind of MEDEVAC from a vessel, and our concern was especially with rotary wing. The CDC came out with guidelines which some of you may have read, that had to do with fixed wing aircraft -- the flow of air, positive pressure, all those kinds of things, cleaning up the aircraft afterwards -- but they didn't have anything early on that had to do with rotary aircraft. So when I asked the question, I was told we were the first ones to ask, so we got a product, and CDC is great like that, they really do respond.

The last thing that they were supposed to do -- and here's where we had sort of a new action, which was that if we learned of somebody aboard who was suspected of having SARS, we would make sure that they notified the quarantine authorities. That's new. It seems like an obvious thing, it seems simple, but it was not previously

something the Coast Guard really thought about much.

(Slide)

It did turn out that in Title 42 and 42 Code of Federal Regulations, the U.S. law gave Coast Guard enforcement authority for quarantine, but there had never been in recent history much of a need to do that, and nobody was very concerned or even very knowledgeable about what we would do in that situation. So that was discussed and, because of that, we established a coordination between the CDC Division of Quarantine and the Coast Guard, and we believe this is a new liaison and it's ongoing. There's an MOU being developed, and I think this will be a happy combination of expertise.

(Slide)

I want to start with my last slide. When I talk about the smallpox program -- I actually had several slides that I could have put in here, but I wanted to keep it to one page, so I picked out this one which shows a week-by-week depiction of the percentage of people screened for smallpox vaccination who were exempted for one

reason or another. And I show it because I think it shows a remarkable evenness or straight line in terms of what percentage were exempted. It does turn out to be a greater percentage in the Coast Guard than what's seen in the other services, and I believe the reason for that is because, first of all, a higher percentage of Coast Guard than of other services is eligible or being considered for vaccination. They are also not deploying out of CONUS right away. So, in the other services where they might be getting the vaccination as they board, that's not so for the Coast Guard. And so the close contacts at home have much more of an impact on our exemption level.

(Slide)

And, lastly, my second to last slide, I want to just bring up the topic again of adverse events. I have about 50 -- actually, I had exactly 50 reports of adverse events associated with smallpox vaccination. Most of them I actually have VAERS for, which is pretty impressive, I think.

The number we have vaccinated looks awfully small compared to the other services, but

it is a large percentage of our Active duty and Reserve personnel. We have had, as you learned yesterday, more than our share of pericarditis, or suspected pericarditis in the Coast Guard than in the other services. I have records of 17, I'm certain that they're not all confirmed cases, but they are all at least suspected cases of pericarditis. And why is this that we have more than our fair share? We touched on this yesterday. I just want to emphasize again, about one-third of Coast Guard patient visits occur at civilian facilities. Civilians, I believe, in discussion with a lot of people, civilian providers are much more aggressive in their approach to chest pain than are most military providers who see a lot of chest pain due to costochondritis or other sort of non-cardiac causes for chest pain. So, as was mentioned, some of these people had to go back two or three times to actually then be worked up for pericarditis. That was not so in the civilian community. I believe they treat every serious chest pain as a possible cardiac event. It obviously varies by provider, but I think much more

so in the civilian community.

Finally, we did have a cluster of pericarditis, suspected pericarditis in Clearwater, Florida. There were 6 of our 17 are in Clearwater, although they are mostly in different units in Clearwater. We also have a couple of other sites that have at least two cases, and I suspect, without looking into it further which I will do, but I suspect that these are areas where a lot more of the care is provided by civilians as opposed to military. That's all I have for today.

DR. OSTROFF: Thank you very much. Are there questions from the group?

(No response.)

I have one quick one. In terms of your smallpox complications, do you know if the number of pericarditis cases is similar to what's been reported in the other services?

CDR. LUDWIG: In terms of symptoms?

DR. OSTROFF: No, in terms of laboratory findings. I'm wondering whether (inaudible words).

CDR. LUDWIG: No, I believe that they

are the same kinds of lab findings, complaints and so on.

DR. OSTROFF: Thanks. Col. White.

