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WEDNESDAY, SEPTEMBER 17, 2003

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P R O C E E D I N G S

(8:03 a.m.)

DR. OSTROFF: Trying to have military precision, we're going to try to get started. We have a fairly ambitious agenda this morning, so it's important for us to try to keep on schedule.

Rick, do you have any administrative remarks to make before we get started? And the only thing that I will mention is that we're going to have one change in the schedule to try to accommodate Dr. Brown, who has to leave a bit early to take a train back to Washington. And so on the schedule we will flip Col. Grabenstein's presentation with Dr. Brown's presentation, but a couple of remarks first.

COL. RIDDLE: Just a couple of things.

Remember, on your travel vouchers, if you can go ahead and fill those out possibly on your way back home and get those in to us, we can get you paid. And especially, being at the end of the year, if you could get them in pretty quick so we can execute them before the end of this month -- the end of the fiscal year. So, if you could get them in to us pretty quick so we can execute them before 1 October.

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1           If you have any transportation needs,  
2 please see Karen and she will arrange for taxis  
3 or carpools or whatever we need to get folks back  
4 to the airport today. And if you haven't signed  
5 the sign-in roster, please do that.

6           As far as CME, Severine has CME  
7 evaluation forms for people in the audience that  
8 didn't get them. And so if you fill out your  
9 evaluation form, they'll have the certificates  
10 for you today for the CME -- for the Board  
11 members, it's in your notebook, in the plastic  
12 sleeve -- and we'll take care of that.

13           A reminder -- we have a lunch over at  
14 the O-Club. They did move the Eagle up  
15 yesterday. They actually have to take the mast  
16 off to get her under the bridge, so she's up at  
17 the Academy. We'll be over there. It's a buffet  
18 lunch, \$10, at the O-Club, open to everybody.  
19 And then they have some cadets that are going to  
20 give us a walking tour of the Academy and then a  
21 tour of the Eagle this afternoon. So everybody  
22 is certainly welcome to go over and do that.  
23 We'll have maps, and we'll try to get out of here  
24 as close to 12:00 o'clock as we can. We're  
25 supposed to be over there at 12:30 for lunch, and

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1 we'll just carpool from outside.

2 Again, our next meeting is going to be  
3 down in Florida at Hurlburt Field, and I want to  
4 thank the Air Force and Col. Woodward for  
5 assisting and really picking out a good venue for  
6 this meeting. I talked to him this morning, and  
7 he's guaranteed good weather.

8 (Laughter and simultaneous  
9 discussion.)

10 DR. OSTROFF: Okay. Our first  
11 presentation of the morning is on the Healthcare  
12 Needs For A New Generation of War Veterans. We  
13 really appreciate you taking the time to give us  
14 an update on things going on in the VA.

15 DR. BROWN: Thank you very much, and  
16 thank you very much for inviting me and thinking  
17 to include the Department of Veterans Affairs,  
18 whom I work for, in these activities. I think  
19 this is one of these ideas that, in thinking  
20 about it, it seems -- obviously, you kind of  
21 wonder why we didn't do this before. We at the  
22 VA, the way we think of ourselves is DOD gets its  
23 Active Duty service members for a couple of  
24 years, for maybe 5 percent of their adult life,  
25 and then we at VA get them and have to provide

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1 their health care for the remaining 50 or so --  
2 the 95 percent of their adult life. That's kind  
3 of the perspective of the time frame that we  
4 think about in terms of the health care that we  
5 have to provide.

6 (Slide)

7 What I'm going to talk about today is  
8 some activities -- you get the sense here that  
9 everything is changed, everything is different,  
10 and everyone is busy responding to the issues  
11 that Operation Iraqi Freedom has raised in terms  
12 of health care issues and other issues for Active  
13 Duty service members, but really there's been a  
14 very strong counterpart to that within the  
15 Department of Veterans Affairs.

16 When Operation Iraqi Freedom began, we  
17 came under a lot of pressure and a lot of  
18 scrutiny with members of Congress, members of the  
19 public, members of the press coming to ask us  
20 "What are you doing to get ready to provide  
21 health care to this new generation of veterans,  
22 veterans of, for practical purposes the Second  
23 Gulf War", and it made us sort of sit down and  
24 take a look at our internal activities. Our  
25 Secretary became concerned, Secretary Principi

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1 became concerned about how we could answer that.

2 What have we been doing since the end of the  
3 first Gulf War in 1991 to get ready to think  
4 about veterans from future wars. We didn't know,  
5 of course, at the end of the first Gulf War that  
6 we would be going back necessarily to Iraq, but  
7 we knew that we would be involved with future  
8 conflicts that would involve environmental  
9 exposures -- involve some of the same types of  
10 issues that the VA saw after the first Gulf War  
11 in 1991.

12 (Slide)

13 This first slide is obviously out-of-  
14 date, it says five months -- it really should  
15 now, of course, say six months, but when I wrote  
16 this five months was the time. As I mentioned,  
17 we've gotten questions from the medica, from all  
18 sources, people asking us "What are you doing to  
19 get ready". And, basically, the theme of my talk  
20 is that we've actually, I believe, done quite a  
21 lot of activities to get ready for veterans from  
22 future combat missions since the 1991 Gulf War.  
23 We've been paying attention and we've developed  
24 quite a number of excellent programs.

25 (Slide)

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1           The first thing that we did, we  
2 scurried and got together immediately after  
3 Operation Iraqi Freedom began, and we were  
4 concerned at that time -- it turned out not to be  
5 the case, but we were concerned that we were  
6 going to start getting back veterans who had been  
7 casualties in Operation Iraqi Freedom, and that  
8 we needed to get our health care providers ready  
9 to handle the types of injuries and wounds that  
10 might be associated with this war, whether it was  
11 from small caliber arms, or whether it was  
12 possible chemical attacks -- if you put your mind  
13 back into March of this year, there was a concern  
14 that our service members were going to come under  
15 attack from chemical or biological weapons. To  
16 tell you the truth, most of our doctors at  
17 Department of Veterans Affairs are not themselves  
18 veterans and they have very little experience --  
19 even if they are in an inner-city area where  
20 violent crime may be common, they are not  
21 typically going to see the kinds of injuries that  
22 are associated with military deployments,  
23 particularly if it's a matter of chemical or  
24 biological exposure.

25           We do a lot of education within

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1 Department of Veterans Affairs for our health  
2 care providers. We put on a broadcast to try and  
3 focus on information to get our health care  
4 providers ready for these veterans who might come  
5 back with the types of injuries that are  
6 associated with this type of modern warfare.

7 Now, it turned out in the long-run  
8 that that, fortunately, thank God, it didn't  
9 happen that way, but that was the first thing we  
10 did to try and get our own health care system  
11 sort of up and running and able to respond to  
12 this.

13 (Slide)

14 Looking a little farther back than  
15 that, we've developed some clinical guidelines  
16 for our health care providers, and we did this in  
17 conjunction with Department of Defense and, in  
18 fact, this is how I first got to know Col.  
19 Riddle. Col. Riddle and I spearheaded this  
20 program to develop clinical practice guidelines  
21 for VA and DOD health care providers, and we've  
22 done two of these. One is a general guideline to  
23 post-deployment health, this is for service  
24 members who come back, who have concerns that  
25 their health problems were caused by their

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1 deployment -- whatever the specifics of that are  
2 -- that their health problems are associated  
3 simply with their deployment, and how do you deal  
4 with a patient who has those concerns.

5 The second guideline we've done is on  
6 unexplained pain and fatigue in military  
7 populations. These are typical guidelines in the  
8 sense that they use best medical evidence for  
9 diagnoses and treatment, and both VA and DOD  
10 highly recommend these guidelines for evaluation  
11 of all returning combat veterans. And on my  
12 slide the font is that font that you can click-  
13 on, but in the handouts you can see the Website.

14 It says "Available at" -- well, the Website is  
15 in your handouts. It printed okay in the  
16 handouts, I noticed, even though it didn't --

17 DR. OSTROFF: Right. And I'll point  
18 out for folks that this handout is at the very  
19 end of Tab 8, the last handout in Tab 8.

20 DR. BROWN: Right.

21 LtCOL. GIBSON: WWW.pdhealth.mil.

22 DR. BROWN: Well, that's the DOD site.

23 Of course, the better site is  
24 www.va.gov/environagents, but it reproduces the  
25 same work. Thanks, Roger.

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1 (Slide)

2 Another activity that we worked on, we  
3 established some new specialized health care  
4 programs. We've established two new War-Related  
5 Illness and Injury Study Centers, one at  
6 Washington, D.C. VA Medical Center, and the  
7 second at the East Orange, New Jersey VA Medical  
8 Center. These two new centers are set up to  
9 provide specialized health care for veterans from  
10 combat and peace-keeping missions who experience  
11 difficult to diagnose but disabling illnesses.  
12 And if you want to get more information about  
13 these, it's in -- this is only a VA activity, so  
14 you have to go to the VA Website which is in your  
15 handout.

16 The counterpart to this program is  
17 roughly Chuck Engel's program at Walter Reed.  
18 This is a similar program, although it has some  
19 differences designed for separated veterans.

20 (Slide)

21 As I mentioned, we spend a lot of time  
22 trying to educate our health care providers about  
23 health care issues that are unique to veterans.  
24 We developed something called a Veterans Health  
25 Initiative independent study guide called "A

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1 Guide to Gulf War Veterans Health". We developed  
2 this in about 1999. It was originally designed  
3 to provide health care information on veterans  
4 from the first Gulf War in terms of their  
5 environmental exposures -- all the types of  
6 occupational health exposures that were related  
7 to that deployment, but we think it's every bit  
8 as relevant for veterans of the current conflict  
9 in Iraq.

10 And one of the things that I think is  
11 particularly unique about, I think makes it  
12 particularly useful, is we deliberately designed  
13 it to be useful both for clinicians to educate  
14 clinicians about the types of health problems  
15 that they might see in veterans from that combat  
16 mission, but it's also designed to be transparent  
17 to be readable by veterans and their families.  
18 And I heard a little bit about this yesterday, I  
19 think there's a general trend within VA to try  
20 and push -- it's not quite that we're trying to  
21 push more responsibility -- well, I guess it is  
22 that we're trying -- we're trying to push more  
23 responsibility for health care information onto  
24 the veteran himself or herself to become educated  
25 about what kinds of health issues that they might

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1 need to think about when they talk to their  
2 clinician. So we're making these types of  
3 guidelines using a kind of language and a kind of  
4 design to make them accessible to anyone who is  
5 interested. It's available in print, on a CD-  
6 ROM, and also on the general Website for Gulf War  
7 information at [www.va.gov/gulfwar](http://www.va.gov/gulfwar). You can take  
8 it for CME credit, if you're interested -- get  
9 six credits, I think.

10 (Slide)

11 Outreach to veterans is, of course, a  
12 key concern, ongoing concern for VA. One of the  
13 things we did is publish 1 million copies of a  
14 brochure called "A Summary of VA Benefits for  
15 National Guard and Reservists Personnel". I  
16 didn't bring a copy with me, but it's a little  
17 fan-fold thing that folds out. Reserve and Guard  
18 are a population that we are particularly  
19 concerned about. They tend to, in our  
20 experience, drop through the cracks when they  
21 come back, separate from military service,  
22 separate from Active Duty, and then they don't  
23 necessarily take the kind of advantages that they  
24 really should or have available to them of VA  
25 health care, and they, in a sense, would fall

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1 through the cracks.

2 We targeted this in a single brochure  
3 that summarizes all of the benefits the VA  
4 provides for this population, and we've printed,  
5 as I say, a million copies of it in an effort to  
6 make sure that it gets distributed to every  
7 single Reserve or Guard person, or his or her  
8 family. And we've used the veterans service  
9 organizations and various outlets to try and get  
10 that information out to make sure that when Guard  
11 and Reserve come back and separate, that they'll  
12 get shunted into the appropriate VA programs that  
13 they have available to them as quickly as  
14 possible, as smoothly as possible.

15 We did a similar brochure, "Health  
16 Care and Assistance for U.S. Veterans of  
17 Operation Iraqi Freedom". This is a similar  
18 brochure aimed at sort of in general to veterans  
19 and their families, and also their health care  
20 providers, about some of the things like  
21 infectious disease that they might be susceptible  
22 in that area, or exposed to in that area, and  
23 some environmental exposures, what information  
24 that we have. And that's also been sent out to  
25 all our health care centers. Of course, if they

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1 keep extending the period of the duration of  
2 service, I think the main health care problem  
3 we're going to see in this population are going  
4 to be geriatric, at this point. It's a joke.

5 (Laughter.)

6 (Slide)

7 Improvements in health care  
8 eligibility. One of the problems that we've had  
9 particularly with Reserve and Guard is when they  
10 -- particularly after the first Gulf War -- when  
11 they came back, we ended up having a somewhat  
12 negative interaction in the first interaction  
13 that we would have with new combat veterans,  
14 combat veterans who are separating from service  
15 and then thinking about coming to VA for health  
16 care. The interactions could sometimes be quite  
17 negative because the way VA health care is set  
18 up, it's free for veterans who have combat or  
19 service-connected injuries, then you get free  
20 health care. If it's not combat-related, then  
21 you can still get health care, but we'll charge  
22 you for it, and that's just the way we're set up.

23 These are rules set by Congress. But it puts it  
24 as an inevitable conflict between a new veteran  
25 who believes -- is convinced, they are absolutely

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1 certain that their health care problem is related  
2 to their military service. And our VA raters who  
3 have to say "Well, is it really, I'm not so sure.  
4 You say it is, but maybe it isn't".

5 Anyway, just to streamline that  
6 process to get around that initial encounter, we  
7 got the authority from Congress to provide two  
8 years of health care specifically for combat  
9 veterans regardless of whether the combat  
10 veteran's illness or injury is related to their  
11 military service. Even if it's not obviously  
12 related, we can just get them in, get them free  
13 health care for that two-year period. And I  
14 think that that's going to be very helpful in the  
15 long-run for trying to streamline getting  
16 veterans into health care and getting their  
17 health care problems taken care of, and making  
18 their experience in dealing with VA a positive  
19 one rather than an adversarial one. And that's  
20 in that brochure which is -- actually, it's a  
21 secret location.

22 (Laughter.)

23 I don't know what happened. We've  
24 printed thousands of these brochures and passed  
25 them out to all our medical centers and trying to

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1 get the word out to those who need it. And it's  
2 on that same Website that's in your handout.

3 (Slide)

4 I think probably many of you know  
5 about our special depleted uranium program that  
6 we run at our Baltimore VA Medical Center. It  
7 really lets any veteran who has concerns about DU  
8 exposure to have access. It's a little 24-hour  
9 urine test, and they can have themselves checked  
10 out. Actually, their main focus is on victims of  
11 so-called "friendly fire" and people who have  
12 depleted uranium shrapnel in their bodies, and  
13 following their health over time. That program,  
14 of course, is still available to current  
15 veterans, those who are fighting in Iraq today.

16 (Slide)

17 This is my last transparency, Veteran  
18 Health Status Surveillance. And I think that  
19 this is one slide that I was looking at last  
20 night that most relates to the conversations that  
21 were happening here yesterday where the context  
22 was DOD data needs, DOD data needs for health  
23 care optimization or for various purposes. But,  
24 of course, VA has very powerful health care data  
25 needs as well. We absolutely are under-the-gun

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1 to follow the health status of specific groups of  
2 veterans because everyone wants to know what's  
3 going on with veterans from the 1991 Gulf War.  
4 We're getting questions what's going on with  
5 veterans who we're seeing from the current War in  
6 Iraq.

7 Our ability to follow these veterans  
8 and track their health care utilization, for  
9 instance, within VA, the kinds of symptoms, the  
10 kinds of diagnoses that they receive when they  
11 receive health care at VA for every encounter  
12 that they receive, are very sophisticated. I  
13 don't know if we have terabytes of data, but we  
14 have a lot of data, and we can follow this very  
15 closely if we have a roster of who served in a  
16 war. We have such a roster for everyone who  
17 served in the 1991 Gulf War, and it's a very  
18 powerful tool. We can tell you every veteran who  
19 has ever visited VA and every diagnosis they ever  
20 got. It's a very powerful tool for both  
21 inpatient and outpatient visits.

22 So far yet we have not got that roster  
23 of service members who served in the current Gulf  
24 War yet from DOD, and so we can't do that yet,  
25 but I'm sure we will. And, of course, we have

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1 our registry, our Gulf War Registry Program.  
2 That's a whole topic in itself.

3 I think that that -- yes, that's my  
4 final transparency. Thank you. I'd be happy to  
5 try and answer any questions.

6 DR. OSTROFF: Let me ask the group if  
7 there are questions. Pierce? And please  
8 identify yourself for the Transcriber.

9 DR. GARDNER: Pierce Gardner. Thank  
10 you. This committee earlier discussed some of  
11 the problems that occurred in the first Gulf War  
12 Syndrome, and the data collected in the field was  
13 very sparse, and I believe that's improved quite  
14 a bit. And now you have a sophisticated system  
15 for following the returning veterans.

16 What I'd like to know is have you  
17 figured out a way to connect the field data and  
18 the Stateside data in a way that will be helpful  
19 certainly in further studies of Gulf War  
20 Syndrome. I served on one of the evaluating  
21 committees, and the lack of data on which to do  
22 any epidemiology, and the dose response curve on  
23 somebody today is kind of the same as somebody  
24 who had been there eight months, and whether they  
25 flew over 30,000 feet -- these are all not clear.

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1       So, I guess my first question is can you connect  
2 the field data with the U.S. data?

3               And, secondly, you've done a lot of  
4 steps -- how are you going to evaluate the  
5 success of the steps you've taken, particularly  
6 with regard to educating -- when you educate the  
7 health workers and you make veterans aware of  
8 things, have you changed life?

9               DR. BROWN: Well, those are both good  
10 questions. I think my answer to the first  
11 question is we are set up -- we do a lot of  
12 epidemiological work on veteran health, from all  
13 areas, from all deployments. And we've done a  
14 number of excellent studies -- epidemiological  
15 studies and longitudinal studies -- on veterans  
16 from the first Gulf War, including standard  
17 morbidity and mortality studies. And once we're  
18 able to identify, for example, the veterans who  
19 served in the first Gulf War -- we've done  
20 mortality studies that show -- I think some of  
21 the most remarkable data about this population is  
22 that their rates of mortality are no different  
23 than veterans who weren't deployed to the Gulf,  
24 and they are less than half that of their age-  
25 matched peers back in the United States.

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1 DR. GARDNER: I think the problem with  
2 that data was that you had such haphazard data  
3 from the field with regard to what the exposures  
4 were.

5 DR. BROWN: We certainly have  
6 haphazard in terms of exposure, but we have  
7 excellent data in terms of who was there. So,  
8 following mortality and morbidity -- now, as far  
9 as what we'll be able to do -- as soon as we get  
10 a roster of who served in this current war, we  
11 will certainly be conducting similar  
12 mortality/morbidity studies on that population,  
13 but we haven't got that yet. But when we do, we  
14 certainly will start those studies.

15 I think in terms of integrating data  
16 on exposure in the current conflict and trying to  
17 use that to explain -- for example, any health  
18 findings that we find in those studies -- I  
19 really can't comment on that. I have not seen  
20 that data. I don't think anyone at VA has seen  
21 what's available. Obviously, we would be  
22 interested in that and trying to use it.

23 Your second question about how do we  
24 know that any of this works is something that  
25 bothers us and we worry about a lot. I got a

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1 request once from a couple of veteran service  
2 organizations, and they said why don't we order  
3 all of our doctors -- why don't we just tell them  
4 they have to take all that CME credit, they have  
5 to look up the independent study guides that we  
6 developed on, say, Gulf War health, we should  
7 just send out an order. And I said, well, you  
8 know, we're a civilian operation. I can send out  
9 an order but, if no one follows it, there's not a  
10 whole lot I can do. What we try and do is  
11 produce the best products that we can and make  
12 them as accessible as we can so that we think  
13 that our providers will use them. And that's  
14 really -- that's kind of the best -- and,  
15 frankly, we have to just then hope for the best.