COL. WHITE: Good afternoon. I should point out, start off with, I'm not the official representative from the U.K., that's Col. Mike Staunton, who couldn't be here today. I arrived in the U.S. November of last year, and just to confuse matters slightly further, I replaced David Brown. My previous assignment was Program Manager for the Advanced Development and Acquisition of Medical Countermeasures, so I was sort of a miniature and slightly less expensive version of Col. David Danley. And I'm really glad that I've had these cross-hairs, that Col. Clayton referred to yesterday, removed from me in this assignment.

(Slide)

There are three things I'd like to share with you today, which are just really my choice. Col. Riddle agreed that they might interest you, I hope they do.

(Slide)

First thing is our strategic plan, if

you like, for preventing or managing post-war syndromes. This was initiated as a result of a paper provided in December by Professor Simon Wesley, who is a civilian advisor to the Minister of Defense, and will be well known to you probably as an author of papers on Gulf War illnesses.

Professor Wesley recognized that unexplained medical symptoms have been an inevitable sequel to previous conflicts, and will continue to be so. And he also asked the rhetorical question, can we prevent another Gulf War Syndrome, and answer his own question, no. So perhaps this slide should really be entitled "Managing Post-Conflict Syndromes".

I don't really intend to go through each of these measures and report on how the MOD is progressing, save to say that these matters are all in-hand, if you like, for the current operation, but I will pick up on one or two of the topics as we go through them. This is not a 10-point plan, unfortunately, it's an 11-point plan.

As far as the baseline data, I've got a slide coming up to discuss that a bit further.

(Slide)

Something that has been mentioned earlier today, operational location tracking. We have a sort of high degree of tracking available to us now as far as troops going in and out of the operational theater in Iraq, and a slightly less well developed ability to track them within theater, but hopefully that's improving.

(Slide)

My second agenda item, if you like, deals with research. I won't talk about that just now, and just talk about blood sampling for a minute. Thank you for suggesting this wonderful idea which got to the ears of our politicians, and they said wouldn't that be a good idea to do this thing, and after a bit of negotiation we have persuaded them that we won't be taking blood samples after this operation.

(Slide)

On to this item of post-conflict health research, Op Telic -- not to confuse you, that's what we call Operation Iraqi Freedom, and don't ask me to explain what Op Telic is all about, but it is

Greek, I can tell you that. It's Greek to me.

Just to deal first of all with things that we've got ongoing before we deal with the actual post-conflict health research, this study here has actually been completed, commissioned by the Ministry of Defense, and it's available on the Web if you want to have a look at it. It's actually a very interesting study which compared systems used by a number of countries, including the U.S. And the second study which is truly ongoing at the moment aims to validate the use of pre- and post-deployment surveys, and we have collected pre-deployment data from around 1,000 personnel.

Moving on to the actual post-deployment health research -- and this was announced a couple of weeks ago in Parliament, a program of research to deal with possible physical and psychological health concerns following the operation in Iraq.

As you can see, it involves a pilot study of just a few people to get a feel for the sorts of concerns that they are going to raise, and that will be conducted as soon as people return

from their post-deployment leave. A larger sample will be surveyed once they resume their normal duties, although I'm not quite sure how we are now going to define what normal duties are, considering that this thing was written up I think when we had a different perception of what might happen in Iraq. Further work is required to determine the size and the scope of the cohort and the control, and to develop the protocol and design the questionnaire, and this is unlikely to take less than six months to actually kick off, if you like.

I just got back from that one. These two studies here and the clinical evaluation of any concerns arising, and these are being conducted by Professor Wesley's group at King's College, London.

(Slide)

The compilation of exposure data will be conducted by the Institute of Occupational Medicine in Edinburgh, and the other items will be conducted inhouse, apart from the uranium testing will be conducted within the Ministry of Defense Laboratories and using an independent laboratory.

The Medical Assessment Programme is the

equivalent of your Post-Deployment Health Center, and basically that was set up for veterans of Gulf War I, and it's going to be made available to everyone who is involved in this operation.

MS. EMBREY: I'd like to thank you for that last bullet because it's the equivalent of what we are now --

(Laughter.)

COL. WHITE: Thank you.

(Slide)

And, finally, I was hoping to be able to brief you on the findings of this important review, the MOD commissioned, but unfortunately -- it was meant to be published today, but it is now not going to be published until Thursday. So if you are interested in having a look at it, I must say it hasn't got any surprises for those that are involved in Gulf War illness research, but it may prove some disappointment for some of the veterans, I have to say. You can access that from the MRC Website, but if you go to publications/press releases, you have to drill down quite a bit to find it. I'll just give you a very quick overview

of the process and the objectives. I'm not quite sure why no one from the DOD came, I think the invitation list was entirely in the hands of the MRC and maybe they only knew about people from the VA, I don't know.

(Slide)

These are the objectives. Look at the report if you are interested, I'll leave it at that. Thank you.

DR. OSTROFF: Thank you very much. Let me ask if there are any questions?

(No response.)

I'm curious, can you speak to the quality of the uranium test?

COL. WHITE: To the quality of it?

DR. OSTROFF: (Inaudible.)

COL. WHITE: We have a thing called the Depleted Uranium Oversight Board, which has its own Website, which is a bunch of independent scientists and one or two veteran representatives, whose job really is purely to validate the laboratories being used to conduct the uranium testing. I can give you a bit more information on that later, if you

want. But, yes, we're pretty sure that we're doing a reasonable test.

DR. OSTROFF: Other questions?

(No response.)

Thank you. Our last update will be from Col. Fensom.

LtCOL. FENSOM: Good afternoon. In my never-ending quest to save you from the abominable fate of death by PowerPoint and also to help you catch up, I would seek your indulgence in making some informal comments.

The first one is probably the most important because it comes with wishes from our Surgeon General Col. Cameron, and our Director General Health Services Gen. Matu (phonetic), and that is to pass on, along with my own, of course, our very sincere condolences on your lost comrades-in-arms most recently in these operations. For myself, having been around to see soldiers from Canada and from other countries as well as yours die in some pretty awful places very far away from home, even though I may not be deeply religious, I sure believe those guys have a special place in

Heaven.

At the same time, I think from the Canadian medical group, I'd like to pass on to you as well our very sincere congratulations on this incredibly successful campaign. Aside from the stunning military success, I think that one thing that's particularly impressed Canadians and I think has resonated around the world, is the very high standard of conduct of the forces combined with evidently a great compassion for the Iraqi people has been extremely visible, and I personally believe that it's taken the winds out of the sails of many potential opponents and naysayers, and I thought you might just appreciate our very heartfelt Canadian perspective on some of those things.

As all of our Allies long-time know, we are now entering a phase in war which may be more difficult and protracted, and that being, of course, the stabilization phase. I thought I'd just update you a little bit about Canadian activities in general in that regard. We, of course, are continuing to command the International

Naval Interdiction Surveillance Force, and that will carry on. We are sending some combat engineers to Iraq specifically for water and purification expertise. And my companions and comrades north of the border are very busy these days getting ready to deploy about 2,000 troops to Afghanistan. I t's a full battle group and headquarters for a commitment of one year, which we hope will be enough to take them through their first election, and hopefully also allow some of your folks a bit of relief in that theater.

And I will now get to the actual issue of the day for Canadians on the Preventive Medicine side, and that of course being SARS. This has been a very up close and personal experience for us. In general, my impression is that we've felt pretty good about the relatively rapid containment that occurred, and also somewhat relieved, I have to say. But we also see great potential here for lessons learned, and I see a number of opportunities arising for that.

One of potential interest to this group that I've been involved in arranging in the last

week or so is a research team from the Advanced Concepts Division of DTRA came to me, and I put them in touch with the appropriate Canadian contacts in Health Canada, in the public health municipally and militarily, and they are going up to Toronto next month to conduct a bit of a lessons learned type survey, but also a more detailed research look at specific elements of risk communication and how it was done in this scenario, particularly looking at how you do differential risk communication in a multi-ethnic environment like Toronto, and how you do differential risk messaging for higher risk groups such as, in this case, health care workers and their families. And hopefully there will be some interesting findings out of that.

They also expressed a specific interest in the quarantine, how it was applied, lessons learned from that. Basically, we threw a very wide net and applied it very quickly. It was voluntary, and there was a high level of compliance with it, although we did have I believe 6 or 7 people who were put in jail for failure to comply.

The other piece of that that I think is of specific interest to DTRA is what sort of contingency planning may or may not be appropriate in terms of military response relative to enforcing quarantine as a last resort scenario. And so we look forward to collaborating with them in the study, and I'll certainly update the Board on what their findings area.