16 MS. EMBREY: Can I comment, too, on  
17 that? DOD and VA have, as a result of the  
18 efforts of the Presidential Task Force, had a  
19 series of strategic objectives to try to improve  
20 the transition of data about a service member's  
21 medical history over their career, and to provide  
22 that to the VA in a more timely fashion, and  
23 preferably electronically, in a way that is very  
24 effective for them to use it. I would say that  
25 we are about 40 percent prepared to do that.

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1           We are providing electronic data, but  
2 it is incomplete, it's not a whole record on  
3 electrons, but that doesn't speak to the issue of  
4 integrating field information, environmental  
5 results, things like that. That is not  
6 integrated, it's kept in separate records, it's  
7 not medical.

8           So, we have a big challenge within the  
9 Department, which is part of the reason why we  
10 wanted your opinion about what we should be  
11 capturing in terms of surveillance, what's  
12 important because right now that's not considered  
13 part of the medical record.

14           DR. BROWN: I would just follow that  
15 up by saying -- echoing that sentiment. When you  
16 think about what kinds of data DOD should  
17 collect, I hope that you extend that to thinking,  
18 well, what would eventually Department of  
19 Veterans Affairs need to follow that along.  
20 There's what DOD might need for its immediate  
21 purposes, but then eventually that soldier is  
22 going to separate and then VA will have to take  
23 responsibility for taking a look at what's going  
24 on with that soldier.

25           DR. GARDNER: That's a specific

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1 example like I guess a little later in the  
2 morning when we're talking about the pneumonia  
3 syndromes, one would like to know -- we know  
4 about the severe hospitalized pneumonias and the  
5 ones that get evacuated, the 100-some cases. We  
6 don't know much, I don't think, about the less  
7 severe respiratory illnesses and other things  
8 that might be going on, and the medical  
9 encounters that may not have resulted in  
10 hospitalization but might have some importance.  
11 And so ideally we'd integrate all the way from  
12 every field encounter to perhaps somebody who did  
13 go to seek help for respiratory problems that  
14 were considered not very significant might show  
15 up a year later with a pulmonary issue that we  
16 would worry about. So, I think there is that  
17 need to go from the field to the VA system.

18 MS. EMBREY: You're absolutely right -  
19 - and I don't mean to take your time, forgive me  
20 -- just to inform the group, during this OIF, DOD  
21 established for the first time a theater-wide  
22 medical surveillance capability that was  
23 electronic. It was designed to be able to  
24 capture medical encounter data electronically,  
25 and to move that around in a meaningful way.

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1 I would say the implementation was  
2 spotty, so it's not as good as we wanted it to  
3 be, but I think we'll get better as we have more  
4 time to fully implement.

5 DR. GARDNER: My point is, there are  
6 clearcut improvements on both sides, but at some  
7 point we need to bring those together.

8 DR. BLAZER: I'd just make one  
9 additional comment. Having worked with the  
10 Institute of Medicine on some of the issues  
11 around -- and I don't know how much progress is  
12 made, and I don't know how much progress actually  
13 could be made in this -- one of the major  
14 problems in trying to connect exposure with  
15 individuals was that it was very difficult to  
16 pinpoint exactly where a soldier was on a given  
17 day, and even a given hour, because of just the  
18 way wars progress. And they were very elaborate  
19 developments of the plume to which soldiers were  
20 exposed, but it wasn't always easy to pinpoint  
21 exactly where the soldiers were on a given day in  
22 order to try to connect them to a particular  
23 exposure.

24 So I think my lesson, having no  
25 background in this, was that it's just --

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1 connecting exposure to illnesses is very  
2 difficult in a theater, and it's not just the  
3 illnesses, it's actually trying to figure out  
4 where the individual was at the time of the  
5 exposure.

6 DR. BROWN: I would echo that point  
7 very strongly. My office is the Office of Public  
8 Health and Environmental Hazards, and we have  
9 responsibility for trying to look at  
10 environmental health issues related to all  
11 deployment from Vietnam on. And my sense is that  
12 trying to do occupational health, essentially  
13 what amounts to occupational health  
14 investigations or occupational health  
15 epidemiological studies on combat soldiers,  
16 people fighting wars, is stupid. It's just  
17 impossible. You aren't going to be able to get  
18 the kind of data that you need. It's just a  
19 hopeless task to try and collect that kind of  
20 information in a shooting war.

21 DR. FORSTER: I have a sort of  
22 simpleminded question. What proportion of combat  
23 veterans actually end up having a medical  
24 encounter at the VA?

25 DR. BROWN: Well, it depends on, of

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1 course, how you measure that. Again, I don't  
2 have terabytes of data, but I can give you a  
3 couple of pieces of information. There are about  
4 700,000 veterans who served up to the cease fire  
5 in Desert Storm/Desert Shield -- 700,000, almost  
6 three-quarters of a million. Of those, about  
7 585,000 are separated and therefore eligible for  
8 VA health care. And of those, half, a quarter of  
9 a million, have had an encounter with a VA  
10 Medical Center at least once on an outpatient or  
11 inpatient basis, at least once. The average is a  
12 little higher than one.

13 I think what practically happens is  
14 veterans use us selectively. They use us for  
15 certain things. For instance, we have the best  
16 pharmacy services that you can imagine. You can't  
17 beat our deals. So everybody uses us for that,  
18 and they may use us for other specialized health  
19 care as well.

20 Anyway, the short answer is about half  
21 of eligible veterans from Desert Storm/Desert  
22 Shield have seen us at least once.

23 DR. OSTROFF: Just one or two quick  
24 questions for you and then we're going to have to  
25 move on to try to keep on schedule.

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1           With opening up the potential for all  
2           deployed individuals to access VA health care for  
3           some period of time after they return, whether  
4           they have service-related disabilities or not, do  
5           you have enough capacity in the system to be able  
6           to accommodate all of them?

7           DR. BROWN: Yes, we think so. I mean,  
8           we think we would have ended up seeing them  
9           anyway, in the main. This just streamlines what  
10          we think would have happened anyway. When a  
11          veteran first comes to VA for health care, it  
12          used to be, as I say, somewhat adversarial -- you  
13          know, them against us. But usually, if they  
14          persisted, we would see them.

15          There may be some added cost -- we had  
16          to go through a cost analysis of this proposal  
17          before we went through it, and it may cost us a  
18          little bit of money for the extra health care, on  
19          the assumption that there will be a little bit of  
20          extra health care provided that wouldn't have  
21          been provided otherwise. But to us, that was  
22          kind of a no-brainer. I mean, we felt we were  
23          obliged to do that. We have an obligation to  
24          these veterans who have served in combat, to make  
25          sure that they get into our services.

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1           If you are thinking about our backlog  
2 and so forth, our infamous backlog for getting  
3 appointments, that is a problem, and that's just  
4 a matter of resources. If Congress gave us more  
5 money, then we would -- I'm not supposed to say  
6 that.

7           (Laughter.)

8           Congress gives us all the money we  
9 need.

10          DR. OSTROFF: One last question.

11          DR. MALMUD: Leon Malmud. Do I  
12 understand that any individual who has served in  
13 the Armed Forces, whether or not he or she has a  
14 service-related disability, is eligible for VA  
15 pharmacy benefits, meaning reduced --

16          DR. BROWN: Correct.

17          DR. MALMUD: So that any of us who has  
18 ever served could go to a VA --

19          DR. BROWN: Uh-oh.

20          DR. MALMUD: It's an important  
21 question because we see the question arising  
22 daily in our outpatient clinics at a hospital in  
23 the city. And I understand from just two  
24 individuals -- and I couldn't quite comprehend it  
25 until you just repeated it again -- that anyone

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1 who has ever served, whether during combat or  
2 not, is eligible for VA pharmacy benefits at a  
3 reduced cost?

4 DR. BROWN: Yes, but you have to  
5 understand, any veteran is eligible for VA health  
6 care, including pharmacy benefits, regardless of  
7 whether their illness or injury is related to  
8 their military service. The difference is if you  
9 come for treatment for, say, something that  
10 happened to you in your later years that's  
11 obviously unrelated to your military service, you  
12 are still eligible, but we will charge you. We  
13 will charge you a co-payment.

14 Having said that, our co-payments for  
15 our pharmacy benefits are quite reasonable, and  
16 many veterans -- for many American veterans,  
17 their only contact with VA is to get good deals  
18 on their meds.

19 DR. MALMUD: We have a large  
20 transplant service and patients are taking  
21 extraordinarily expensive drugs, and they are  
22 going to the VA for their drugs, though the  
23 disease was late an onset in their lives and it  
24 was totally unservice-related. Now, what budget  
25 does it come out of, does it come out of the

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1 military budget?

2 DR. BROWN: No. We have an  
3 independent budget. We have a budget of  
4 something like \$50 billion. We have a big  
5 budget.

6 DR. MALMUD: But we're not draining  
7 the military budget by referring those patients  
8 to the VA for their drugs?

9 (Laughter and simultaneous  
10 discussion.)

11 DR. BROWN: We're all going to the  
12 American taxpayer, you know.

13 DR. MALMUD: It's the same source.  
14 Which line item it is. Thank you.

15 DR. OSTROFF: Thank you so much.  
16 We're going to have to move on. We greatly  
17 appreciate it and will look forward to additional  
18 updates in coming meetings.

19 Our next presentation is by Col.  
20 Grabenstein.

21 COL. GRABENSTEIN: Thank you, sir,  
22 appreciate it. Thank you for the invitation to  
23 come join you. I'm going to show a mixture of  
24 slides today, some that you have seen before, but  
25 I left them in the presentation basically for

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1 reference, and I'll move through those relatively  
2 quickly. And then I wanted to give you the most  
3 recent information we have in terms of our  
4 surveillance of smallpox vaccine safety --

5 DR. OSTROFF: And this is Tab 6.

6 (Slide)

7 COL. GRABENSTEIN: But to orient you,  
8 we began vaccinations actually on the 16th of  
9 December, three main groups to be vaccinated,  
10 about roughly 2,000 people in Epidemic Response  
11 Teams, people who would go leave the warmth of  
12 their own bed to go fly into a smallpox outbreak;  
13 medical teams that are hospitals and large  
14 clinics, a little bit over 10,000 people; and  
15 then principally the Mission-Critical Forces,  
16 principally the forces in the CENTCOM area of  
17 responsibility as well as people in support of  
18 them.

19 (Slide)

20 We now have screened something greater  
21 than 565,000 people, vaccinated something greater  
22 than 492,000 of them. This is one that hasn't  
23 changed much except for the denominators -- 71  
24 percent primary vaccinations, hence, 29 percent  
25 revaccinations, 87 percent male, 13 percent

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1 female. I'll show you data on exemptions later  
2 that's a little more specific. And it's the same  
3 old sick call data. I think since your last  
4 meeting, we've had the review of the program  
5 published in Journal of the American Medical  
6 Association as well.

7 (Slide)

8 This is new. This is our effort at  
9 four sites to collect data on the progression of  
10 the vaccination sites, so this is dramato-  
11 kinetics, or something like that, but it is based  
12 on a little bit over 1100 people calling in to a  
13 telephone number or going to a Website and  
14 telling what they saw at the vaccination site.  
15 Now, they were told to report in daily, and so  
16 here you see compliance with that, that we have  
17 an average of six reports per person, with a  
18 fairly wide standard deviation, but still pretty  
19 reasonable data. It's about 89 percent male, 11  
20 percent female, and a bit skewed, older than the  
21 average vaccinee, it's because the biggest site  
22 contributing is the Pentagon.

23 So, here you see the Unknown, people  
24 who didn't look at their vaccination site, but no  
25 reaction of a macule, then a papule, then a

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1 vesicle, then a pustule, then the scab, then the  
2 scab falling off. And I think it portrays rather  
3 vividly what we're seeing.

4 The next step with this effort is to  
5 go back and correlate it with a clinically  
6 confirmed take to see if we can triage people to  
7 what is essentially reading their takes by having  
8 them describe what they see at their vaccination  
9 site, and so that confirmation or concordance  
10 analysis remains to be performed. The other big  
11 thing is that this mix is primaries and  
12 revaccinees together, and we really need to get  
13 those separated out, which we will do in coming  
14 weeks.

15 (Slide)

16 This is the adverse event data. The  
17 first 526 vaccinees at the sites where this was  
18 conducted, principally itching, feeling lousy and  
19 muscle ache. But if you take the same data  
20 collection method we used for the site evaluation  
21 and graph the symptoms over time, you get an  
22 immense increase in the amount of information.

23 This is the line for itching, and from  
24 my own response, I think this is the drying out  
25 of the scab that causes a plateau so it doesn't

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1 continue straight down.

2 This is the exudate -- leaking fluid,  
3 so exudate from the vaccination site and its  
4 reaction -- swelling and the balance.

5 DR. OSTROFF: Sounds like they read  
6 the textbook.

7 COL. GRABENSTEIN: Well, maybe they  
8 did.

9 (Slide)

10 These are the systemic symptoms.  
11 Swollen lymph nodes is the yellow line, muscle  
12 ache in orange, headache in purple, joint ache in  
13 black and, interestingly, chest pain -- which  
14 will bear on some of our cardiac discussions --  
15 peaking a little over 2 percent at Day 7. For a  
16 variety of reasons, not least of which is the  
17 myocardia question -- or principally driven by  
18 the myocardia question -- we are organizing a  
19 prospective analysis with sera blood, draw sera  
20 ECGs to evaluate vaccinees to pursue this a  
21 little further.

22 (Slide)

23 This is a little out of sequence. It  
24 shows this as the exemption data. I probably  
25 should have had this up a little bit further to

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1 the front. But these are the analyses of the  
2 screening forms collected before vaccination. We  
3 now have about 4900 of them analyzed, and the  
4 principal contraindications to vaccination are  
5 highlighted in blue, skin in a contact, skin in  
6 the cell, a pregnancy in the contact being the  
7 leading three among our vaccinees. This also we  
8 will be subjecting to considerable additional  
9 review.

10 (Slide)

11 This should be 492,000. These numbers  
12 have changed hardly at all since I reported to  
13 you last. Still only 1 encephalitis case.  
14 Generalized vaccinia is at 33. A few more  
15 contact transfer cases. They are 14 family  
16 members, 7 adult intimate contacts, 8 friends,  
17 still zero patients -- I'll show you more about  
18 this in a later slide -- no new uses of VIG. The  
19 myocarditis count is at 56 -- I'll show you more  
20 of that in a later slide. Still no eczema  
21 vaccinatum. Still no progressive vaccinia. The  
22 three not attributed deaths is 1 heart attack,  
23 which I'll talk about; a pulmonary embolism case,  
24 and an unexplained death case, both of which are  
25 being evaluated by your joint AFEB/ACIP Safety

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1 Working Group.

2 (Slide)

3 So the myocarditis -- this is also a  
4 comparable slide -- is the same slide I showed at  
5 the last meeting. These are the parameters for  
6 the first 18 cases.

7 (Slide)

8 The new data is this, which is through  
9 the end of July, 53 people, 52 of whom are male;  
10 51 probable cases, 2 confirmed cases of the 53  
11 primary vaccinees.

12 The incidence rate now appears to be  
13 15 per 100,000 primary vaccinees, a relative risk  
14 of 7, with a very tight clustering in time  
15 between Days 7 and 14, roughly.

16 These are the follow-up data on 35 of  
17 the 53 cases at this amount of time elapsed after  
18 diagnosis. Eighty percent report complete  
19 clinical recoveries, 20 percent report an  
20 intermittent chest pain type of response. Of the  
21 28, 22 have normal echo, 13 cases have normal  
22 stress test. Of the 20 percent, of the balance,  
23 the only thing in objective fashion is the two of  
24 them have some nonspecific resting ECG changes  
25 which we're going to pursue a bit further. So

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1 that's the situation with those. Here's the 20  
2 percent, principally chest pain and a bit of  
3 fatigue. So, by and large, recovery has been  
4 quite good -- not perfect -- and we're continuing  
5 to evaluate and assess, and also gather the data  
6 on the balance of the patients.

7 (Slide)

8 This is data from the Naval Health  
9 Research Center.

10 DR. OSTROFF: John, can I ask how many  
11 of those individuals are back on full duty?

12 COL. GRABENSTEIN: You certainly can  
13 ask.

14 (Laughter.)

15 Rick, do you know the value? I don't  
16 think anybody -- nobody is on convalescent leave,  
17 and so they are all at duty, whether they are in  
18 limited in any way or not, I'm not aware of any  
19 with limited duty.

20 COL. RIDDLE: I think in talking to  
21 Rob, the extreme is some of the guys are actually  
22 redeployed back in Iraq, to the one extreme.  
23 Some of them may be still on some restricted  
24 duty, restricted exercise. So, in essence, the  
25 full gamut, the vast majority are back to normal

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1 duty as they were prior to the illness.

2 COL. GRABENSTEIN: It also would vary  
3 with the duration of time that's elapsed since  
4 their event. Some of these are still relatively  
5 recent. And the one nonspecific ECG change case  
6 is a Reservist whose unit is demobilized, so he's  
7 in a bit of a different kind of situation.

8 COL. RIDDLE: But the one that I know  
9 of with the most morbidity is medically induced  
10 morbidity associated with his steroid --

11 COL. GRABENSTEIN: Right, this is the  
12 fellow -- his steroids were tapered extremely  
13 slowly and may have developed some iatrogenic  
14 problems related to sustained height of steroids.

15 Pregnancies. Thanks to the Naval  
16 Health Research Center, which is the DOD  
17 collaborating arm in the National Smallpox  
18 Vaccine in Pregnancy Registry collaborating with  
19 the CDC, there are 149 women registered in this  
20 program, mean age of 23 -- the range you see  
21 there -- first pregnancy for about two-thirds of  
22 them. Of the 149, 40 percent were vaccinated  
23 before conception, they conceived after  
24 vaccination; 28 percent were vaccinated after  
25 conception, but very shortly thereafter, before a

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1 pregnancy could have been expected to be  
2 positive; 32 percent vaccinated after four weeks  
3 gestational age.

4           Of the 149 pregnancies, 129 progressed  
5 to the second trimester; 13 had spontaneous  
6 abortions; 5 had elective abortions; 2 had  
7 ectopic pregnancies. The miscarriage rate was --  
8 depending on what you use as your denominator,  
9 whether you include or excluded the elective  
10 abortions or the ectopics, is either 8.7 percent  
11 or 9.5 percent, with an expected value for this  
12 age group of 9 to 12 percent. The ectopic  
13 pregnancy rate was 1.3 percent, with an expected  
14 value for this age group of 1 percent to 2  
15 percent.

16           So our conclusion at this point is  
17 that vaccination during or just before pregnancy  
18 had no apparent effect on early pregnancy  
19 outcomes. Monitoring continues. Products of  
20 conception were tested in three or four cases,  
21 all came up negative for vaccinia among the  
22 miscarriage cases. Any questions on this?

23           DR. HERBOLD: Yes. One observation --  
24 and I don't know if meds looked at this -- but if  
25 you look at the distribution of the ages, you've

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1 got a pretty wide age range. And if it's  
2 possible to do an analysis -- that 41-year-old is  
3 just way out there, and then the rest of them  
4 cluster, say, between 23 and 30 -- you might be  
5 able to get a tighter estimate of the expected  
6 rate.

7 COL. GRABENSTEIN: The 41-year-old is  
8 an outlier. I don't remember the mean and  
9 standard deviation --

10 MS. EMBREY: It's right there in  
11 front, it's 23 years old.

12 COL. GRABENSTEIN: I'm sorry -- I  
13 don't remember the standard deviation on the  
14 mean, but the 41-year-old is -- I think she's  
15 based most of her statistics on the late teen to  
16 20-year-old age group.