I don't think that we've begun to scratch the surface in terms of lessons learned. Some of the things I'm hearing from my colleagues is, you know, it took us a world global HIV epidemic to look at global blood precautions, universal blood precautions. Perhaps what will come out of this in terms of overall clinical practice, especially in heavy nosocomial transmission settings like the hospitals in Toronto, that we may be looking at universal respiratory precautions down the road. All of these things need to be looked at.

What's been very heartwarming, I think, for Canadians from the outset is the instant support, information sharing and collaboration that

occurred between Health Canada, Province of Ontario Health Department, and CDC, Health and Human Services, and various experts south of the border. I think that bodes well for our future ability to respond to homeland security issues of a medical bent, if you will. And conscious of that, we've also been in discussion with the North Concerge (phonetic), and are going to in fact put a Canadian Medical Staff Officer in the Command Surgeon's staff at NORTHCOM, specifically to make sure that those military medical planning responses to these kind of homeland security continental issues are coordinated right from the get-go. We're also actually this year putting in a full-time Canadian Medical Intelligence Analyst on the AFMIC staff for many of the same reasons, to make sure that we have that ongoing coordination and information sharing.

I also would like to take a quick opportunity, knowing time is short, to say goodbye to my departing colleagues. When I first was asked to come to a meeting where there was going to be a "pig" involved, I wondered if there was a particularly unsavory character I hadn't met yet.

Now I know what it stands for.

To Jeff Yund, I'd like to say I'll always remember him for his wisdom and humor, which is a great unique combination. He had this incisive ability, as we say in Saskatchewan, to separate the wheat from the chaff on just about any issue, and get it right down to what matters.

I'll never forget Ken Schor, particularly for his bloody-minded determination to look after those wonderful Marines in the very best way, and sometimes in spite of himself. And his continuing application of operational primacy in his decisionmaking, a wonderful example for all of us.

And to Ben Diniega, who is not here today, his great knowledge and experience, and I think his biggest asset which I think was his biodetector. It was an infallible biodetector for BS in any form.

(Laughter.)

If we could transfer that to biochem, we'd be all ahead. And just seeing the ceremony today, and looking and listening to all of you

folks as I have for the last few years, it made me think back to the history also, and this visit here I went to the Civil War Military Medical Museum and looked at the figure of almost 45,000 troops on the Union side alone in that conflict, who died of dysentery and diarrhea, and I know that the folks here on a day-to-day basis are struggling with problems and issues and trying to solve them, but I think it's easy to lose sight of the fact that the most important thing in force health protection is what doesn't happen. And when you look at how far force health protection has come and how great a combat multiplier it really is, thanks to I think a lot of folks in this room and the work that you do, even in the last decade we often forget the DNBI rate has been cut in half. So, I thought it just might be worthwhile reminding you of the fact that it's clear to me as an outsider that you're building on a great legacy of success. So I will leave it. If anyone has any questions, please feel free.

DR. OSTROFF: Thank you very much, Col. Fensom, for that very helpful presentation.

I have one quick question for you. I'm curious as to how the Canadian military handled the SARS incubation during the personnel movement, in particular, because one of the issues that we grappled with in terms of some of our decisionmaking was to see what was being done the (inaudible) in terms of the problems (inaudible), whether they were imposing any restrictions of individuals in Toronto. Were there any special restrictions (inaudible) for military personnel (inaudible words)?

LtCOL. FENSOM: No, there were not. We actually have a base in Toronto, not a large number of folks. We watched it obviously very closely. We imposed the same screening requirements on our military medical facilities that were recommended by Health Canada for all others. We had Col. Salisbury, who is one of our Public Health Docs in Toronto working closely with the municipal folks there. I suppose those sorts of things are things you look at in contingency planning sense. We didn't feel that we had to go that way in this particular instance, thankfully.

DR. OSTROFF: Great. Let me just say one of the reason that I think that we were able to not follow the WHO lead (inaudible words).

(Technical malfunctions prevented adequate recording of discussion.)

LtCOL. FENSOM: And I think very, very critical as a template model for things that we may have to look at continentally in terms of bio-threats in the future.