17 DR. OSTROFF: Is anyone systematically  
18 looking at this 32 percent who were vaccinated  
19 after four weeks gestational age, to see if there  
20 are any consistent systematic failures as to how  
21 they got vaccinated?

22 COL. GRABENSTEIN: We've looked by  
23 sites to see if any particular sites had higher  
24 rates of pregnancy than others. My assumption  
25 going into that analysis was that we did have a

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1 site that had an unusually high number of  
2 pregnancies, and then when we obtained the number  
3 of women vaccinated for the denominators it ended  
4 up that they all standardized and there were no  
5 outliers by site. So our collective analysis is  
6 that we've not seen anything systematic going on  
7 where any one, say, was more or less careful than  
8 other sites. In individual cases, I'd have to  
9 ask Megan for what she's evaluating, but she's  
10 not told me of anything, and I have no reason to  
11 believe that there is anything specific.

12 MS. EMBREY: I talked to Meg about  
13 this specifically, and she said that in the cases  
14 where they did vaccinate at that point, the  
15 pregnancy test came out wrong -- I mean, it was  
16 undetectable at the time that they gave them.  
17 And they either submitted to the test and it  
18 didn't come out positive and they got it and then  
19 found out that they were, or they lied when they  
20 weren't running tests.

21 DR. GRAY: I was in on that  
22 teleconference also, and I think the consensus  
23 was there wasn't much that could be done to  
24 prevent this -- I mean, the various ways they  
25 looked at it, the false testing or the women who

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1 were unknowledgeable about pregnancy. So there's  
2 not a lot of intervention I think that we could  
3 do.

4 (Slide)

5 COL. GRABENSTEIN: Contact transfer of  
6 vaccinia. We have 29 cases, 27 of the skin, 2 of  
7 the eye. This is 12 spouses and 2 children. The  
8 one child is -- I think I've told you all the  
9 story of the soldier in Alaska who transferred  
10 vaccinia to his wife, who developed lesions on  
11 the areola of her breast, who then transferred  
12 the vaccinia to the mouth and lip of the suckling  
13 child -- have I told you that story?

14 DR. OSTROFF: No.

15 COL. GRABENSTEIN: Well, that's the  
16 story.

17 (Laughter.)

18 We've submitted it to the NMWR --

19 MS. EMBREY: And Believe It Or Not.

20 (Laughter.)

21 COL. GRABENSTEIN: So that's the  
22 story. And the other child is a not very  
23 persuasive case at all. It is described as three  
24 papules, with no further review. The soldier was  
25 deployed, and the wife and child went back to

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1 family and was lost to follow up. So we are  
2 reattempting to gain contact with that family to  
3 conduct a more detailed survey.

4           Seven adult intimate contacts, six  
5 "sports" partners. One was a basketball bump-  
6 and-run, and several were wrestling, tussling  
7 kinds of male-to-male encounters. Other friends-  
8 2, patients-0. Not much clustering  
9 geographically -- four in Colorado, four in  
10 Texas, four in North Carolina -- but that's not  
11 surprising given the number of troops, the  
12 denominators for the sites, and then the balance  
13 that you see there. Nineteen of nineteen were  
14 PCR and/or culture-positive, the others were not  
15 tested. So this 29 is some of suspect, probable  
16 and confirmed cases, and I've given you my level  
17 of skepticism about one of the cases.

18           Incidence rate 5.9 per 100,000 --  
19 these are all also primary vaccinees -- 8.4 per  
20 100,000 primary vaccinees; historical rate -- the  
21 conservative rate is 2 to 6 per 100,000. You  
22 could find a reference that would take you up to  
23 9 per 100,000, so I'm not sure we're very far out  
24 of an historical range, and I have some reason to  
25 believe we made a more intense observation than

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1 the historical data. And given that far fewer of  
2 the contacts are immune themselves, there's far  
3 more susceptibility to a contact transfer. So,  
4 although we wish these numbers were zero, we're  
5 not doing too badly.

6 Principal risk is people who share the  
7 same bed. Secondly, failure to use bandages  
8 or bandage according to directions is leading  
9 cause. Greg?

10 DR. POLAND: John, I think compared to  
11 the other complications of smallpox vaccination,  
12 some of these skin complications like contact  
13 transfer, these historical rates are probably  
14 underestimates.

15 COL. GRABENSTEIN: I would think so.  
16 What's gratifying is that all of these cases have  
17 been relatively uncomplicated and that sort of  
18 thing.

19 (Slide)

20 Pneumonia. I certainly would not want  
21 to detract from Col. DeFrait's presentation to  
22 follow me, but we have investigated thoroughly  
23 the possibility that the string -- the series of  
24 pneumonia cases identified out of CENTCOM --  
25 evaluated fully whether or not it could have been

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1 related to anthrax and/or smallpox vaccination.  
2 So on that tangent alone, I'll present the next  
3 few slides.

4           So we start with what's our normal  
5 expectation of how much pneumonia should we  
6 encounter? Army data, 2002, worldwide, 10  
7 hospitalizations per 10,000 people per year for  
8 this string of ICD-9 codes, and you see the  
9 corresponding confidence intervals, but this is  
10 biased by pneumonia among basic trainees, so if  
11 you exclude basic training posts, it drops to 5.

12       So the comparison I'm going to make is an  
13 historical comparison rather than a randomized  
14 one, or what have you, so just keep that in mind.

15           Among soldiers who got anthrax vaccine  
16 only, did not get smallpox vaccine in the  
17 deployment months, 2.4 pneumonia hospitalizations  
18 per 100,000 per year. Among those that got  
19 smallpox vaccine only, not anthrax vaccine, 3  
20 cases per 10,000 per year. Not very many of these  
21 people, so it's a pretty wide confidence  
22 interval. Of those who got both, and there were  
23 quite a few, 3.3 with a narrower confidence  
24 interval, but our conclusion is that these core  
25 values are statistically comparable, so this

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1 shows us no indication that there is a  
2 predilection for pneumonia among anthrax or  
3 smallpox vaccinated people.

4 CDR. LUDWIG: John, at one point you  
5 said per 100,000 people.

6 COL. GRABENSTEIN: All those rates are  
7 for 10,000 -- I'm sorry. All those rates are for  
8 10,000.

9 (Slide)

10 Now, if there was a correlation  
11 between vaccination and pneumonia, we might  
12 expect there to be temporal clustering. If there  
13 is no association, we would expect the  
14 distribution of cases to be random over time, and  
15 essentially a flat line. And so we look for the  
16 time elapsed between smallpox vaccination and  
17 pneumonia admission for the 19 ventilator cases  
18 that Col. DeFraités will be discussing with you  
19 in greater detail, and statistically we found a  
20 flat line, that unlike the myopericarditis  
21 situation where you have the flat ground, the  
22 "Washington Monument" at Days 8 to 14, return to  
23 baseline flat level again, this is pretty much a  
24 flat line throughout, going from 1 week post-  
25 vaccination to 25 weeks post-vaccination.

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1 I've marked with a "plus" sign the  
2 cases among this group who had eosinophilia, and  
3 it likewise is evenly distributed across the  
4 entire interval.

5 (Slide)

6 This is the same data array for time  
7 elapsed between first anthrax vaccination and  
8 pneumonia admission, ranging from roughly 9 weeks  
9 out to I think this is 163 weeks. That fellow was  
10 vaccinated back in 1999, if I remember correctly.

11 And, again, the eosinophilic cases among --  
12 cases with eosinophilia among the group likewise  
13 distributed.

14 (Slide)

15 And then most recent anthrax  
16 vaccination ranging from 1 or 2 weeks out to  
17 about 23 weeks post-vaccination. So our  
18 conclusion is no association with vaccination.

19 (Slide)

20 Summarizing what we've identified so  
21 far -- what we believe is that our screening has  
22 been able to reduce adverse events to or below  
23 the levels known from the 1960s. That came at the  
24 cost of excluding about 15 percent of the  
25 eligible vaccinees, for what that's worth --

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1 probably an appropriate trade-off in an era of  
2 eradication.

3 We expected to use vaccinia  
4 immunoglobulin about once per 10,000 vaccinees,  
5 and used it twice in a half a million people. In  
6 terms of delivery in time -- if you're thinking  
7 about mass immunizations in post-outbreak  
8 scenarios, it's not the sticking of the arm that  
9 takes the time, it's the talking to the people  
10 that takes the time.

11 We had very high "take" rates both  
12 primary and revaccinees, primaries using the  
13 three jabs -- which was a concern back last fall.

14 I talked with you last time about the alarm over  
15 rashes. I showed you the data on the secondary  
16 spread of vaccinia, greatest risk to bed  
17 partners, and then the risk of myopericarditis.

18 (Slide)

19 Now, back in February, you all were  
20 kind enough to evaluate our program and gave us  
21 some points to consider, and I've addressed each  
22 of those here. I believe we have dealt with all  
23 of them. The audits are progressing. We are  
24 working with the DOD IG to get the audit design  
25 of immunization documentation finalized. We now

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1 have 4900 notes to be able to evaluate, plus  
2 Voxiva is the contractor that had the software  
3 that enabled us to collect the take and the  
4 symptom data; provided to Rick the CHPPM report  
5 on risk communication -- I think that's gotten to  
6 you; the long-term evaluations; inpatients in-  
7 theater, Ms. Embrey talked about; pregnancy  
8 registry, I've shown you the results;  
9 prophylactic use of VIG we've made available but  
10 have not had any cases where it was detected soon  
11 enough to be able to take advantage of it.  
12 Smallpox vaccinations are a bit less novel than  
13 they used to be, but you're still welcome to come  
14 watch one of our sites doing it. So the  
15 invitation is still open, we just have to figure  
16 out where and when.

17 And I think, Rick, your point there  
18 was you thought it appropriate for the Board to  
19 close out this item on its agenda, or something  
20 along those lines. I'm not sure how you want the  
21 minutes to reflect that.

22 COL. RIDDLE: Yes, we actually talked  
23 about that yesterday, and that's one of the open  
24 items we have for the Board to do, is, in  
25 essence, do a followup to that preliminary report

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1 as -- I don't know if we'd call it a final report  
2 or another interim report -- noting the actions  
3 that you've taken in response to the  
4 recommendations that were made.

5 DR. OSTROFF: I think that's a good  
6 way to phrase it. Questions? Grace?

7 DR. LEMASTERS: I still have some  
8 question about the women who develop pregnancies  
9 during the vaccination process, or before or  
10 after. Sixty percent of the pregnancies that  
11 occur had occurred to women who were vaccinated  
12 after they were pregnant. Now, these HCG tests  
13 for pregnancies are effective within 2 to 3 days  
14 after conception. So I don't understand why we  
15 wouldn't be able to identify pregnancy. I mean,  
16 can you explain what the procedures are? Are  
17 women, all women tested for pregnancy before they  
18 are given --

19 COL. GRABENSTEIN: My understanding  
20 from Cdr. Ryan was that it was a longer interval  
21 than a few days, but I'll defer to experts on  
22 that. We make pregnancy testing available. We  
23 do not oblige women to be tested because we have  
24 heard from a great number of women, "I know  
25 whether I'm pregnant, thank you very much". And

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1 so acting on that basis, we've had quite a number  
2 of women who were surprised, who thought they  
3 were not pregnant, got vaccinated, and discovered  
4 that they were, given an opportunity to be tested  
5 and declined to take that opportunity. There's  
6 149 stories in this group of 149 women. I don't  
7 mean to belittle or to demean the situation, but  
8 we don't want to vaccinate the women if they are  
9 pregnant, so it's a search.

10 COL. UNDERWOOD: I'd like to respond.

11 This is Paula Underwood. I was at Fort Stewart  
12 where we vaccinated over 10,000 people for  
13 smallpox, and initially we did not require them  
14 to be tested. So perhaps these that were tested  
15 after -- they were given the vaccine after they  
16 were pregnant actually did not know they were  
17 pregnant, and they weren't required testing.  
18 But, laterally, we did, in fact, require all  
19 women to be tested if they were going to be  
20 deployed, unless they had had a hysterectomy or  
21 had gone through menopause.

22 COL. RIDDLE: We actually reviewed the  
23 literature, there's about 20-some-odd papers on  
24 studies that have looked at either objectively  
25 testing using a variety of means, or subjectively

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1 asking pregnancy. The very best that you can do  
2 is to do both, is to screen them orally and  
3 tailor the screening questions. The screening  
4 questions have been changed a little bit over  
5 time, that we use. And then for those that have  
6 a suspicion of pregnancy, to objectively test  
7 them. I think probably some of the lessons  
8 learned is that those that think that they may be  
9 pregnant, even though they may objectively test  
10 negative, don't vaccinate them. Wait a week or  
11 so and retest them before you vaccinate them  
12 because they may be in that interval of time  
13 where you can't detect the pregnancy.

14 COL. GRABENSTEIN: And in our case, we  
15 did not have the luxury of time in many  
16 situations because the women were getting on a  
17 plane within a few days, and we didn't have that  
18 week to wait.

19 The other piece of it is that the  
20 expected rate of pregnancy in a group of women of  
21 this age is roughly 8 per 1,000 per month, and  
22 what we saw was essentially 1.5 per thousand for  
23 this interval. So we didn't get it to zero, but  
24 we did reduce it from what might otherwise have  
25 been expected.

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1 DR. LEMASTERS: Well, 50 percent of  
2 all pregnancies are unplanned pregnancies, so  
3 there's a big denial factor going on with "do you  
4 think you are pregnant" by asking women. So,  
5 again, HCG tests are very sensitive now for  
6 detection very early in the pregnancy, and I  
7 personally think that women ought to -- I mean, I  
8 was glad to hear you implemented the requirement  
9 for testing of the pregnancy, you could reduce it  
10 down to almost none.

11 COL. RIDDLE: I don't know if you want  
12 to discuss the trials, but in the trials that  
13 were done where they actually did the objective  
14 testing --

15 COL. GRABENSTEIN: These are the  
16 commercial vaccine trials you're talking about?

17 COL. RIDDLE: Yes, they vaccinated a  
18 lot more pregnant women than we did on a rate  
19 basis.

20 DR. LEMASTERS: Well, yes. I mean, I  
21 think we didn't do a great job just lowering it,  
22 but you don't want to come up with a major issue.

23 DR. OSTROFF: Okay. Greg, and then  
24 John Herbold, and then Dr. Haywood.

25 DR. HERBOLD: John Herbold. John, you

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1 mentioned the rate limiting steps in the mass  
2 vaccination. We had a similar experience in the  
3 civilian sector doing a functional exercise. Did  
4 you all capture any time data, because we think  
5 these are show-stoppers. If we had had 1,000  
6 people lined up in Del Rio, Texas for our  
7 exercise rather than 50 volunteers circulating  
8 over and over through our vaccination line, we  
9 would have been shut down because it took more  
10 than a half an hour to educate and train each  
11 person. And then we never really got to the  
12 point of filling out all the required paperwork  
13 because we were just being -- we were being shut  
14 down by following the letter of the law of the  
15 CDC requirement.

16 So, if we had to go to a post-event  
17 mass vaccination scenario in the civilian sector,  
18 either we would not get it done, or we would have  
19 to go to an abbreviated approach.

20 COL. GRABENSTEIN: I don't have any  
21 time/motion data like that. In our situation,  
22 this was preparation for overseas movement, so  
23 they were getting screened for multiple things,  
24 and these were gymnasiums where they were going  
25 from station to station to station -- dental

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1 exam, HIVs, wills -- it would be useful our own  
2 purpose, but I'm not sure that it would be  
3 directly applicable to the scenario you're  
4 describing.

5 COL. UNDERWOOD: Can I respond to  
6 that?

7 COL. GRABENSTEIN: Please. Practical  
8 experience here, yes.

9 COL. UNDERWOOD: We marshalled most of  
10 our -- because that is a rate-limiting step -- we  
11 marshalled more screeners, if you will, providers  
12 at tables, and we had a flow of traffic so that  
13 it was very efficient.

14 The other thing is we gave the  
15 screening tools to the individuals as they stood  
16 in line, to answer the questions. And we had the  
17 educators up front as well, while they were  
18 educated first, they got the form, they filled it  
19 while they stood in line waiting to see the  
20 screener. We had specific screeners for those  
21 individuals who answered "no" to every screening  
22 question so that we could also marshall a quick-  
23 line, if you will, and that helped.

24 DR. OSTROFF: Dr. Haywood, one quick  
25 question.

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1 DR. HAYWOOD: Among the post-  
2 vaccinated myocarditis suspects were serological  
3 enzymes done, cardiac enzymes?

4 COL. GRABENSTEIN: They will be done.  
5 The study has not begun yet. We've got a  
6 protocol that's pretty well -- if you're talking  
7 about the prospective study of vaccinees to  
8 evaluate essentially subclinical or the base of  
9 the iceberg instead of the tip of the iceberg, it  
10 has not yet begun, but sero-enzymes will be part  
11 of that.

12 DR. HAYWOOD: But among the 18 cases -  
13 -

14 COL. GRABENSTEIN: Among the 56 cases,  
15 the reason we have no suspect cases is that --  
16 well, the reason -- to be probable, you have to  
17 have elevated cardiac enzymes, so they all have  
18 cardiac enzymes.

19 DR. OSTROFF: Okay. I'm going to have  
20 to take prerogative so we stay on schedule, but I  
21 have one last question to ask, which is the big  
22 question. Maybe either you or Ms. Embrey can  
23 comment on where the smallpox vaccination policy  
24 is going.

25 COL. GRABENSTEIN: I defer to Ms.

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1 Embrey.

2 MS. EMBREY: Thank you, John. I  
3 believe that the Department's success in  
4 implementing the program thus far bodes well for  
5 any expanded or continued program. We have a  
6 proposal before the "King" -- the Secretary of  
7 Defense -- that we have prepared to present  
8 options to him on whether we stay the course for  
9 the current scope of personnel being vaccinated,  
10 whether we expand that to other threat areas, and  
11 he hasn't made his decision yet because we keep  
12 getting postponed.

13 So I believe we will continue to do  
14 this as long as we perceive a threat, and for the  
15 forces that have been identified.

16 DR. OSTROFF: Thank you. Our next  
17 presentation is by somebody who I see on  
18 television probably as often as I see the "King".

19 So, congratulations, I think. Col. DeFraités,  
20 thank you for your willingness to come up and  
21 share some information on an investigation that  
22 I'm sure has a great deal of interest here among  
23 the Board members. This is at Tab 7.

24 COL. DEFRAITES: Thank you, and good  
25 morning. Actually, I'm here in place of Col.

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1 Bruno Petrucelli, who originally was scheduled to  
2 give this briefing, but he wasn't able to make  
3 it.

4 I'm going to try to go quickly. I  
5 know a lot of the Board members are familiar with  
6 this topic, so I would ask you to sort of look at  
7 the handout that goes into great detail, and I'll  
8 go through all the slides, but if we could get  
9 through the briefing, and I'd be happy to answer  
10 questions.

11 (Slide)

12 This is what I'm going to try to cover  
13 this morning, is covered on this slide.

14 (Slide)

15 To frame the discussion here, since  
16 March, which sort of starts -- there are two  
17 landmarks in March of '03, one is the beginning  
18 of offensive operations in Iraq, and the second  
19 is really the turn of the seasons in the Middle  
20 East. Since that time, there have been about 100  
21 cases of pneumonia that were admitted to Level 3  
22 facilities. Those are the deployed Combat  
23 Support Hospitals. So pneumonias of all kinds  
24 that just had a diagnosis of pneumonia since the  
25 1st of March.

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1                   Nineteen of these pneumonia cases  
2 required intubation and assisted ventilation.  
3 Two of the 19 severe cases -- that's what we're  
4 calling "severe pneumonitis" -- 2 of the 19 died,  
5 and I'll get into more details of those later.  
6 This led to a working case definition of what we  
7 call "severe pneumonitis" in pneumonia, as anyone  
8 deployed to the whole CENTCOM Area of Operations  
9 which, as you know, covers from Pakistan to the  
10 east as far as the Horn of Africa to the west,  
11 north to Iraq and south to Somalia -- or Kenya,  
12 actually, and that were diagnosed with a  
13 bilateral pneumonia requiring intubation and  
14 ventilator support, since the 1st of March. So,  
15 for the most part, of these 19 severe cases,  
16 that's the case definition I'm going to be using  
17 for this talk.

18                   As most of you know, there's been an  
19 MNWR article published just last week that had a  
20 slightly different look at these -- it still  
21 comes out to 19, but we talked about suspected  
22 and probable confirmed cases of eosinophilic  
23 pneumonitis. So as this presentation develops,  
24 you'll see how that changed, but I wanted to give  
25 you a full flavor of how this has sort of evolved

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1 over time.

2 (Slide)

3 And here are at least most of the 19  
4 cases at least displayed over time, and you can  
5 see that these cases occurred fairly wide-ranging  
6 from the first 2 in the beginning of March, 2 in  
7 April, 1 in May, and then there were 6 in June, 4  
8 in July, and 4 in August. There have been none  
9 since the 20th of August.

10 Other notable facts about these cases,  
11 only 2 of them are from the same military unit,  
12 the 2nd Battalion, 8th Infantry Regiment, part of  
13 the 4th Infantry Division. That was cases that  
14 were in April and in August, so there were four  
15 months separating those two that had that one  
16 unit in common.

17 (Slide)

18 Here is a demographic description of  
19 these 19 severe cases. Most were men. The median  
20 age was 24. Most were Army, but we had 1 Marine  
21 and 1 Sailor. The service component, the ranks,  
22 the duty Military Occupational Specialty, pretty  
23 much were representative of the troops that were  
24 deployed to the CENTCOM AOR. I already covered  
25 the facts that the date of illness onset was

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1 spread out over time. The 2 fatalities, 1  
2 occurred in June and 1 occurred in July, though  
3 he became ill at the end of June, but he died in  
4 July.

5 The deployed locations of interest.  
6 Since most of these cases occurred since the  
7 beginning of offensive operations in Iraq, 13 of  
8 the 19 cases were stationed in Iraq at the time  
9 they became ill, 3 were in Kuwait, and then 1  
10 each came from Qatar, Uzbekistan, and Djibouti,  
11 which is on the Horn of Africa.

12 So the correlation with location in  
13 severe cases is probably biased a little bit  
14 toward Iraq. Certainly, we didn't have any that  
15 were in Afghanistan, though Uzbekistan is a  
16 direct support -- it's practically Afghanistan  
17 geographically, but most of them came from Iraq,  
18 and most of them occurred in the summer months.

19 (Slide)

20 Just for some background information,  
21 for the latest year that we have background  
22 information for pneumonia of all kinds, just to  
23 help this into perspective, for the age group of  
24 15 to 44 years of age, 10.5 persons per 10,000  
25 population in the year 2000 were admitted with a

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1 diagnosis of pneumonia in the United States.  
2 Again, 2000 is the last year that we have those  
3 type of statistics.

4 (Slide)

5 If you look at community-acquired  
6 pneumonia in the United States, most often this  
7 entity is treated successfully in an ambulatory  
8 setting with broad-spectrum antibiotics,  
9 presumptively, and there is usually not -- for  
10 the usual "walking pneumonia", if you will,  
11 there's not a big workup. The etiologic agents  
12 are the usual suspects of Strep pneumonia. M.  
13 catarrhalis, L. pneumonia, and a long list of  
14 viruses, et cetera. And this is rough estimates  
15 -- about 50 percent of them, of the walking  
16 pneumonias, don't have an identifiable etiology  
17 either because it is not pursued and the patient  
18 improves, or other reasons.

19 (Slide)

20 As far as the military data, what we  
21 have in the same type of framework -- in other  
22 words, those that require admission -- you can  
23 see here the data for U.S. military from '98  
24 through the full year, calendar year 2002. You  
25 can see that overall this period of time, the

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1 rate per 10,000 per year is anywhere between 4  
2 and 10. You can see that it looks like the rates  
3 have gone up, especially in Marines and Army, for  
4 some reason. However, this overall rate, even at  
5 its highest, is comparable to the U.S. population  
6 in the age group that corresponds to our Active  
7 Duty population. Again, this is all Active Duty  
8 personnel on this chart.

9 (Slide)

10 So, just in summary, what this means  
11 in terms of our military experience, especially  
12 in deployments, we do have some background  
13 information from the Gulf War. And, again, the  
14 Gulf War, Desert Shield and Desert Storm, took  
15 place from August of 1990 -- and most troops were  
16 gone out of the theater by July of the next year,  
17 or certainly a lot quicker than that, and most  
18 were probably departed in March, April and May.  
19 But the data from deployed hospitals was about  
20 8.6 cases per 10,000 person-years. And this came  
21 from a reliable source of Cdr. Meg Ryan at Naval  
22 Health Research Center, looking at that data.

23 So, in general, military admission  
24 rates compare favorably with our observed  
25 approximately 100 cases in Southwest Asia,

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1 looking at the deployed population. So the  
2 overall rate of admission at the end of the day  
3 looks like about what you'd expect. And, again,  
4 now we want to focus on these more severe cases.  
5 Five to eight percent of all Army personnel that  
6 were on that table at 10 cases per 10,000 per  
7 year, about 5 to 8 percent admitted for pneumonia  
8 required some kind of ventilator support. And,  
9 again, that compares to -- if you look at this  
10 roughly 100 cases that 19 of them required  
11 ventilator support, that certainly is a higher  
12 percent of, given a pneumonia, that you need a  
13 ventilator. So that number still is higher than  
14 what we'd expect from our usual brick-and-mortar  
15 or fixed facility treatment of pneumonia. How  
16 comparable those two situations are I leave to  
17 you. Certainly, a combat scenario or deployed  
18 hospital scenario may not lend itself to a good  
19 comparison with the standard of care in a fixed  
20 facility in terms of whether you intubate a  
21 patient or not, but that's what the data have.

22 Also, as far as background is  
23 concerned, there have been 17 Army deaths  
24 attributed to pneumonia or Adult Respiratory  
25 Distress Syndrome for the five years that ended

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1 in 2002. So our 2 deaths in-theater -- and,  
2 really, I'm not aware of any other deaths due to  
3 pneumonia in the Army this year -- at least  
4 primary pneumonia -- as the primary cause. So,  
5 again, about 3 cases that we expect per year in  
6 the Army, we've had 2 in a month and, in a way,  
7 that led to concern that there was something  
8 going on that we needed to look into.

9 (Slide)

10 TSG stands for The Surgeon General.  
11 The Surgeon General of the United States, of  
12 course, is Adm. Carmona. As far as I'm  
13 concerned, The Surgeon General is Gen. Peak, the  
14 Army Surgeon General, and that's how it shows up  
15 on this slide, but that's our abbreviation for  
16 Gen. Peak. He tasked CHPPM, the Center for  
17 Health Promotion and Preventive Medicine, to form  
18 a formal Epidemiologic Consultation, or EPICON.  
19 It's a mechanism that we've had in the Army since  
20 the late '70s, I guess, to get expertise directed  
21 toward a particular problem.

22 The way they organized themselves was  
23 two deployed teams and one home team. One group  
24 went to Landstuhl Regional Medical Center, since  
25 most of the cases that came out of theater that

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1 were MEDEVAC'd, arrived at Landstuhl and were  
2 treated there, and then the other team went into  
3 Iraq, and this is a description of the makeup of  
4 that team.

5 We also had augmentation of the team  
6 from Centers for Disease Control, Dr. Steve Redd  
7 from the Center from Environmental Health. He  
8 came up to CHPPM on the 12th of August and stayed  
9 with Bruno. And if Bruno could be here, I know  
10 he would love to be here to present this to you.

11 (Slide)

12 This is more of the same. Also, we  
13 had, as many of the members here present know,  
14 through two weeks ago had weekly teleconferences  
15 with members of the AFEB and also the Armed  
16 Forces Institute of Pathology. Certainly, these  
17 two fatal cases, we've had a lot of support from  
18 the Medical Examiner's Office. And in addition  
19 to the two fatal cases, we had formal  
20 consultation with the Mayo Clinic, in addition to  
21 the Centers for Disease Control. So we had a lot  
22 of assistance, I think expert assistance in  
23 dealing with this problem.

24 (Slide)

25 I want to go through a typical

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1 clinical presentation of these cases. They all  
2 were febrile, really no neutropenia, at least 9  
3 had white counts greater than 12,000. The  
4 interesting part, of course, and the bottom line  
5 is that 10 of the 19 had eosinophilia either  
6 peripheral in lung tissue or broncho-alveolar  
7 lavage, 8 of the pleural effusions. We had 4  
8 cases that have had infectious agents that we  
9 feel can be implicated in their pneumonia, 2 had  
10 Strep pneumonia, 1 had Q-fever, and 1 had  
11 Acetobacter baumannii. The Acetobacter was  
12 one of the August cases. Interestingly enough,  
13 15 of the 19 cases smoked cigars or cigarettes,  
14 including all of the eosinophilic cases, 9 out of  
15 the 10 eosinophilic cases were also recent onset  
16 smokers. All of these cases were treated upon  
17 presentation with broad-spectrum antibiotics.

18 So, a lot of times that precluded,  
19 especially in-theater with some of the early  
20 cases, of getting a good bacteriologic workup.

21 (Slide)

22 As far as the negatives that we have  
23 so far, testing is incomplete in all of these 19  
24 cases, but the negatives, the pertinent negatives  
25 that we have so far, is Hantavirus -- what I mean

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1 by this is at least in some of the cases we have  
2 negative, confirmed negative findings -- for  
3 Hantavirus, SARS, Legionella, Mycoplasma,  
4 Adenovirus, Influenza, TB, and Valley Fever or  
5 Coccidiomyces immitis, at least by culture on the  
6 2 fatal cases, that hasn't been found. That's  
7 not to say that they've been entirely ruled out  
8 because we still haven't filled in the full  
9 matrix on all the cases with all the negatives.  
10 So there may be a couple more -- several more  
11 that turn up to have, but serology, especially  
12 with convalescent sera, might have some serologic  
13 evidence for an infectious agent.

14 (Slide)

15 This is a sample of a typical case,  
16 29-year-old man, National Guardsman, comes in  
17 with somewhat of a fever and fatigue, with  
18 shortness of breath, develops usually a dry  
19 cough. And what usually brings them in,  
20 especially for the second time -- they come in  
21 for fever once -- what brings them in again is  
22 the shortness of breath. Some of them had a much  
23 quicker onset than this, but within hours or a  
24 day or so, but the shortness of breath brings  
25 them back in. Admitted to the Combat Support

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1 Hospital and started on antibiotics. Then  
2 respiratory distress quickly worsens and then  
3 either based on pulse oximetry or in-clinical  
4 findings, gets intubated.

5 (Slide)

6 This is a typical x-ray finding on  
7 admission. See the bilateral sort of diffuse  
8 infiltrates, looks like atypical pneumonitis.

9 (Slide)

10 Other findings in this particular  
11 case, notable peripheral eosinophilia 26 percent,  
12 with absolute count of 2600 eosinophils per  
13 microliter. In clinical history, he dips  
14 tobacco, but his brand wasn't available in Iraq  
15 and he started smoking two weeks before  
16 admission. The dust, of course, reports that the  
17 dust in the air was very bad -- whatever that  
18 means. I mean, it's there. We've seen it on  
19 CNN.

20 Nobody that he has been in contact  
21 with has been ill with a similar illness. This  
22 particular case had a positive PPD before  
23 deployment but did not take INH, and is negative  
24 for asthma, and he's taking doxycycline for  
25 malaria prophylaxis.

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1 (Slide)

2 This is another typical finding, is  
3 that usually these cases, after they get so  
4 severely ill and develop respiratory failure, get  
5 intubated, get managed on ventilators, and then  
6 are extubated fairly quickly. He was MEDEVAC'd  
7 to Landstuhl and then extubated the day after he  
8 arrived, and then he ended up coming back to the  
9 States, which again is what's typical. None of  
10 these cases were returned directly to theater.  
11 Everyone came back to home station. Now, some  
12 were from Germany, so they stayed in Germany from  
13 Landstuhl.

14 (Slide)

15 Now just to talk a little bit about  
16 the phenomena of eosinophilic pneumonia, which  
17 I'm not sure exactly that's what we're dealing  
18 with. We certainly have pneumonitis with  
19 eosinophilic features. Typically it's been  
20 described as acute febrile illness with a short  
21 duration, and development of hypoxemic  
22 respiratory failure, diffuse pulmonary opacities,  
23 an broncho-alveolar lavage eosinophilia rate of  
24 greater than 25 percent, and if you get lung  
25 biopsies on these, you show an eosinophilic

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1 infiltrates and, of course, you know, the issue  
2 with the eosinophilic pneumonia in the literature  
3 is that it's basically a diagnosis of exclusion,  
4 idiopathic and then absence of other known causes  
5 of eosinophilia. This isn't the same thing as  
6 hypersensitivity pneumonitis, which is a distinct  
7 entity in and of itself.

8 (Slide)

9 These are a long list of potential  
10 causes for the eosinophilic pneumonia, none of  
11 which really -- except if you exclude perhaps  
12 this business of the inhalation injury following  
13 building collapse -- case report of a firefighter  
14 in New York City with the World Trade Center, as  
15 a matter of fact, you had a very similar onset  
16 several weeks -- a couple of weeks, I think,  
17 after the collapse of the building, he was  
18 involved in rescue effort without using  
19 respiratory protection. He actually was found to  
20 have asbestos fibers in his alveoli, on his  
21 broncho-alveolar wash, and by very similar  
22 clinical course. But, again, all of these  
23 medications and some fungal infections and  
24 Coxsackie Virus, not all of which, by the way --  
25 we haven't implicated any of these in the 19

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1 cases, but we haven't really ruled out all of  
2 them in all the cases.

3 (Slide)

4 I wanted to talk a little bit more  
5 about the smoking connection. This slide shows  
6 the same cases I displayed before, but we've got  
7 categorized in three ways the cases. The striped  
8 diagonal lines show that they have all three  
9 factors -- severe pneumonia, smoking, and  
10 eosinophilia. So these striped ones are -- you  
11 didn't show up on this slide if you didn't have  
12 severe pneumonia, so that's a given. But if you  
13 had eosinophilia without being a smoker, you were  
14 shown as a solid bar, and if you were severe and  
15 a smoker and eosinophilia -- now, actually, I  
16 think this one bar here should be turned to a  
17 striped line because I think he was found out to  
18 be a smoker as well.

19 (Slide)

20 This is a slide showing the broncho-  
21 alveolar lavage showing the prominent eosinophils  
22 from one of the cases, so there's no doubt about  
23 it, at least in his case.

24 (Slide)

25 This is another way of looking at the

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1 data. This is a display of -- the question was  
2 how common is eosinophilia on troops that have  
3 been EVAC'd from Landstuhl from Operation Iraqi  
4 Freedom, and this is a display showing the  
5 eosinophil counts on the X-axis and the number of  
6 soldiers EVAC'd to Landstuhl and, of course,  
7 we've had a lot of wounded and ill that have gone  
8 back to Landstuhl, and the distribution of  
9 eosinophil are most commonly among the MEDEVAC'd  
10 soldiers for all reasons, regardless of what the  
11 reason for MEDEVAC was. Most often, their  
12 eosinophil count is very low. And here you can  
13 see the eosinophil -- and I've just distributed  
14 these numbers for clarity -- the case by Social  
15 Security Numbers identified. So this fellow here  
16 doesn't have anything to do with the 600, he's  
17 basically displayed here that his eosinophil  
18 count fell here, his eosinophil count was here,  
19 but you can see that our cases of pneumonitis  
20 fall well outside the range of what we'd expect  
21 even given the OIF. So it doesn't seem like  
22 eosinophilia is that common among OIF medical  
23 evacuees, but it's certainly still very  
24 distinctive and a distinguishing characteristic  
25 of these pneumonitis cases. That's the point of

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1 that slide.

2 (Slide)

3 We do have some findings from the past  
4 limited -- and it's interesting, after this, of  
5 course, becomes publicized, we start hearing more  
6 and more health as folks remember situations, but  
7 this is one that's published in Military  
8 Medicine. These are two soldiers who were  
9 deployed for training purposes to the National  
10 Training Center in the Mohave Desert, Fort Irwin,  
11 California, 1997. Very typical and very similar  
12 clinical presentations to what we've seen with  
13 these eosinophilic cases from CENTCOM AOR this  
14 year. Both of these guys were smokers and both  
15 recovered, but both had a very similar ARDS  
16 picture with eosinophilia in 1997. So one  
17 wonders if you have some connection with smoking,  
18 some other two-hit theory of being a soldier  
19 maybe in the desert, with some other respiratory  
20 irritant from the sand, plus the cigarette  
21 smoking that is a risk factor for this condition.

22 (Slide)

23 The connection with smoking an  
24 eosinophilic pneumonitis, some of the evidence  
25 comes from case reports, mostly from Japan, new

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1 onset smokers less than 30 years of age, that  
2 have been smoking less than one month, presented  
3 with a clinical presentation very similar to what  
4 we have here.

5 (Slide)

6 The other things that were done in  
7 conjunction with this epidemiologic investigation  
8 -- which, of course, there are a lot more details  
9 that I can go into -- but in terms of what else  
10 did we do in terms of other actions sort of  
11 globally. Early on we published a prevention  
12 message -- I mean, not knowing what exactly we  
13 were dealing with, but in terms of just what  
14 could be prudent advice given to try to prevent  
15 pneumonia. Certainly, we emphasized hydration,  
16 avoidance of smoking, dust protection using  
17 personal protective measures, using a dust mask  
18 of some kind, and if you are indoors sweeping up  
19 the dust, you use wet mopping techniques rather  
20 than dry sweeping. And emphasizing not only to  
21 seek care for yourself if you have fever and  
22 cough, but also watch out for your buddy. So  
23 these messages were put out to the field in  
24 general.

25 And then, also, even though we had no

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1 evidence that this was person-to-person spread,  
2 that we emphasized if you do have situations  
3 where you might be crowding, to avoid crowding  
4 situations in billeting. We thought anywhere that  
5 you could get out of the heat, these guys would  
6 find air conditioned places wherever they could  
7 find them, and probably pack as many people as  
8 they could into them, and so we wanted to avoid  
9 those situation.

10 And the other key piece of this has  
11 been certainly something that's been emphasized  
12 from OSD and the Surgeon General's Office is  
13 communication with the families of the soldiers  
14 and also other stakeholders, including Congress  
15 and the public. And we've had several  
16 opportunities to speak to Congress, senior DOD  
17 leaders and the public directly.

18 (Slide)

19 The way ahead in terms of where we  
20 stand now, as I mentioned, is to pursue the  
21 confirmation of these pertinent negatives that  
22 I've mentioned. We're also looking into other  
23 association of eosinophilic pneumonia with a  
24 desert or deployment environment, so we're  
25 looking for additional cases. And to pursue the

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1 association of this with cigarette smoking and  
2 other exposures with the current deployment by  
3 doing a case-control study, and that's underway  
4 now, and it's going to include patients that are  
5 evacuated from theater with other conditions  
6 other than pneumonia.

7           The only thing I wanted to mention in  
8 terms of what's new since I put these slides  
9 together is we've already heard that there may be  
10 additional cases that have not been captured in  
11 this 19 -- for example, those that may have been  
12 evacuated to the 8th Fleet Hospital which was set  
13 up at Roda, Spain. I heard from there, I guess  
14 their Senior Medical Officer, their equivalent to  
15 Deputy Commander for Clinical Services, that  
16 indicates that he thinks that they've got maybe  
17 two to three, maybe four cases.