DR. OSTROFF: Thanks very much. We're down to our last presentation if hopefully the group can bear just more before we bring this session to a close. That puts pressure on Col. Neville to be (inaudible) in terms of getting through your presentation. This is a presentation about the influenza surveillance. I suppose you have a lot of slides.

(Laughter.)

COL. NEVILLE: I'll try to go through them quick. I actually added 4 slides in the middle of it that you don't have in your packets, but I'll explain that when I get to it.

(Slide)

As you've heard today, I'm from the Air Force Institute for Operational Health, which is a new name change. I say A-F-I-O-H. I've heard AFIOH, AF-I-OH. I'm going to say A-F-I-O-H. We'll see what happens as time goes by.

(Slide)

Just to recognize some of the contributors to the information I'll show today, some of this comes from the Naval Health Research Center in San Diego. Megan Ryan and Kevin Russell and Tony Hocksworth in particular. And my parent organization, 311th Human Systems Wing at Brooks City Base -- it's not an Air Force Base anymore, either, by the way. And some of my colleagues, of course, include Linda Canus (phonetic), Andrea Kroll, Joe Feig (phonetic), and Angela Owens who prepared a lot of this information.

And DOD GEIS is sort of an overseeing organization for us. Influenza Surveillance is done under the auspices of DOD GEIS. This is the exact same slide I've shown before to the AFEB, except the date at the bottom is different.

The basic Influenza Surveillance

Program in DOD hasn't changed really. There's two main components -- population-based which is managed at NHRC in San Diego, and they primarily do trainee populations of all the services. And there's another slide that will describe that in just a second.

And the etiology-based which is managed at Brooks City Base -- I should change that -- and there's another slide in a second the will show how that systematically progresses.

Also, the Army Medical Centers do clinical virology, but there's no systematic collection for surveillance purposes.

(Slide)

So the population-based surveillance at NHRC -- this little map isn't intended to be here so you can read it -- but those are the training sites that they include in their surveillance system. And they basically have research assistants, if you will, at these participating centers that collect demographic data, population data, febrile respiratory illness rates, and collect samples from selected patients or trainees

with FRIs and send those to NHRC where pathogens are identified. And any influenza that's identified, selected samples shared with CDC, as needed.

(Slide)

So, just a couple of quick slides on NHRC's data for this season. Most of it here, this blue, is adenovirus which obviously reflects the trainee -- military trainee population that they're surveying. Not a whole lot of flu. It's kind of hidden in these numbers, not a whole lot of influenza that comes out of these populations.

(Slide)

For the past almost five years, over 11,000 specimens. Pretty much the same as the earlier slide, mostly adenovirus, some negative, and not a whole lot of influenza, but there's some in there. It's very important to note that this trainee population, the U.S. military training population draws from around the nation, including some other countries, and it's a highly concentrated population and a highly immunized population because most of the year they get the

influenza immunization when they come, so this would be a very useful population perhaps to identify emerging strains. As far as I know, there's no other vaccinated population in the world that is more consistently surveyed than these trainee sites.

(Slide)

This is the influenza-specific infection rates at basic training centers for the past four or five years since '98, and it's seasonal obviously. There's an occasional case in the summer months, but mostly in the winter.

(Slide)

Sort of a little bit of a side note, this is adenovirus and total FRI, just to show you the kind of data that NHRC compiles routinely.

(Slide)

Most FRI rates are attributable to adenovirus in that setting.

There may be another slide in your packets, I can't remember. I just for curiosity superimposed those two, and it's interesting that the influenza peaks are smaller, are right when the

adenovirus is waning, for whatever reason that is. That's interesting.

(Slide)

So the etiology-based surveillance program run out of Brooks Air Force Base, guidance and direction from DOD GEIS, from AFMOA. Within AFIOH, there's Epi Services, which is a Public Health Officer, Preventive Medicine physicians, epidemiologists, and they do number-crunching and program guidance to the sentinel sites. The laboratory sends instructions and supplies to the sentinel sites. The sentinel sites send the specimens back to the lab. Data-sharing all around here. And any influenza that's isolated, selected influenza isolates, particularly those from overseas, are sent to the CDC where there's a lot of collaboration, and those can help drive vaccine decisions.