18           One of our cases of the 19 did go  
19 through Roda. We know about him. He ended up at  
20 Walter Reed, so that's how we know about him, but  
21 there may be others. He basically reports that  
22 they extubated and sent back to theater, so I'm  
23 waiting to hear more details about those  
24 particular cases, so we may have a few more that  
25 we can add.

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1 DR. OSTROFF: Okay. We have time for  
2 a couple of questions. First, Pierce, and then  
3 Greg.

4 DR. GARDNER: Having sat through these  
5 phone calls, I learned a couple of new things  
6 today that I'd like to just follow up on. First  
7 of all, I wasn't aware that malaria prophylaxis  
8 was being routine in Iraq.

9 COL. DeFRAITES: Well, I don't know if  
10 it's routine. It was certainly a policy that was  
11 in place.

12 DR. GARDNER: The case that you  
13 presented --

14 COL. DeFRAITES: The case presented  
15 was on doxycycline.

16 DR. GARDNER: -- was on doxycycline,  
17 and menocycline is listed as one of the causes of  
18 eosinophilic pneumonia, so I think that's an  
19 interesting new exposure that I hadn't considered  
20 previously, that we need to certainly look at.

21 COL. DeFRAITES: Well, the issue with  
22 the prophylaxis, I guess, a couple of things to  
23 note. One is that a policy is in place,  
24 compliance is -- and especially in Iraq, there's  
25 been some question of whether it's needed at all,

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1 and certainly compliance is an issue. The other  
2 issue you need to know is, certainly, for 4th  
3 Infantry Division, that division medically  
4 decided to put their soldiers on Mefloquine. So,  
5 certainly, those two soldiers from the 4th  
6 Infantry Division were taking Mefloquine, they  
7 didn't take doxycycline. So as far as a common  
8 exposure, just be aware of that.

9 DR. GARDNER: The other thing  
10 registered earlier is that 10 of the 19 have  
11 pleural effusions, and I think your x-ray of the  
12 case you presented probably does. Were any of  
13 those sampled -- those would be valuable  
14 specimens if they had been tapped. My question  
15 is how many of those were looked at and sampled,  
16 or did they all just disappear spontaneously?

17 COL. DeFRAITES: I don't know how many  
18 were tapped, and I don't know what specimens  
19 might have been saved from those pleural  
20 effusions.

21 DR. OSTROFF: Greg?

22 DR. POLAND: A couple of questions.  
23 For good reason, the 19 have been pretty  
24 intensively focused on, but -- and while it's a  
25 specific, it's not a very sensitive indicator of

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1 what might be happening. Do we know much about  
2 the 81 other cases? I mean, we might consider  
3 somebody who is sick enough to be in the hospital  
4 and on antibiotics and getting oxygen  
5 supplementation but not intubation, as a close  
6 call and maybe reflective of the spectrum of  
7 whatever this entity is.

8 COL. DeFRAITES: Well, of this list of  
9 100 cases, the team in Iraq had the opportunity  
10 to travel to some of the Combat Support Hospitals  
11 to try to obtain whatever data they could, and  
12 that team, by the way, should be back in Texas  
13 today, I think, or soon anyway, depending on  
14 whether they catch a plane or not, but they are  
15 on the way back. And a lot of their data, we  
16 need to wait until they redeploy to actually see  
17 what they have. But the report is, just looking  
18 at x-ray confirmation of some of these  
19 "pneumonia" cases, they can only confirm so far  
20 45 of the 100. But, still, I expect that number  
21 to change, but we have a lot of those questions  
22 in terms of how many of those do we have for  
23 eosinophil counts, for example. In a Combat  
24 Support Hospital, probably none.

25 DR. POLAND: I guess the point is just

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1 that whether it's 80 or 40, whatever, that they  
2 will get the data on those individuals.

3 COL. DeFRAITES: We can. Whatever  
4 clinical information we can, we're going to get.

5 DR. POLAND: Two other sort of quick  
6 questions. On the four that a bacteriologic  
7 diagnosis was made in, did they have  
8 eosinophilia?

9 COL. DeFRAITES: One did. One of the  
10 Strep pneumonia -- actually, the one who had a  
11 Strep pneumonia blood culture positive also was  
12 eosinophilic.

13 DR. POLAND: And the smokers, were  
14 they new smokers?

15 COL. DeFRAITES: Well, nine out of the  
16 ten eosinophilic ones were recent onset smokers.

17 DR. POLAND: And then we've talked  
18 about --

19 COL. DeFRAITES: Of the 19 cases, 15  
20 of them had smoked -- were smokers, were  
21 identified as current smokers. I don't know of  
22 those 15 how many were recent smokers, the only  
23 number I have is of the 10 eosinophilic ones, all  
24 10 were smokers. Nine of the ten were identified  
25 as recent onset smokers.

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1 DR. POLAND: And I never got this  
2 quite cleared up in my own mind, these guys are  
3 buying cigarettes in-theater. Are they buying  
4 Iraqi cigarettes, or they are buying black market  
5 American cigarettes?

6 COL. DeFRAITES: It's hard to say.  
7 They are buying cigarettes from a number of  
8 sources. What we have learned about the  
9 cigarette trade, I guess, so far is that it's  
10 very difficult to know the origin of a particular  
11 pack -- the tobacco in a particular pack of  
12 cigarettes that could be very well American  
13 tobacco that gets repackaged. We wanted to avoid  
14 the term "Iraqi cigarettes" for a number of  
15 reasons. One is it turned out to be not as  
16 important as we thought originally, that most of  
17 the smokers we identified are buying American  
18 brand cigarettes from the Army and Air Force  
19 Exchange Service, AAFES source. So they are  
20 getting the same whatever -- I mean, the source,  
21 such as it is. We haven't tracked back to see  
22 where AAFES obtains all of their cigarettes, but  
23 it's going to be very complicated. I'm not sure  
24 it's going to be all that helpful to decide  
25 because right now our feeling is it really

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1 doesn't make that much difference where you get  
2 your cigarettes, unlike early on, we were  
3 wondering if the street vendor cigarette issue  
4 might be more important. Right now, I don't  
5 think the feeling is that it's that important  
6 right now.

7 DR. OSTROFF: One last comment and  
8 then we're going to have to break; otherwise,  
9 we're going to get way, way off schedule. Greg.

10 DR. GRAY: This is Gray. I think this  
11 is still very dynamic, and I think it would be  
12 very good to get another report on this in the  
13 next meeting. In addition to the EPICON that we  
14 haven't fully heard, there is a clinical  
15 evaluation, a recall, if you will, to Walter Reed  
16 for perhaps some immunological stimulation  
17 testing that would mirror some of the studies  
18 done in Japan that will be certainly interesting  
19 to the Board.

20 DR. OSTROFF: Thanks very much. Why  
21 don't we go ahead and take a five-minute break so  
22 that we can try to get back, and I'm going to  
23 insist on very crisp presentations in terms of  
24 the Preventive Medicine updates. I will say in  
25 terms of this particular investigation, it really

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1 saddens me greatly to think that we're creating  
2 the next generation of lung cancer patients for  
3 the VA system to take care of in the future,  
4 which is what apparently we are doing in these  
5 deployments.

6 (Whereupon, a short recess was taken.)

7 DR. OSTROFF: Okay. According to my  
8 agenda, we're now a half an hour behind, and so,  
9 again, we need to have nice, crisp updates. And  
10 according to my list our first update is going to  
11 be from Health Affairs, and I see the good Col.  
12 Gibson standing up there ready to go. And I'll  
13 point out for the Board members that these  
14 presentations are in Tab No. 8.

15 LtCOL. GIBSON: Good morning. I'm  
16 going to go ahead and start, and because of the  
17 time crunch that we're in right now, there are  
18 four slides at the end of this briefing, I was  
19 going to provide an interim very sketchy update  
20 on our status with Post-Deployment Health Forms.

21 It's real preliminary. I would prefer that we  
22 defer this to next meeting, and we will give you  
23 a much more in-depth approach to this. I was  
24 expecting to have a little more data from an NQMP  
25 review of those data before this meeting, and it

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1 hadn't quite arrived by the time we got here.

2 (Slide)

3 I'm going to update you basically on  
4 three policy issues relative to preventive  
5 medicine that we're working on. In June of this  
6 year, the President of the United States formed a  
7 working group on SARS, and inter-agency federal  
8 working group to develop a concept of operations.

9 There's a coordination document. At this point,  
10 this document provides a basic diagram of  
11 guidance for federal, state and/or local  
12 governments on how they would respond to a  
13 moderate or severe outbreak of SARS. It is a  
14 diagram, it's not a blueprint. It relies heavily  
15 on augmentation from federal, state and local  
16 operating procedures. I would point out that as  
17 of last Friday I went to a meeting with the CDC  
18 and we're well on our way to having a  
19 comprehensive set of operating procedures or  
20 recommendations from CDC on how local, state and  
21 how the Department of Defense would respond with  
22 respect to the specific recommendations in a  
23 number of areas.

24 (Slide)

25 In this CON plan, HHS is a clear

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1 leader on SARS response and control, with CDC as  
2 their main technical expert. The other agencies  
3 who supply supporting roles include the  
4 Department of Defense as well as many others. On  
5 our SARS Working Group, there were 11  
6 departmental representatives and other agencies.

7  
8 DHS -- and this fits in with the  
9 Emergency Powers Act -- DHS would take a lead in  
10 a SARS response if and when those three  
11 situations were to occur -- Presidential National  
12 Disaster Declaration, HHS defers to DHS, or the  
13 President designates DHS for the lead. This CON  
14 plan is based on what you probably have all seen  
15 as a risk-based approach where we start with a  
16 pre-outbreak scenario and progress to a pandemic.

17 I have seen, after looking at several of these  
18 plans including what CDC is working with as far  
19 as their stratifications between Stage 0 up to  
20 Stage 4, what DOD worked on during their exercise  
21 of SARS which went from Stage 0 through Stage 6.

22 They are all very similar, but there are several  
23 differences that will need to be taken into  
24 consideration as this thing continues to evolve.

25 (Slide)

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1           As far as Department of Defense's play  
2 on this CON plan, we are to provide assistance  
3 primarily to HHS and upon approval of the  
4 Secretary of Defense. There are situations  
5 certainly where the assets that we have available  
6 to us will be doing something else, we won't be  
7 able to provide direct assistance, but it will be  
8 in these specific areas. As you can see, it  
9 includes thing like civilian disturbance control.  
10       So it's a wide variety.

11           (Slide)

12           In that light, as we went through the  
13 process in the Department of Defense to outline  
14 how we would support this CON plan, it became  
15 quite evident to us that it's bigger than just  
16 medical. There are more things that need to be  
17 considered as we respond to a SARS outbreak or  
18 any other type of outbreak. This caused us to  
19 realize that we really need to take a look at how  
20 we respond to outbreaks and public health  
21 emergencies and a recognition of needing an  
22 overall plan. This is outside of the Emergency  
23 Powers plan.

24           So we are in the process and we have  
25 in coordination a document to the Joint Staff, to

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1 their planners, to develop an overarching plan  
2 for response to public health emergencies and  
3 disease outbreaks, and they'll engage the  
4 services of Combat Commanders, et cetera. And  
5 we're talking about an overall plan that would  
6 include things like security and logistics and  
7 transportation, and then have annexes to that  
8 plan that would address specific diseases and  
9 specific types of emergencies. As I said, that's  
10 in coordination at the present time. All of the  
11 services have informally agreed to it, and the  
12 Joint Staff is actually somewhat excited about  
13 beginning work on this.

14 (Slide)

15 Quarantine. As you well imagine,  
16 quarantine can have a dramatic effect on the  
17 Department of Defense, particularly with respect  
18 to SARS, from both sides -- from the restriction  
19 of movement of our folks as well as the impact on  
20 host nations. One of our fears as the SARS  
21 epidemic occurred was the fear of bringing it  
22 into Iraq and what it would do to the host nation  
23 -- politically, ethically -- there's many, many  
24 issues on it.

25 Because of that, there's a couple of

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1 things that we have -- the Emergency Health  
2 Powers for Military Installations Policy  
3 document, a DOD Directive that is now in force  
4 that outlines specific special powers that  
5 military installation commanders can invoke in  
6 the event of an emergency, a public health or any  
7 other type of emergency, and the other is what we  
8 have done is task a task force of the Defense  
9 Science Board to address our quarantine guidance.

10 They met last Monday, had a wonderful meeting,  
11 identified areas for improvement. We'll have  
12 several other meetings as we go forward on this  
13 and expect to develop or have recommendations for  
14 further development of DOD instructions, et  
15 cetera.

16 (Slide)

17 And that's it. We're not going to  
18 cover this today. I will provide this briefing  
19 to you -- or Steve -- one of us will provide this  
20 briefing to you at the next meeting. Thank you.

21 DR. OSTROFF: Thanks very much.  
22 Questions or comments for Col. Gibson? Pierce?

23 DR. GARDNER: A couple of quick ones.

24 Certainly, the issues of military preparedness  
25 and deployment I think are important. We need to

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1 certainly keep in perspective SARS in six months  
2 worldwide killed about 900 people, and influenza  
3 in the United States in an annual year alone  
4 kills 50,000 people. And so it's about during  
5 the 18 or 20 week influenza season, the world  
6 experiences about half of one week in the United  
7 States. So, the biggest problem I see coming up  
8 this coming year is the patient who presents in  
9 January with a severe respiratory illness, the  
10 pressure will be on is this influenza or --  
11 unlikely, but still a consideration -- is this  
12 SARS?

13 Our response has been influenza we  
14 don't worry about quarantine, we don't even  
15 attempt to isolate because we think the infection  
16 is so ubiquitous, particularly in young people,  
17 whereas if it's SARS we threaten to close down  
18 cities and the military implications are severe.

19 The emphasis has been on developing  
20 quick diagnostic tests rather disappointingly in  
21 that the SARS tests are not very sensitive early  
22 in the illness, and the influenza tests are  
23 somewhere 70 to 90 percent, they are good but not  
24 perfect. So we have a very significant problem,  
25 I think, operationally for what to do if there is

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1 influenza and some SARS identified both at the  
2 issue of quarantine -- I worry a little bit that  
3 we oversold quarantine and may have had a little  
4 luck in the downward curve. The approach to  
5 influenza and SARS is going to be so different  
6 that we are going to set ourselves up for  
7 different operational choices.

8 LtCOL. GIBSON: Your points are well  
9 taken. The issues of quarantine are not only  
10 being addressed by us, but they are being  
11 addressed by a multitude of other agencies  
12 because of exactly what you're talking about.  
13 The meeting last Friday in Atlanta went into  
14 great depth with respect to, in the face of  
15 influenza cases being able to differentiate SARS.  
16 I would argue that the sensitivity and  
17 specificity of the currently available tests,  
18 while not perfect, are reasonably good. The  
19 problem is we're now in a state of zero  
20 prevalence. Positive predictive value is  
21 abysmal, but the tests themselves in a high  
22 prevalence environment would be somewhat  
23 effective.

24 DR. GARDNER: I understood that the  
25 tests have been not very effective in the first

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1 week of illness.

2 LtCOL. GIBSON: The data presented to  
3 us indicates 95-99 --

4 DR. OSTROFF: Early in the course of  
5 disease --

6 LtCOL. GIBSON: Early in the course of  
7 illness, the type of sample collected, the  
8 possibility of contamination, are all factors  
9 associated with it. Those things were very, very  
10 evident in the discussions last Friday, and the  
11 work that's going on should reflect that.

12 DR. OSTROFF: The other problem, of  
13 course, is being able to do the tests in rapid  
14 enough fashion to be able to guide your  
15 decisionmaking in terms of what you have to do.  
16 I think many of us look at what just happened in  
17 Singapore and hope that we can evolve to a model  
18 where basically they just flipped on the switch  
19 and put all of the measures in place so rapidly  
20 based on one particular case that it amazes me  
21 how effortlessly they did that based on their  
22 experience earlier in the year. Of course, most  
23 places in the United States are not Singapore is  
24 the problem. And I was amazed and impressed at  
25 how efficiently they put in place every single

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1 control measure that they had last spring.

2 DR. GARDNER: One question that I'd  
3 like to hear, I can't think of any other  
4 respiratory virus in which children aren't a very  
5 significant part of either the illness or the  
6 epidemiology. And SARS stands out what appears  
7 to be an exception, although I'm not sure we have  
8 sufficient data on children to know. It makes a  
9 big difference what you do in a community  
10 regarding closing down daycare centers and  
11 schools versus the adult isolation.

12 DR. OSTROFF: Not to belabor the  
13 point, but in many of the areas that had problems  
14 with SARS, they did close down the school  
15 systems, but part of the reason they did that is  
16 because parents were afraid to send their kids to  
17 school, not because they thought that they were  
18 necessarily propagating the outbreaks, and so  
19 people didn't want to send their kids on buses  
20 and do all kinds of other things where they may  
21 potentially have been exposed.

22 DR. GARDNER: Do we have some  
23 serologic data on the kids?

24 DR. OSTROFF: There are a number of  
25 studies that are being done looking at household

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1 contacts of individuals where there were known  
2 cases of SARS, and at least what I've heard  
3 preliminarily suggests that the serologic data  
4 appear to be what the clinical data appear to be,  
5 which is that for some reasons kids just didn't  
6 seem to get disease or get infected at nearly the  
7 rate that you would predict for most other  
8 respiratory illnesses, and nobody quite  
9 understands why.

10 Col. Jones.

11 LtCOL. JONES: Okay, sir. I may go  
12 through these slides relatively quickly.

13 (Slide)

14 What I want to begin with is a brief  
15 overview of Occupational and Environmental Health  
16 Surveillance.

17 (Slide)

18 I know it's going to be a little tough  
19 to read this slide, but you've got the slides in  
20 your book.

21 (Slide)

22 Basically, we're looking for a  
23 comprehensive approach from before anyone deploys  
24 all the way to post-deployment. In between,  
25 we've got base camp assessments that would be

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1 going on, moving on to assessment of risks from  
2 particular types of exposures that may occur.  
3 But, again, what we're looking for is a  
4 comprehensive assessment, and the goals that we  
5 have for each of those are depicted there.

6 (Slide)

7 I just want to very quickly mention a  
8 couple of things with regard to our guidance.  
9 The main instruction that deals with health  
10 surveillance is undergoing a major revision.  
11 It's out for staffing right now. So that will be  
12 very important.

13 Also, with regard to how we're doing  
14 on our policy, Dr. Chu issued a memo in May of  
15 '03 expressing some concern about how well we  
16 were doing in actually capturing and archiving  
17 this data. It directed that specific documents  
18 be archived, and also the time frame for  
19 submission of those reports. He also directed  
20 that the Joint Staff develop procedures for  
21 ensuring that this takes place, and so the  
22 Director of the Joint Staff signed out some  
23 guidance with regard to that. What we try to do,  
24 of course, is not to make things more difficult  
25 for folks, but to actually establish some

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1 procedures using existing reporting mechanisms  
2 and things where we can actually begin to track  
3 and make sure we're actually capturing this data.

4 (Slide)

5 I'm going to very quickly talk about  
6 the three kinds of data that we are attempting to  
7 collect. The actual intelligence data, the  
8 preparation of the battlefield before anyone  
9 deploys; surveillance data, this would be the  
10 routine type data and base camp assessments; and,  
11 also, when specific incidents occur, like the oil  
12 well fires would be a good example, the sulphur  
13 fires, to weight the yellow cake storage facility  
14 when there were some concerns about exposures  
15 there, are examples.

16 (Slide)

17 And I'm not going to go into each of  
18 these, they are in your book.

19 (Slide)

20 But I want to talk about what we are  
21 trying to do in terms of actually capturing this  
22 data. (Slide)

23 So the time frames are -- there is  
24 another database -- I know we've talked about  
25 several -- Defense Occupational and Environmental

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1 Health Reporting System is going to be the place  
2 where we now have a Web-based system for the  
3 field to be able to input this data.

4 (Slide)

5 And, again, we've got two kinds of  
6 data, the actual sample data itself and then the  
7 actual reports that are generated as well,  
8 anything from situation reports to other specific  
9 reports that are developed, and the time lines  
10 are shown here.

11 (Slide)

12 I'm going to go quickly into DNBI  
13 monitoring now.

14 (Slide)

15 I talked about this at our last  
16 meeting, and I talked about the Joint Medical  
17 Workstation. The idea is to get a common medical  
18 operating procedure. A piece of that is DNBI  
19 reporting, and that was implemented on very short  
20 notice, as Ms. Embrey mentioned, during Operation  
21 Iraqi Freedom. The main issue as we looked at it  
22 was that a lot of the units that were not  
23 reporting that should have been reporting. Part  
24 of that may have been training issues, may have  
25 been connectivity issues, other issues, but that

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1 has gotten much better since that time. We're  
2 finding, of course, that we can issue guidance  
3 and say you need to do these things, but we also  
4 have to make sure that we have procedures in  
5 place to ensure that it gets done. And so that  
6 has gotten much better. And it's also being  
7 expanded now to the U.S. Forces Korea in their  
8 brick and mortar facilities to start out with.  
9 Eventually, that will move to the field units in  
10 Korea. So a systematic approach. Again,  
11 ultimately what you'd like to see is that we have  
12 that common medical operating picture for  
13 commanders for nonbattle injury in all theaters  
14 of operation as an ultimate goal. And JTF-  
15 Liberia has also been using the system, but only  
16 for weekly reporting thus far.

17 (Slide)

18 I'm going to very quickly talk about  
19 the Force Health Protection strategic document.  
20 This is our vision document that was published in  
21 1999. Generally, I think, a very well accepted  
22 document in our community, but it was getting a  
23 little bit old and also a lot of things have  
24 happened.

25 (Slide)

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1           So the need for update was clearly  
2 determined. Dr. Winkenwerder wanted to see it  
3 updated. They convened subject matter experts to  
4 do that. The Joint Preventive Medicine Policy  
5 Group, which many of us in this room on the  
6 military side sit on, was one of the groups that  
7 looked at two of the major pillars. The Joint  
8 Readiness Clinical Advisory Board looked at  
9 casualty care and management, and Health Affairs  
10 looked at the infrastructure piece. Again, the  
11 document was very well received, we got a lot of  
12 good comments, and it's expected to be published  
13 in October 2003. So, basically, the text is  
14 complete. Now it's just working with the  
15 publishers to develop the CD-Rom and glossy  
16 versions.

17           (Slide)

18           Why did we have a need to do this  
19 update? Well, there's a lot of things that have  
20 happened over the last few years. We had the  
21 SECDEF and the Chairman of the Joint Chiefs of  
22 Staff priorities -- winning the War on Terrorism,  
23 enhancing joint warfighting, and transforming the  
24 force -- all at the same time.

25           The MHS Strategic Balanced Scorecard

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1 was discussed earlier, and the issue of weapons  
2 of mass destruction, the big issue, that  
3 certainly has become much more prominent.

4 (Slide)

5 Really, I'm not going to go into each  
6 of the pillars and the changes that were there  
7 because there's not enough time. You can read  
8 through those, if you are interested, but  
9 basically the basic structure and content was  
10 maintained. I think as we looked at it we felt  
11 it was still a very good document, but what  
12 you're going to find is that there's emphasis in  
13 various areas with regard to the things that I  
14 just mentioned -- weapons of mass destruction, in  
15 particular, CBRN type threats stressed throughout  
16 the pillars in a much more definitive way. And I  
17 think that probably the section that got the most  
18 change was the one on casualty prevention and  
19 protection, and that was even changed in title  
20 because the protection piece emphasizing the need  
21 to protect forces from particularly the  
22 chemical/biological/radiological type threats.

23 (Slide)

24 And, again, I'm not going to go into  
25 that in detail.

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1 (Slide)

2 Again, I think the document was very  
3 solid to begin with, we think it's even better  
4 now in reflecting more the current priorities of  
5 our leadership. It has been fully staffed, and  
6 we think that it continues -- the previous  
7 capstone document I think has served us well in  
8 terms of looking at our performance during  
9 Operation Iraqi Freedom and Operation Enduring  
10 Freedom, but we are again setting the vision for  
11 where we need to go from here.

12 If you look at the document from '99,  
13 you see that we have come a long way. Obviously,  
14 we still have a long way to go, and you've heard  
15 presentations already on some of those issues  
16 that come up.

17 That's my last slide, unless you have  
18 any other questions.

19 DR. OSTROFF: Col. Jones, thanks very  
20 much. Questions or comments from the group?

21 DR. HERBOLD: One question or  
22 observation. It's great to see the Joint Staff  
23 engaged in this. My question is are all these  
24 programs, processes, directives, being integrated  
25 and is a standard set of data being collected,

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1 and is everybody doing it the same way?

2 LtCOL. JONES: I think increasingly  
3 the answer is yes, increasingly. These are joint  
4 systems, and the approach has been a joint  
5 approach. The major guidance other than the DOD  
6 instruction and directive thus far has been the  
7 Chairman's memo with regard to health  
8 surveillance. That's really been what's guided  
9 us. That's probably now wrapped up into the DODI  
10 to a large extent. But I would have to say I  
11 think for the most part we're becoming  
12 increasingly joint and in terms of the way we  
13 approach these things, not only in terms of how  
14 we approach the problem but in terms of  
15 collecting the data and putting in the common  
16 systems that we can then also draw out the data  
17 later in a common way. So I think we've come a  
18 long way. I don't think we're there yet, but  
19 we've made a tremendous amount of progress, I  
20 think.

21 MS. EMBREY: To respond to that, the  
22 capstone document which Dave briefed has really  
23 changed how we look at what we want to do in the  
24 Department, and when I first came into this  
25 position we realized that if that was the way the

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1 medical community and the Department wanted to  
2 move, then we needed to codify that in directive  
3 and policy and instructions. We needed to review  
4 and validate our approaches to the problems and  
5 challenges to the system through that prism.

6 We established a Force Health  
7 Protection Council, which is all of the two-stars  
8 plus a bunch of the Preventive Medicine folks and  
9 even some of the training folks. And what we are  
10 trying to do now is to address not only all these  
11 challenges, but how can we do this in a joint  
12 fashion, including surveillance, including  
13 reduction of preventable injuries and disease.  
14 It's a completely different way of doing  
15 business, and I think we all had growing pains.  
16 Initially, we didn't like necessarily sitting in  
17 the same room, but I think we're getting better  
18 at it.

19 DR. OSTROFF: In 60 seconds or less,  
20 could you give us a little bit of information  
21 about the more specifics on the mental health  
22 strategy?

23 LtCOL. JONES: Well, this is a vision  
24 document, and what you're going to see is that  
25 even the things that I picked up -- I tried to do

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1 a comparison of the documents to each other, so  
2 there is more emphasis on the mental health  
3 strategy. I wouldn't be able to give you a lot  
4 of detail on that. Again, it's a vision  
5 document, so it is pretty high-level type  
6 wording. A lot of detail is often not in there,  
7 it's enough to guide us, but I would say -- the  
8 main thing I would say is that there certainly is  
9 more emphasis on having an actual strategy. It  
10 doesn't say what the strategy is. The vision  
11 document doesn't lay out the fact that this is a  
12 complete strategy because what we were trying to  
13 do is cover the whole force protection gamut in  
14 about 40 pages. So it's not the strategy itself,  
15 but it lays out what we need to do.

16 DR. OSTROFF: Very good.

17 DR. LAUDER: Tammy Lauder. Just real  
18 quick to clarify, are these then potential pieces  
19 of data that we have -- going back to your  
20 question that you want the Board to answer -- is  
21 this information that we have that we can perhaps  
22 use towards outcome measures -- and getting back  
23 to his question if they are standardized -- then  
24 is this useful information to use in the future?

25 MS. EMBREY: I think it's the outline

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1 of where we want to go and the topics we want to  
2 be addressed to be effective, but I don't think  
3 it gets to data definitions.

4 DR. OSTROFF: Thank you very much.  
5 Our next presentation is from the Army. We have  
6 Col. Underwood.

7 COL. UNDERWOOD: Thank you. Good  
8 morning.

9 (Slide)

10 This is really not just a review --  
11 many experts in this audience and well-published  
12 on this subject, but of course we know that ARD  
13 is a leading cause of morbidity. Especially at  
14 basic combat training posts, the military is very  
15 susceptible. We have the classic triad of the  
16 host, the agent and the environmental factors  
17 coming together to provide that "opportunity" of  
18 disease and, therefore, we have conducted routine  
19 surveillance of ARD in basic trainees going back  
20 to 1967.

21 (Slide)

22 Just a reminder -- don't need to  
23 remind you -- but up there is the case  
24 definition, I'll let you read through that.

25 (Slide)

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1           We have routine tracking of indicators  
2 of streptococcal disease activity, and weekly  
3 calculation rates of the strep recovery rate and  
4 the index, the Streptococcal ARD Surveillance  
5 Index, called the SASI, that was developed by  
6 John McNeill at WRAIR. When we monitor sick call  
7 at TMCs, Troop Medical Clinics, for trends in  
8 Acute Respiratory Disease.

9           (Slide)

10           Just to go over these indices again --  
11 strep recovery rate and how that's calculated,  
12 strep cultures among the cases times 100 divided  
13 by the total cultures of those cases, and that's  
14 calculated weekly. And then the SASI, which is  
15 an index -- it's the strep recovery rate times  
16 the number of ARD cases per 100 over the number  
17 of trainees, and that's calculated weekly. The  
18 trip wire in that is over 25 for two consecutive  
19 weeks, and then we start worrying about that.

20           (Slide)

21           We vaccinate trainees against  
22 everything. Unfortunately, now we can no  
23 longer, as you know, vaccinate them against  
24 adenovirus 4 and 7 since the production of that  
25 ceased in '96, and then we ran out of stocks of

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1 that in the late '90s.

2 (Slide)

3 This update really wants to get to the  
4 heart of what we're doing with Bicillin  
5 prophylaxis at our basic combat training posts,  
6 and it's variable.

7 Fort Leonard Wood reports Bicillin  
8 prophylaxis. They've used that in their trainees  
9 continuously since '96, and if they discover  
10 strep disease within a company or battalion of  
11 recruits four weeks or more after the original  
12 prophylaxis, they will administer another dose to  
13 the entire company or battalion. That's Fort  
14 Leonard Wood, Missouri.

15 (Slide)

16 What does Fort Knox do? They report  
17 Bicillin prophylaxis has not been used since  
18 1996. They did use it, however, for one  
19 streptococcal disease outbreak among trainees.

20 Fort Sill, Oklahoma, they report  
21 Bicillin prophylaxis for every trainee since  
22 1998. They also administer a second dose if  
23 strep disease is found four or more weeks after  
24 the original dose.

25 (Slide)

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1 Fort Jackson, South Carolina, they did  
2 not use Bicillin prophylaxis. And Fort Benning,  
3 Georgia, they use Bicillin prophylaxis in  
4 trainees, and they've used it continuously since  
5 1998.

6 (Slide)

7 The Chiefs of Preventive Medicine at  
8 these Combat Training Post installations submit  
9 the Acute Respiratory Disease Surveillance  
10 Report, that's called the ARDSR, on a weekly  
11 basis. And then the Army Medical Surveillance  
12 Activity collects those and coordinates that and  
13 analyzes that. So let's get to the slides here.

14 (Slide)

15 These are also reproduced in your  
16 books. So, what happens at Fort Leonard Wood.  
17 Just as a reminder, Fort Leonard Wood is one that  
18 uses Bicillin prophylaxis, and then they  
19 rephylax if they have a case. And you can see  
20 there that they have some laterally more ARD  
21 activity, but their SASI index is fairly low, so  
22 the activity of a strep is really below baseline.  
23 Now, they had a bit of a peak there, if you look  
24 back, in the early 2000, in spite of using  
25 Bicillin prophylaxis.

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1 (Slide)

2 Let's look at Fort Knox and what goes  
3 on there and, really, they've remained below the  
4 baseline pretty much both in their ARD activity  
5 as well as their SASI index, although you can see  
6 over here, more recently their ARD rate is  
7 starting to climb. And just as a reminder, Fort  
8 Knox does not use Bicillin prophylaxis.

9 (Slide)

10 Let's take a look at what's going on  
11 at Fort Sill. At Fort Sill -- and just as a  
12 reminder, Fort Sill uses Bicillin prophylaxis --  
13 you can see several spikes of high activity for  
14 strep. And I talked to Dr. John Brundage about  
15 that, he really can't quite explain that. But  
16 notice that their ARD activity is low also, even  
17 though there's a spike in strep activity there.

18 (Slide)

19 And then let's look at Fort Jackson.  
20 As a reminder, Fort Jackson does not use Bicillin  
21 prophylaxis, but Fort Jackson has not tripped the  
22 wire for ARD or strep activity in the last couple  
23 of years.

24 (Slide)

25 And then, lastly, let's look at Fort

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1 Benning, and Fort Benning is sort of all over the  
2 place -- a lot of ARD activity. The SASI index  
3 has remained low except in the earlier part of  
4 the graph there. And, again, you notice that  
5 even though the SASI index spiked, the ARD  
6 activity was not in concordance with that.

7 Subject to your questions, that  
8 completes my briefing.

9 DR. OSTROFF: Let's open it up to  
10 comments or questions. Can you enlighten us as  
11 to how such a disjointed approach to Bicillin  
12 prophylaxis evolved?

13 COL. UNDERWOOD: I'm certainly not the  
14 expert on this. In fact, Dr. Petrucelli -- he's  
15 not here -- he was supposed to present this. I'm  
16 kind of standing in as a pinch-hitter here. I do  
17 know that -- I know that this august body  
18 considered other activities that could be done in  
19 light of the fact that we were losing our  
20 capability of vaccinating against adenovirus 4  
21 and 7, so they considered other measures. And  
22 correct me if I'm wrong, but one of those  
23 measures was to consider using Bicillin  
24 prophylaxis to control the amount of  
25 streptococcal activity. But what is of interest

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1 to me is that it's not necessarily concordant in  
2 some cases, and there is --

3 DR. OSTROFF: Yes, but I think that it  
4 harkens back to -- with the Board's current --  
5 you know, previous observations that there's  
6 probably a lot more that goes into determinations  
7 about when and where respiratory illnesses occur  
8 that are probably a lot more administrative in  
9 terms of what they do in ventilation and close  
10 contacts, et cetera, that probably vary markedly  
11 from one of these locations to the next that also  
12 has a strong determining factor.

13 COL. DeFRAITES: I might be able to  
14 answer a little better since I've been kind of at  
15 the helm, Col. Underwood hasn't. Really, disease  
16 control practice -- we have a general policy that  
17 lists Bicillin as one of the tools that can be  
18 used. The main issue is tracking what's going on  
19 at your installation and then employing those  
20 tools. There's a lot of local pressure, I guess,  
21 or preferences in terms of whether you employ  
22 Bicillin or not. A lot of these spikes of ARD  
23 without strep reflect outbreaks of adenovirus.

24 In general, our approach is we don't  
25 dictate that everyone must use Bicillin or not

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1 use Bicillin, we tend to work on an individual  
2 basis. And, again, it's interesting that some of  
3 these places, like Fort Leonard Wood, have  
4 traditionally been the hotbed of strep, for  
5 whatever reason.

6 The other thing about Fort Sill is  
7 some of these outbreaks are also linked to other  
8 populations, and it's linked in a way to the  
9 Marines at San Diego in that they actually have  
10 Marines training for Artillery School at Fort  
11 Sill, and there has been introduction and cross-  
12 pollination, if you will -- one-way street. We  
13 don't send any soldiers to San Diego, as far as I  
14 know, but these Marines coming in there bring in  
15 their strep from San Diego may be a factor, at  
16 least in some of the more recent outbreaks, but  
17 they have been linked.

18 DR. OSTROFF: Blame it on the Marines.

19 (Laughter.)

20 CDR. LUDWIG: Could I just comment  
21 briefly? Sharon Ludwig. In a former, I was the  
22 ARD Control Officer for the Army for about four  
23 years, in '94 to '98, or something like that.  
24 The policy on using Bicillin was really based on  
25 experience at the local installation, and I was

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1 on an outbreak investigation at Fort Leonard  
2 Wood. They had stopped using Bicillin for a  
3 while, and in '96, they started again after the  
4 outbreak of strep infection.

5 So there was no Army-wide policy, as  
6 Bob mentioned, basically because the experience  
7 differed at each installation. And it was based  
8 roughly on their experience.

9 DR. OSTROFF: Glen, and then Greg.

10 DR. MORRIS: Just, again, looking  
11 briefly at these data, it sure does suggest that  
12 the prophylaxis, if anything, seems to be  
13 associated with higher levels of strep. And I  
14 think we're beginning to recognize increasingly  
15 that prophylactic use of antibiotics may have  
16 significant impact on subsequent occurrence of  
17 disease modifying the existing flora, changing  
18 colonization, and I think that this really is  
19 something that perhaps a very careful look needs  
20 to be taken, and potentially this is one area  
21 where it may not be judicious to use prophylaxis.

22 I realize there's a kind of local history, but  
23 sometimes local history is more sort of anecdotal  
24 than it is in terms of data-driven. And these  
25 data are somewhat persuasive.

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1 DR. OSTROFF: Well, I'd be a little  
2 cautionary, though, because part of it is that  
3 there are certain locations that have  
4 traditionally had problems with strep, and those  
5 are the locations that then tend to use the  
6 prophylaxis. Those that don't have problems with  
7 it tend not to use it. And so saying which is  
8 cause and which is effect is sometimes difficult.

9 DR. MORRIS: It's difficult.  
10 Although, I guess the question is are the  
11 recruits coming to these places from --

12 COL. UNDERWOOD: All over the country.  
13 They are geographically representative of a  
14 microcosm of the U.S. I mean, they are not  
15 necessarily from that specific state, for  
16 example. Does that answer your question?

17 DR. MORRIS: That answers my question.

18 DR. OSTROFF: If you're from Arkansas,  
19 you don't go to Fort Leonard Wood, is what it's  
20 saying. Greg.

21 DR. GRAY: This is Greg Gray. I guess  
22 two other things to think about, one is there's a  
23 good paper -- I think it's in Emerging Infectious  
24 Diseases this month, with Gakstetter (phonetic)  
25 and Musher (phonetic), that document at an Air

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1 Force Base an unusual, perhaps more virulent, EMM  
2 type was implicated in a Group A strep outbreak  
3 that they had there -- finally, six years later  
4 they got the paper out.

5 The other thing that is important to  
6 consider when you wrestle with is PPG (phonetic)  
7 important or not is the proportion of people who  
8 were receiving nothing we showed, pretty well  
9 documented in a New England Journal article ten  
10 years ago, that one of the reasons that we had an  
11 epidemic in the Navy in San Diego was because  
12 about 7 percent reported an allergy self-report  
13 and received nothing, and they were a reservoir  
14 for the continued transmission.

15 DR. OSTROFF: Well, I might suggest  
16 that this is a fertile area for a potential  
17 question to come to the Board in the future.

18 Thanks very much. Let's move on to  
19 the Navy presentation. We have a new presenter,  
20 Capt. Kilbane, and I'm just wondering whether  
21 it's going to be the Navy or the Marines that are  
22 going to talk about the malaria because one of  
23 them has to do that.