I should also add that our laboratory is a clinical reference laboratory for the Air Force, the only virology capable lab. And os we get clinical specimens from all the MTFs in the Air Force, and some other services as well. So we use

those clinical specimens, combine that in the whole influenza surveillance program, although that's not designed as surveillance.

(Slide)

So here's a map that you should have in your packets there showing the sentinel surveillance sites around the world. And the only thing that changed from last year are these little green stars here. They may be hard to see, but in March of this year we identified and stood up these four new surveillance sites at operational bases, three Air Force, one Army. We've gotten some from Saudi Arabia, Prince Sultan Air Base, which actually isn't a sentinel site, but the last I knew of, we have gotten specimens from there. Only one influenza H1, I believe, so nothing really dramatic. But this is an area of the world that the World Health Organization does not have good influenza surveillance data from. So on the World Health Organization maps,it's either white or yellow, or they say "not participating" or "no information" typically.

(Slide)

And a few slides about the results of the data from this year from Brooks. This is the total number of specimens received by week and the percent positive.

(Slide)

The portion of positive isolates from the whole surveillance program, a lot of adenovirus, that comes from Lackland and Shepherd Air Force Base, but a lot of them are influenza. A lot of positives.

(Slide)

Influenza A and B this year was a little bit different than other years in that Influenza A and B were found throughout the whole season, almost parallel.

(Slide)

This is just comparing the CDC's influenza data, so the DOD program found it a little bit earlier, which is attributable to the Pacific Rim sentinel sites.

(Slide)

These are the slides I inserted, so they are not in the little packets there, just for

curiosity. This may be a better way of presenting the data that's on the next chart that's in your packet maybe, but these are from the Asian Pacific sites, including Alaska. H3 is the yellow one, so early on in October we started getting some of those, and a fair number in November, and then December, and so on.

(Slide)

And the Americas, the CONUS sentinel sites didn't really start until December. There's on here that might have been a B, I think. And there's more Influenza B. I'll talk about this in just a moment.

(Slide)

And then the Europe and Middle Eastern sentinel sites. They get a little bit more skewed later in the year.

(Slide)

And this is just all those last three slides together. So we don't type every isolate that we get. Some of those Bs and As are untyped, but we do that -- if we get a whole bunch from one base, we don't type every single one just because

it takes a little time to do that.

(Slide)

That's the chart that I think is in your packet, just again showing that there was more Influenza A from the Pacific than from the other places, generally speaking. A little more Influenza B from CONUS and Europe.

(Slide)

Just a word about this NATO-WHO workshop that we did in St. Petersburg, Russia about two weeks ago, I guess it was. The title there "Strengthening Influenza Pandemic Preparedness Through Civil-Military Cooperation". Largely funded by NATO. Also funded partially by CDC and partially funded by DOD GEIS. My understanding is it's the first time that there was a workshop co-sponsored by NATO and World Health Organization. There were about 60 participants from 18 different countries. We tried to get at least two people from each country, a military and civilian influenza specialist. It was hosted by the Research Institute for Influenza in St. Petersburg, of the Russian Academy of Medical Sciences. They do

a heck of a lot of research in influenza there. Treatment, as well as vaccines, as well as the pathogen surveillance.

Just one quick summary, it was three days, of course, but then there's a lot of stuff we talked about, but 5 of the 15 nations present actually had an approved Pandemic plan, and the U.S. of course is not one of those.

And Russian national TV had us on their news. Most of the questions were about SARS, as it turns out,but that's okay.

(Slide)

Just a quick summary. There's a diversity of isolates, mostly from Asia and Pacific were H3N2, Americas were H1s, and B/Hong Kong was from pretty much everywhere this year. There was some variation in the hemagglutinin compared to last year's viruses, and this apparently translates into a little bit of antigenic difference from last year's circulating viruses as well, but I'm told that they have not been able to identify a strain that will grow well enough to produce vaccine, so we're sticking with the old vaccine from last year,

the same strain, but that will bear some close surveillance.