24 CAPT. KILBANE: Well, I'll talk about  
25 the malaria issue, but just to let you know,

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1 originally I was going to try to defer some of my  
2 time for LCdr. Zinderman to make his  
3 presentation, and then we have the malaria issue  
4 come up.

5 I'm Edward Kilbane. Most of my career  
6 in the civilian world and in the military has  
7 been as a pathologist, so I'm very interested in  
8 the laboratory aspects of this.

9 Just two items that I would like to  
10 tell you about from Naval Medicine is, one is as  
11 I have just gotten this job at the Bureau of  
12 Medicine and Surgery, it has become very apparent  
13 to me that a lot of the public health and  
14 preventive medicine efforts in the Navy are  
15 highly fragmented. One of our projects for this  
16 year is to do an assessment of how this should be  
17 managed, and in that effort we put in an  
18 application to the National Public Health  
19 Leadership Institute at North Carolina, to try to  
20 get some of their guidance and facilitation in  
21 doing this process.

22 The other thing that I would like to  
23 just give you a quick update on is the malaria  
24 situation with the Marines. On the 15th and 16th  
25 of August, we had the Quick Reaction Force go

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1 ashore in Monrovia. That was approximately 150  
2 Marines that were in that group. By the 24th to  
3 the 26th, that group redeployed back to their  
4 ship. Initially, many of them had some  
5 nonspecific symptoms of aches and pains that  
6 passed within 48 hours.

7 Then on the 3rd, 4th, 5th of  
8 September, many of them started running very high  
9 fevers, diarrhea, other symptoms. The diagnosis  
10 of malaria was made based on smears on the 4th of  
11 September, and the situation changes daily. As  
12 of Friday, we had 51 people under treatment. As  
13 of Monday, 54. And now Col. DeFraithe tells me  
14 as of today there are over 70 under treatment.

15 When you put everybody together, you  
16 get approximately 225 people who were at the  
17 International Airport. This is the approximately  
18 150 people in the Reaction Force plus support  
19 people who shuttled back and forth.

20 The investigation of this outbreak is  
21 right now under the control of the Joint Task  
22 Force and the European Command. It's not being  
23 run by the Navy, although we've sent a Navy  
24 investigator out at their behest, who is doing  
25 this, and he is aboard the ship, so our

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1 communication with him is not real great. And I  
2 would expect at our next meeting we'll give you  
3 the full update on what the results of that  
4 investigation are.

5 So, if you have any questions of me,  
6 right now the investigation is ongoing, and they  
7 are looking at everything, of course, so I'll  
8 answer any questions that you have right now.

9 DR. OSTROFF: Can you give us some  
10 sense as to what the investigation constitutes?  
11 I mean, is there some sort of a formal  
12 epidemiologic study being done?

13 CAPT. KILBANE: There is, there are  
14 questionnaires that are being done onboard the  
15 ship. The same questionnaires are being  
16 administered to the patients who have been at  
17 Bethesda. Bethesda has had over 30 of the cases.

18 Some of the cases have been in Landstuhl. Many  
19 of the cases right now are being treated aboard  
20 the ship, don't require MEDEVAC. So that is  
21 going on right now. Any other details of the  
22 investigation they haven't shared with me yet.

23 DR. CLINE: Are the questionnaires  
24 being administered on an anonymous basis?

25 CAPT. KILBANE: Yes.

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1 DR. CLINE: Because I don't see how  
2 you could get accurate information otherwise.

3 MS. EMBREY: There is also the EPI  
4 team that's been sent from EUCOM.

5 CAPT. KILBANE: Pardon?

6 MS. EMBREY: You might want to address  
7 the EUCOM EPI team that's been deployed.

8 CAPT. KILBANE: As far as I know, the  
9 offer has been made and EUCOM is responding. I  
10 don't have any further details on that myself.

11 DR. OSTROFF: Pierce, and then I think  
12 there was another comment over here.

13 DR. GARDNER: I guess the astounding  
14 thing here is the incidence over such a small  
15 short period of time.

16 DR. OSTROFF: Inconceivable to me.

17 DR. GARDNER: Pre-chloroquine or any  
18 kind of prophylaxis treatment you could send  
19 people into this area, and you're up to 70 cases  
20 and it's almost a third of the folks in a short  
21 period getting ill. I can't imagine --

22 DR. OSTROFF: If you tried.

23 DR. GARDNER: If you sent them there  
24 and sat them down in the evening in short-sleeve  
25 shirts, you wouldn't -- this exceeds any

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1 incidence rate I've ever heard of, by a lot.

2 CAPT. KILBANE: Well, we've don't know  
3 if they've been in Speedos and combat boots, you  
4 know. This is something they're going to look  
5 into, and it's very odd because this seems to be  
6 a unique situation for people who have been at  
7 the airport. We've had other forces in the  
8 country, in other places, but just at this time,  
9 at this place, there seems to be an astounding  
10 attack rate. So, again, it's subject to the  
11 investigation.

12 DR. OSTROFF: I have to ask the  
13 question -- I mean, I have no idea what the long-  
14 term plans are for Liberia, but I guess the  
15 question is what is going to be done differently  
16 to make sure that the next group that deploys  
17 into Monrovia doesn't have the same fate, because  
18 we don't know what happened, but all I know is  
19 you don't want to do the same thing again that  
20 just happened. So you have to do something  
21 different.

22 CAPT. KILBANE: Yes. And I've already  
23 gotten calls from the Canadians who are deploying  
24 forces there. Right now, everyone is on both  
25 Mefloquine and doxycycline, just in case to cover

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1 for Mefloquine sensitivity in the falciparum.

2 DR. OSTROFF: I can assure you that is  
3 not the reason.

4 CAPT. KILBANE: Well, you can today.  
5 Last week, we didn't know.

6 COL. DeFRAITES: This is Col.  
7 DeFraites. I wanted to just contribute a little  
8 bit of what the Army is doing to help out with  
9 this. For one thing, only 21, that I know of  
10 today, of the 75 so-called cases, only 21 have  
11 been confirmed by slide diagnosis as being  
12 malaria. It's still a very high number.

13 What is being done now is levels have  
14 been drawn -- blood levels have been drawn to  
15 measure Mefloquine levels of the Marines. I'm  
16 not exactly sure of the timing of the blood, but  
17 I understand it's soon after they got back  
18 onboard ship they had blood drawn for some  
19 reason, and they are using that blood for  
20 Mefloquine. I think CDC is actually doing those  
21 levels.

22 They are also assaying the Mefloquine  
23 tablets that they -- from the same lot or the  
24 same batch, really, that they were taking to try  
25 to add -- shed some light on this situation

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1 because it is astounding to us this high attack  
2 rate.

3 Looking back in this area, though, the  
4 British forces in 2000 ran into some problems  
5 with falciparum malaria in Sierra Leone, and  
6 certainly West Africa is certainly a high-risk  
7 area -- very high-risk area. With that in mind,  
8 it's still pretty amazing in ten days to get this  
9 high attack rate. It's sort of unprecedented.

10 The last time we've had problems and  
11 even a death in the Army due to malaria was a  
12 Special Forces soldier who was deployed to West  
13 Africa, who died with malaria. Whether he died  
14 from malaria or not is still a matter of debate,  
15 but that was the last fatal case we had. So we  
16 definitely have issues and a lot of concern about  
17 how to best protect troops, especially in Africa,  
18 against falciparum.

19 DR. OSTROFF: Is anybody considering  
20 Malarone?

21 COL. DeFRAITES: Well, we're  
22 considering everything right now, but I think  
23 that the immediate decision was made that if we  
24 have to deploy more people, we're going to give  
25 them doxycycline. I think that's the decision

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1 right now, until further notice, which is  
2 probably the best thing to do right now until we  
3 get this Mefloquine thing sorted out. I guess  
4 there's been some hints about in vitro resistance  
5 to Mefloquine from other African countries  
6 without really any clinical correlation in terms  
7 of whether -- I mean, no one feels that  
8 Mefloquine has lost its --

9 DR. OSTROFF: Not in that part of  
10 Africa.

11 COL. DeFRAITES: -- no definite  
12 evidence of Mefloquine resistance in terms of  
13 clinical failure of treatment of Mefloquine. So,  
14 you don't want to throw Mefloquine out too  
15 prematurely. In our experience, the three main  
16 reasons for malaria in troops that otherwise are  
17 supposed to be given a prophylaxis is they didn't  
18 take their pills; second is they didn't take  
19 their pills; and third is they didn't take their  
20 pills. So, I think until further notice we just  
21 have to suspend judgment until we have some more  
22 information to go on.

23 Certainly from, I guess, the early  
24 indications from this group is that there was a  
25 concerted command emphasis on taking prophylaxis.

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1       The other protective measures I don't think were  
2       as well emphasized -- in other words, bed nets,  
3       barriers and repellents, but certainly the  
4       chemoprophylaxis -- we all know chemoprophylaxis  
5       by itself is not adequate, still it's astounding  
6       attack rate, no matter what it turns out to be,  
7       if it's 21 or 75 or probably somewhere in  
8       between, it's still pretty amazing to all of us.

9               DR. OSTROFF: Jackie.

10              DR. CATTANI: Jackie Cattani. I just  
11       wanted to clarify whether, in fact, they're  
12       taking Mefloquine plus doxycycline as  
13       prophylaxis, or just they have switched to  
14       doxycycline.

15              CAPT. KILBANE: The information I had  
16       last week was they were taking both. Now that  
17       may again have changed.

18              COL. DeFRAITES: Was that just the  
19       Marines?

20              CAPT. KILBANE: Yes, that was just the  
21       Marines.

22              COL. DeFRAITES: The Marines that have  
23       redeployed. I think for -- EUCOM I think has  
24       decided that if anyone else goes in there, that  
25       they are going to give them doxycycline.

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1 MS. EMBREY: To put this in context,  
2 the guidance that goes to the people that are  
3 going into Liberia comes from the EUCOM  
4 commander. It's his guidance on what kind of  
5 medical prophylaxis is appropriate to the threats  
6 in his theater. And that's why you have the  
7 Navy/Marine Corps perspective, but they are  
8 guided by the EUCOM commander and the Surgeon's  
9 advice and guidance printed in otherwise updated  
10 guidance on what they should and should not be  
11 doing. So it's very appropriate that you  
12 understand that because they are looking to the  
13 EUCOM Surgeon and the guidance that comes from  
14 there on the right way to go, and they are  
15 working together. EUCOM is the one that has  
16 initiated the epidemiological investigation in-  
17 country.

18 The Navy, on the other hand, and the  
19 Marine Corps are working very diligently to do  
20 the questionnaires, to try to understand the  
21 situation on the ground with the patients, and to  
22 get good information to inform that  
23 investigation.

24 It's also important to know that the  
25 EUCOM guidance was, as Dave briefed to you

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1 before, that there would be weekly DNBI reporting  
2 in terms of medical surveillance, and this weekly  
3 reporting the Friday of the week that it would  
4 occur had not been prepared for the weekend when  
5 all of the evacuations started occurring. So we  
6 have -- our surveillance system wasn't timely  
7 enough to give us advance notice about this, or  
8 to even be -- although on the ground the Navy was  
9 doing -- or the Marine Corps and the Navy were  
10 doing an outstanding job of dealing with it  
11 locally, in the system there was no awareness of  
12 this. And it truly is unusual.

13 So, everybody is alerted, I think the  
14 Navy and the Marine Corps, especially given the  
15 fact that there were some severe complications  
16 associated with this, did an outstanding job of  
17 taking care of the people who were affected by  
18 this. It's amazing that you had one cerebral  
19 case, I think?

20 CDR. McMILLAN: Two.

21 MS. EMBREY: Two. So it popped up, it  
22 was very fast, it's very unusual, and right now  
23 there's a lot of investigation going on. There's  
24 a lot of -- the first data you get is always  
25 about 50 percent wrong, and then after you look

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1 into it you get better data. So please don't  
2 jump to conclusions based on what's being talked  
3 around the table now, let the investigation  
4 occur, let the data come in, and I think the next  
5 time we talk to you, if you want, when we have  
6 better information we can give that to you  
7 through separate meetings or conference calls or  
8 whatever. I just don't think that we -- it's  
9 less than two weeks.

10 DR. OSTROFF: I'm not jumping to any  
11 conclusions at all. All I can say is there was  
12 some system failure here, and what exactly that  
13 system failure was I'm not sure, and I'm not  
14 going to also jump to the conclusion that they  
15 didn't take their medication because there are  
16 other explanations for why this could have  
17 happened. But there was some unbelievable to all  
18 of us sitting around the table who have dealt  
19 with malaria for some period of time,  
20 unbelievable system failure that I don't quite  
21 understand, that needs to be fixed pretty darned  
22 quickly, and I would like to request that in the  
23 same way that we've had some telephone calls  
24 about the pneumonia investigation, if we could  
25 maybe constitute a small group of our malaria

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1 experts around the table that might be able to  
2 help at least bounce some ideas off of you as you  
3 progress in these investigations, or get some  
4 feedback about what the findings of the  
5 investigations are because I think that there are  
6 significant implications here.

7 MS. EMBREY: If you do that, work with  
8 Steve Phillips on my staff. He's the unfortunate  
9 point.

10 DR. OSTROFF: There's probably not a  
11 member around the table that this didn't catch  
12 their attention, so I think that we -- I don't  
13 want to wait until February to hear what the  
14 upshot of all of this was.

15 COL. GARDNER: Some cases did show up  
16 at the next weekly report.

17 CAPT. KILBANE: But these are  
18 reportable events.

19 DR. OSTROFF: Thank you. Our next  
20 update is from --

21 COL. RIDDLE: Is Craig going to do it?

22 CDR. McMILLAN: Yes. I was just going  
23 to introduce him.

24 DR. OSTROFF: That's why you confused  
25 me, it wasn't the right name that was on the

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1 list.

2 CDR. McMILLAN: I'm Cdr. McMillan. I  
3 was just going to introduce the lead investigator  
4 on a subject that we're going to update today,  
5 Dr. Craig Zinderman, from EPMU2.

6 LCDR. ZINDERMAN: Good afternoon. I'm  
7 a Preventive Medicine Officer from EPMU2 in  
8 Norfolk, Virginia -- Navy Environmental and  
9 Preventive Medicine Unit, for those of you who  
10 don't know me, and we'll just launch right into  
11 it.

12 (Slide)

13 We're going to be talking about the  
14 Methasone-Resistant Staph.aureus infections, skin  
15 and soft tissue infections that have occurred at  
16 Parris Island, U.S. Marine Corps Recruit Depot  
17 over the past couple of years. A little bit of  
18 background here. These are all community-  
19 acquired infections in otherwise health recruits,  
20 folks who have not been hospitalized, not been on  
21 antibiotics. They are mostly skin and soft  
22 tissue infections. And we first heard of cases  
23 there in August of 2001, with just a handful of  
24 cases. And shortly after that in the ensuing  
25 winter, the cases went down to the baseline

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1 level, which is about 0 to 2 per month at the  
2 Recruit Depot. Then there was a large outbreak  
3 last year in 2002 overall, which you heard about  
4 last meeting in February. Between August and  
5 December of last year there were 220 cases at the  
6 Recruit Depot in the recruits, and there was an  
7 investigation done by Navy Environmental Health  
8 Center and EPMU2 at Parris Island in November of  
9 last year.

10 Cases again this winter went down, and  
11 then in May of this year again we saw another  
12 outbreak begin, and cases have continued to rise  
13 since then. There's another investigation  
14 conducted by myself and other folks from EPMU2 at  
15 Parris Island in June. We're going to talk about  
16 some of the findings and recommendations from  
17 that.

18 We've defined cases as MRSA positive  
19 cultures that have been taken from the site of  
20 infection, so positive nasal screening cultures,  
21 that doesn't count as a case, these are only  
22 actual infections.

23 (Slide)

24 This slide shows the data from both  
25 2002 and 2003, and you'll just see that cases

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1 began in July, around July and August of last  
2 year, and then the large outbreak; going down in  
3 the winter, in January and February, and then  
4 increasing beginning in May of this year all the  
5 way up to 71 cases in July, and then 99 cases  
6 last month, in August. This data is updated  
7 through September 1st. These are all numbers --  
8 the denominator of recruits at Parris Island  
9 ranges, depending on the time of year, from 3,000  
10 to about 6- or 7,000. It translates -- at least  
11 for the last two months it translates to 11 cases  
12 per 1,000 recruits in July and 14 cases per 1,000  
13 recruits in August.

14 (Slide)

15 Overall, we haven't found a specific  
16 common source at Parris Island where the cases  
17 originate from. There is not an elevated,  
18 remarkably elevated rate in any particular  
19 company or platoon. There's not a remarkably  
20 elevated rate after any particular training  
21 evolution or week of training. Instead, it seems  
22 that increased prevalence in communities  
23 throughout the country, throughout the eastern  
24 half of the United States, parallels the rise in  
25 MRSA that we see at Parris Island, and perhaps

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1 the recruits who come to Parris Island from the  
2 eastern half of the country bring it in as they  
3 are colonized with MRSA when they come to recruit  
4 training.

5           There are lots of factors that can  
6 increase your rate or your risk of infection  
7 during recruit training, particularly the close  
8 contact between recruits. They are always in  
9 contact with one another -- shared sleeping  
10 space, almost always touching in their training  
11 events, hand-to-hand combat training, confidence  
12 training courses and other courses like that.  
13 Hygiene, of course, is a major issue. Hygiene  
14 may not be as good as prior to recruit training.

15       They have limited time for showers and  
16 handwashing throughout the day.

17           Heat and humidity Parris Island is  
18 known for. That increases their growth of  
19 infection of organisms, as well as the fact that  
20 they are always -- or often when they are doing  
21 PT and other activities, they are just wearing PT  
22 gear, so they have a lot of exposed skin, rolled-  
23 up sleeves, and lots of exposed skin-to-skin  
24 contact.

25           The exposed skin also gives them a

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1 high risk for superficial injuries. Just the  
2 nature of their activities and the physical  
3 nature of training, there's a high risk that  
4 they're going to have a lot of superficial  
5 abrasions and cuts just routinely throughout  
6 their training, as well as insect bites.  
7 Spending the majority of the day outside they  
8 suffer a lot of insect bites. Many recruits  
9 report that they scratch these and then that ends  
10 up being their MRSA infection.

11 And then, of course, there's lots of  
12 stress associated with recruit training --  
13 limited sleep, different eating schedule, first  
14 time away from home -- so lots of stress they  
15 undergo, and changes in their immunity because of  
16 that.

17 (Slide)

18 This data just shows an example of  
19 MRSA cases by training week. This is for about  
20 200 cases that have occurred in 2003 so far. And  
21 you see that we have a peak first starting to  
22 rise in weeks 4 to 5, after they've been there  
23 for about a month. I just wanted to note the  
24 rifle range time when they do their weapons  
25 training is about weeks 6 and 7. A lot of

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1 recruits and staff at Parris Island associate  
2 those activities with contracting MRSA infection.

3 During weapons training, they spend most of  
4 their time on the ground in a prone position.  
5 And we do see a relatively small spike a week or  
6 two after rifle range training in weeks 8 and 9,  
7 which is known as the "Team Week" period. Then  
8 cases seem to go down again in week 10, and then  
9 they increase again during the "Crucible". The  
10 Crucible is the final training event. It's a 56-  
11 hour cumulative exercise that's done all in the  
12 field. They don't have any opportunity for  
13 showering or handwashing during this time and,  
14 most often, they don't sleep more than a couple  
15 hours as well, and we see some spike there as  
16 well as after the Crucible, about a week after.

17 (Slide)

18 From the epidemiologic perspective, we  
19 don't see that there's a clustering specifically  
20 in any one particular company or platoon.  
21 Recruits on Parris Island are divided into  
22 different companies. There's about 16 companies  
23 there at any one time, and each company is  
24 divided into about 6 platoons.