And I mentioned this thing at the bottom, in February there was a big peak in the Influenza B isolates. There was an outbreak of febrile respiratory illness in -- well, Little Creek was one of the places -- in the Tidewater area, and so that generated large volumes of respiratory specimens. And I guess it turned out to be a good thing for an exercise anyway. In our influenza surveillance plan there's a process for sharing resources among all the three services -- the Army Medical Centers, NHRC and my organization -- and we actually exercised this plan. So I don't know how many -- several hundreds, maybe a total of 300 over a few weeks -- specimens came to our lab. We shipped a bunch to NHRC, a bunch to Brook Army Medical Center there in San Antonio, and shared that workload, which is exactly what our plan called for, and there's a few lessons learned about sharing information, and some HPPA things, and that kind of stuff. So there were some lessons learned from that.

I think that's all. There are some backup slides in the handouts, but we don't need to go over those -- unless you want to.

DR. OSTROFF: Thanks very much. Let me open it up to questions or comments. We can't go a whole meeting without bringing up our eternal consternation about the adenovirus (inaudible), but since you raised it, I'd just point out that it's remarkable how effective vaccines are because obviously the influenza vaccination program in the military works quite well, and the backup adenovirus vaccination program serves the military quite (inaudible words).

CAPT. YUND: Do you type a subset of the adenos from your (inaudible) patients? Is it all 4 and 7?

COL. NEVILLE: Four and seven. NHRC does a lot more of that than we do, but we only see 4 and 7.

(Technical malfunctions prevented adequate recording of discussion.)

DR. GAYDOS: Joel Gaydos, DOD GEIS. James, in your isolate sentinel site for your

Pacific/Alaska region, on one of your bars you had more than 40 percent adenovirus. I assume that's not a training site.

COL. NEVILLE: If you give me a second, I might be able to look it up. I don't know. That's probably a spot with very low numbers of isolates because that's a percent bar graph. That would be Anderson Air Force Base at Guam. I don't have the number of isolates that they submitted, but I think that's a small number. So it may not be necessarily representative.

DR. OSTROFF: Any other questions?

(No response.)

If not, thanks very much for your presentation. It's getting a bit late. What I'm going to do is just ask Rick if there are any closing administrative comments that he wants to relay, but before I do that let me once again thank all of the presenters for I think a very interesting, informative, and useful couple of days. I will echo Col. Fensom's comments, which I should have made at the opening. We sort of glossed over the fact that there was a major

conflict, and I think our hearts and our thoughts go to all of the personnel who are part of that conflict, and we certainly appreciate the tremendous work and respect all of the Armed Forces, and I think that's certainly why all of us who are here and as all of you know, all you have to do is ask us for help and many of us would drop anything else we are doing at the time to provide that assistance because it's very important to us on this Board.

So thank you again, I think you're all doing a tremendous job, and we look forward to continuous ability to work with you and support you. So, let me turn it over to Rick.

COL. RIDDLE: I just have a couple of comments. I want to reiterate the appreciation that we have for the Preventive Medicine Liaison Officers. If it wasn't for you, we wouldn't have the meetings, we wouldn't have the presentations, we wouldn't be able to have that operational interface. And certainly the short time I have been on the Board, it has been an exceptional working relationship, and we're going to miss all

of you who are leaving. Also, don't forget to turn in your certificates. I think that's program has worked pretty good. People seem to be appreciative of that, so we'll continue to work that in.

I want to thank Jean and Karen and Severine, the folks that acted as hosted us yesterday, and the folks here at USAMRIID that hosted us today. It's a lot of work. They put out a lot to make this happen for us, and we're certainly appreciate that.

Don't forget to turn in your travel vouchers to Jean. If not, get those e-mailed, or a phone call followup. We want to get you paid and make that happen as quick as we can. Again, if you have any comments for us and a way that we can improve the way we do business, please let us know. We added a little bit more time on the agenda for presentations at this meeting, I think it worked well. Particularly in the Executive Session the first day it worked very well. All of those have come from you all as changes you would like to see made.

There will be a news article out on the award, we'll have something up on the Website, and certainly appreciate everybody bearing with us on that. Have a safe trip home, and we'll see you in the fall.

DR. OSTROFF: Before we leave, I'd be very remiss if I didn't acknowledge the fine work that Col. Riddle has done. It's important to me that we wouldn't received the award if not for all the fine work that you did. So let's give him a hand.

(Applause.)

So, with that I'm going to rap the gavel and bring the meeting to a close. Thanks again.

(Whereupon, at 4:45 p.m., the meeting was concluded.)