25 Most of the platoons are affected. Of

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1 all the platoons that were there on September  
2 1st, 40 percent had had at least one case of MRSA  
3 during the time a platoon had been there. Some  
4 platoons are more heavily affected than others.  
5 Those that are heavily affected have attack rates  
6 that range in general from 5 to 15 percent, but  
7 that's been as high as 30 percent for some  
8 platoons.

9           What we're doing now is epidemiologic  
10 surveillance on a weekly basis. We're receiving  
11 data on the cases that have occurred and  
12 pertinent demographic information, epidemiologic  
13 information, so that we can identify what  
14 platoons are having cases and which platoons are  
15 most heavily affected, and then those platoons  
16 can get some direct control measures.

17           (Slide)

18           Hygiene is a big issue that we  
19 reviewed this year. There were some  
20 recommendations made last year as far as  
21 increasing showering time and adequate showering  
22 that they made in November, as well as possibly  
23 using hand-sanitizers. A lot of those  
24 recommendations were put in place, and some Drill  
25 Instructors have indeed ensured that their

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1 recruits get adequate showers every day,  
2 sometimes twice a day, as well as handwashing 4  
3 to 5 times a day, but many were not, so the  
4 hygiene changes were pretty much inconsistent.

5 The Recruit Depot did issue policy  
6 changes to try to make the Drill Instructors  
7 focus on hygiene. They are also issuing personal  
8 hand-sanitizer lotion to every single recruit as  
9 soon as they start recruit training. What we  
10 found this year is that the recruits aren't  
11 actually carrying the hand-sanitizer, so they are  
12 not using them.

13 We also addressed issues of hygiene  
14 inspections. They get hygiene inspections about  
15 once a week where the recruits are actually  
16 looked over -- all their skin, arms and legs --  
17 but that's not routinely done by medical  
18 personnel, at least not frequently throughout  
19 training, so we recommend that that's done weekly  
20 by medical personnel so you can catch more  
21 infections on an earlier basis.

22 Environmental transmission is not  
23 really suspected to be a major factor. MRSA and  
24 Staph aureus is generally spread hand-to-hand  
25 contact or contact with an infected wound so,

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1 therefore, we haven't really focused on  
2 environmental transmission. We did do some  
3 random surface sampling of areas where you might  
4 expect recruits to come in contact with this  
5 year, and all of our samples were negative. In  
6 limited sampling over the past couple of years,  
7 most of them have been negative as well. We can  
8 conduct more environmental sampling if we do have  
9 EPI data that focuses on a particular area or  
10 training event.

11 DR. OSTROFF: Did you sample their  
12 weapons?

13 LCDR. ZINDERMAN: We did take some  
14 sampling of rifles, various rifles that were  
15 present on the weapons ranges that they used when  
16 they were there, and they were negative.

17 (Slide)

18 The direct interventions that we're  
19 doing now is if a platoon is identified as having  
20 more than 5 percent of recruits affected with  
21 MRSA, that Drill Instructor gets interviewed to  
22 see what his hygiene practices are for those  
23 recruits. The Drill Instructor receives training  
24 on MRSA and hygiene prevention, as well as all  
25 the recruits in that platoon. Showers are

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1 enforced in the platoon, as well as frequent  
2 handwashing throughout the day, 4 to 5 times a  
3 day, either with running water or with the hand-  
4 sanitizers. We also prescribe Hibiclens for the  
5 entire platoon to help eradicate the bacteria.

6 The medical providers do a good job of  
7 recognizing the bacteria. They are culturing  
8 everything that can be cultured to help confirm  
9 all the diagnoses, and then they receive that 4-  
10 prong treatment if a case is confirmed.

11 We're also doing genetic testing of  
12 some samples from last year and this year to try  
13 to identify if there is one predominant strain  
14 involved in transmission, or if there's multiple  
15 strains possibly originating from different sites  
16 in the country.

17 (Slide)

18 This is my last slide, and I just want  
19 to say that we're continuing the focus on hygiene  
20 and identifying the platoons that are most  
21 heavily affected, and we're also possibly looking  
22 into some more in-depth studies, and that's an  
23 issue that can be discussed, doing more in-depth  
24 research studies at Parris Island. And I've just  
25 listed a couple there for consideration --

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1 perhaps colonization surveys because you can  
2 screen the interior areas for the presence or the  
3 carriage, asymptomatic carriage of MRSA as well,  
4 as some prophylaxis options. Mupirocin has been  
5 used in hospitals to eradicate MRSA carriage, and  
6 that can be looked at, although there is a pretty  
7 high failure rate and even Mupirocin-resistant  
8 MRSA can develop.

9 So that's it for my presentation.

10 DR. OSTROFF: Thanks very much. We'll  
11 open it up for questions. I guess the good news  
12 here is that we eradicated malaria from the South  
13 Carolina coast.

14 (Laughter.)

15 Yes, it's down in Florida now, so we  
16 have to worry about it possibly coming back.

17 One question I would ask is can you  
18 give us some sense of the severity of these  
19 particular infections and what sorts of  
20 complications have occurred? In many of the  
21 locations where we're having problems with MRSA,  
22 these are really nasty infections, and very, very  
23 difficult to take care of.

24 LCDR. ZINDERMAN: The vast majority  
25 have been very minor skin and soft tissue

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1 infections. They are notified by the lab within  
2 48 hours that it's a positive culture. Often,  
3 they've already been given some treatment. And  
4 when they are called back to the clinic to get  
5 put on this 4-prong treatment, their lesion is  
6 healing. And that's what the providers most  
7 often report.

8           There have been some more severe  
9 cases, even a few cases of osteomyelitis that  
10 were reported to us last year, but that's more  
11 rare. It's not what we widely see with this,  
12 it's usually on the more mild side.

13           DR. OSTROFF: Pierce, and then Barney.

14           DR. GARDNER: It seems to me we've  
15 always felt strongly that colonization precedes  
16 infection, and Staph.aureus in general, and I  
17 would certainly focus on learning more about  
18 these isolates. It seems to me one of the  
19 fundamental questions are these recruits who  
20 arrive with some staph, and because of the stress  
21 and the abrasions and all, now get infected with  
22 their own -- or, as you suggest, is this  
23 spreading throughout groups, and the only way you  
24 really get that is if you fingerprint the  
25 organism, then you can do some real epidemiology.

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1 But I think just collecting the overall clinical  
2 data doesn't get to how they actually got  
3 colonized in the first place.

4 DR. OSTROFF: I'm not particularly an  
5 expert in MRSA, but I've heard several  
6 presentations from our group -- Fred Tenover  
7 (phonetic) in our laboratory, who is the expert  
8 on this -- and there is not a huge amount of  
9 diversity amongst MRSA strains that are producing  
10 community-acquired infections. And so there are  
11 certain clones that have popped up in community  
12 settings and certain clones that are in hospital  
13 settings, and the two of them tend not to mix  
14 very much. And so even if you found that they  
15 are all pretty similar to each other, I'm not  
16 sure it's going to tell you a huge amount.

17 Barney, and then Glen.

18 DR. CLINE: Do you have data on the  
19 anatomical distribution of lesions? I wonder if  
20 that might give us some clue as to --

21 LCDR. ZINDERMAN: We do have the data  
22 on the anatomic distribution. I can provide that  
23 to you, I don't have it to show you right now.  
24 But the vast majority, 80 to 90 percent, is  
25 either on an arm or a leg. The knee is the most

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1 common site, and the elbow is the second most  
2 common.

3 DR. MORRIS: Glen Morris. Just to  
4 follow up on your comment, we're actually looking  
5 at some of these isolates. I'm working with  
6 Scott Thornton, and we're using multi-loci  
7 sequence typing, and actually we're running the  
8 studies this week, but we should have some  
9 answers with the multi-loci sequence typing.  
10 We're seeing some fairly good ability to separate  
11 out some of this stuff.

12 LCDR. ZINDERMAN: I just wanted to add  
13 also that we've recently begun to consult with  
14 and work with some of the experts from CDC on  
15 MRSA -- Scott Friedkin (phonetic) and some others  
16 there. So they will be advising us as we go  
17 along.

18 DR. OSTROFF: Very good. Other  
19 comments? Greg?

20 DR. GRAY: Greg Gray. I think early  
21 on you indicated that possibly insect bites were  
22 contributing, if not transmitting, certainly a  
23 site that gets scratched. So, another  
24 intervention you might try is Deet. And I know  
25 you have sand flies there as well to wrestle

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1 with.

2 LCDR. ZINDERMAN: We've investigated  
3 the issue with Deet, and what we found -- I'll  
4 just give you a quote from a Drill Instructor.  
5 We said, "How do you use Deet in the recruits",  
6 and they have a can of Deet, a personal can for  
7 each recruit. However, they have only 1 per 4  
8 recruits wear it. And we said, "Well, when do  
9 you put it on", and they said, "Well, when I  
10 think they need it". We interpreted that as when  
11 the Drill Instructor gets bit he says, "Use your  
12 Deet". So we recommended frequent application of  
13 Deet using the Deet lotion.

14 DR. GRAY: And the other thing I  
15 wanted to say is you've tried a number of  
16 different interventions here all at the same  
17 time. We're often forced to do that as a public  
18 health official, but now you can't really tell  
19 what's working and what's not. So, wherever you  
20 can, I'd encourage you to set up some sort of  
21 control to see if your intervention is working.

22 And, finally, Roger over there, who  
23 has got a Ph.D. thesis that he's not yet  
24 published, but maybe you could comment on -- I  
25 think what you have differs from what they are

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1 using --

2 LtCOL. GIBSON: I use PCMX,  
3 paramethachlorylzyline (phonetic), as  
4 antimicrobial hand wipe, and did a clinical trial  
5 in basic training. We got a 30 percent reduction  
6 in placebo-based randomized clinical trial, group  
7 randomization, we have 30 percent reduction in  
8 upper respiratory disease, and I believe a  
9 tenfold reduction in group A strep with the use  
10 of these.

11 We recommended four times a day, that  
12 was the protocol. Same sort of thing, the  
13 recruits ended up using them about twice a day,  
14 but we still got effect from that. And you might  
15 think about a change in the product. PCMX has  
16 been around for a long, long time. It's in a lot  
17 of soaps and things like that, but it does show  
18 some good efficacy. It does not smell real well,  
19 though.

20 DR. GRAY: Isn't that something they  
21 could carry in their pockets rather than a  
22 dispenser that they probably won't carry?

23 LtCOL. GIBSON: Yes. They were just  
24 little handwipes like you get when you go to  
25 Kentucky Fried Chicken, that sort of thing,

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1       except there was an antimicrobial in them, and I  
2       found through this study that it was quite  
3       effective.

4               DR. OSTROFF:   Well, fortunately, you  
5       have winter coming on, too.

6               DR. CAMPBELL:   One thing that stays in  
7       common is the Drill Instructors and the staff.  
8       Have you done evaluations of their carriage rate  
9       because they can probably get this thing from  
10      class-to-class.

11              LCDR. ZINDERMAN:   In the investigation  
12      last year in 2002, not this year but last year,  
13      we did nasal screening of over 500 employee staff  
14      members at the Island, and a very low rate were  
15      positive.   Only 24 of those individuals were  
16      positive, and they were all treated, but that's  
17      the data that I have on that.

18              DR. OSTROFF:   I always thought Drill  
19      Instructors were impervious to microbes.

20                               (Laughter.)

21                               John.

22              DR. HERBOLD:   One thing that stays in  
23      common is Drill Instructors and training  
24      instructors and cadet leaders who believe that  
25      they are smarter than the public health advice.

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1 We found serious problems in Basic Cadet Training  
2 at the Air Force Academy about 20 years ago --  
3 not published -- of water-deprivation because the  
4 Drill Instructors had decided "you will drink  
5 when I think that you need to". And somehow the  
6 command authority needs to help educate these  
7 folks that there are important things that they  
8 are liable for when these recruits are in their  
9 care. And I don't know if it needs to turn on a  
10 legal term or not, but somehow the message needs  
11 to get across that "this is your responsibility  
12 and it affects combat effectiveness, it affects  
13 the effectiveness of your training programs".  
14 And that message is not getting across.

15 DR. OSTROFF: Last comment, and then  
16 we'll have to move on.

17 LtCOL. GIBSON: Echoing John's  
18 comments, we're spending quite some time at  
19 Lackland Air Force Base working with recruits.  
20 This sort of thing would wax and wane. We would  
21 make an impression with a group commander, and we  
22 would get reductions in respiratory diseases. We  
23 get reductions in all kinds of things when they  
24 were concerned and pushed that down.

25 A change in command, a change in the

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1 Preventive Medicine Officer, it never got  
2 institutionalized. And I think we need to start  
3 thinking about, as we talk about aerobic testing  
4 and command responsibility for your troops, the  
5 same sort thing in another preventive medicine  
6 arena.

7 DR. OSTROFF: I'll be happy to go down  
8 there and bark at them. Okay. We're going to  
9 move on. Cdr. McMillan?

10 CDR. McMILLAN: Just a couple of quick  
11 points on some stuff that you've got in your  
12 handout. I won't put the slides back up and  
13 stuff, but I want to give a quick follow-up on  
14 the injury prevention program that I think was  
15 introduced to you before.

16 Right now, that's on track and on  
17 time. We got the funding approved and released.

18 The athletic trainers are actually onboard, and  
19 they are starting to collect data now as far as  
20 the injuries that they are seeing. They are out  
21 trying to do some preventive or primary  
22 prevention in the field, working and looking at  
23 ergonomics and stuff. Right now it looks like  
24 the biggest issue with this kind of trial program  
25 is going to be the demand for those services.

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1 They are already quite busy in the clinical  
2 setting and getting them out into the areas for  
3 doing the primary prevention and changing some of  
4 the things we talked about, some of the  
5 institutionalizations of "we've always done it  
6 this way", and maybe that's not the smart way to  
7 do it, we're looking at that.

8 So, just three points on the last  
9 slide that are continuing issues that we're going  
10 to be looking at -- the deployment health issues,  
11 of course, with the malaria issue, is some of the  
12 things that we're looking at; ATSDR study for  
13 Camp Lejune -- they have been looking at well  
14 water contamination and relation to birth  
15 defects. They've got, I guess, a second phase of  
16 a study that appears to be soon coming out, that  
17 we may be asking the AFEB to look at their data  
18 and their findings to help to validate whether  
19 that's really a viable or supportable conclusion.

20 And then, of course, what Dr. Zinderman just  
21 presented as far as the MRSA study expansion. I  
22 mean, we still know we have some areas to look  
23 at, some things to look at, some ways to do  
24 business there. The Deet issue is an example as  
25 far as -- it turns out that the recruits are

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1 actually buying the Deet for themselves at the  
2 Exchange. There's no formal program in which it  
3 is issued to them. They get a little stipend,  
4 that's what they are expected to buy with it.  
5 So, we're looking at issuing this. In fact, they  
6 have a new sunscreen Deet formulation that they  
7 can use and start getting that institutionalized  
8 as far as "you're going out in the field, you  
9 apply this stuff". So those are areas that we're  
10 looking at.

11 DR. OSTROFF: Thanks very much. Any  
12 comments or questions? I know that for those  
13 Board members who are relatively new, the injury  
14 prevention initiative is one that's near and dear  
15 to many of our hearts, and I hopefully will get  
16 an opportunity at some point in the future to go  
17 back to San Diego and be able to see some sort of  
18 reduction in the number of injuries that are  
19 being seen among the recruits there. I'd  
20 certainly like to be able to do that and see some  
21 positive benefits from this. Thanks very much.

22 Other comments?

23 (No response.)

24 Let's go ahead and move on to our next  
25 presentation. Kelly, I'm told that you are going

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1 to defer to Col. Cox.

2 COL. COX: I suspect it's an  
3 inauspicious sign when the prompter is flashing  
4 red before you start.

5 (Laughter.)

6 In keeping with our "buggy" theme, I  
7 thought we'd move on and just use this  
8 opportunity to talk about something that so far  
9 has escaped media exposure, but that honeymoon  
10 period is likely to have ended. I'm told that  
11 some journalist contacted the Deployment Health  
12 Surveillance Directorate yesterday requesting  
13 current facts and figures regarding Leishmaniasis  
14 in our ongoing operations. So this will just be  
15 an opportunity to tell you what we've been  
16 looking at already because we recognize this as  
17 an area of concern. And anytime that a common  
18 name for a condition includes a geographic  
19 location, it sort of is a hint. So, since there  
20 is something known as the "Baghdad boil" over a  
21 number of centuries, we went into this open-eyed  
22 and recognized that we might have some issues to  
23 deal with with Leishmaniasis.

24 (Slide)

25 It turns out that in certain parts of

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1 the country it's worse than usual, and I'm just  
2 going to focus a little bit on Tallil Air Force  
3 Base, which is an Air Force site from which most  
4 of the cases have come to-date, and why that's  
5 unique but not entirely unique, and back with the  
6 Shiite uprising a number of years ago, the  
7 previous regime in Iraq had taken some action  
8 following that -- not necessarily as a reprisal,  
9 but at least that's the way we've interpreted it  
10 -- in that they drained much of the water that  
11 was around this area that had previously been  
12 sort of a swampy area, marshy, and now it became  
13 arid and cracked earth, and it greatly expanded  
14 the breeding ground for the sand flies in that  
15 area. So we knew that there was an unusual  
16 situation. We knew that we couldn't treat it  
17 well, and that there was plenty of reservoir, and  
18 now we had plenty of naive hosts in the area as  
19 well who were getting bitten. And as you can see  
20 by the numbers, there were lots of sand flies  
21 being collected in these traps. And some of  
22 these individuals reported hundreds of bites on  
23 their body. So, having actual disease cases show  
24 up was just the next step.

25 (Slide)

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1           So we did want to try and get ahead of  
2 that, and we recognized that every single bug-  
3 bite couldn't be evacuated and every single  
4 lesion couldn't be sent back out-of-country  
5 either, and so there were some steps taken to try  
6 and help, and the Army was able to insert an  
7 individual who is relatively unique in that he's  
8 a physician, infectious disease specialist, but  
9 also has a Ph.D. in paracytology and pathology,  
10 and works with Leishmaniasis. So that gave them  
11 that rather robust and sophisticated in-theater  
12 capability at Tallil which is not normally going  
13 to be present -- and that was in association with  
14 the Theater Army Medical Laboratory that was  
15 stationed at that same site -- and so those cases  
16 were being reviewed by this individual so they  
17 could get a pretty strong diagnosis prior to  
18 evacuating them back for treatment. And it  
19 wasn't limited just to the people at Tallil, you  
20 could send others from around the area if you  
21 could get them to him for a consultation. But,  
22 obviously, this doesn't apply to the entire  
23 theater and, as you will see, some of the cases  
24 occur in Afghanistan and other places as well.

25           (Slide)

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1           There were just two cases that I had  
2 the most information on because they were Air  
3 Force, and so I was able to track them down for  
4 reportable events, but even then it's a little  
5 bit sketchy.

6           The common theme that we're seeing,  
7 though, as has been in the previous examples  
8 discussed today, too, is that there have been  
9 lapses in personal protective equipment. The  
10 lapses cover a spectrum of what constitutes a  
11 lapse, and sometimes it's that they didn't have  
12 the material, other times the material was  
13 ineffective, other times people just weren't  
14 using it. But in these two cases, the first one  
15 is relatively classic. I can't really identify  
16 how he got exposed and had a lot of bites, but he  
17 had a lesion on his foot. Originally, he  
18 prescribed it to new boots, and so he didn't seek  
19 treatment very soon. And, initially, it was  
20 diagnosed as cellulitis as opposed to  
21 Leishmaniasis, but there wasn't a great delay  
22 there. As you can see, it was only a couple of  
23 days before the actual diagnosis was made.

24           The second case is a little more  
25 worrisome in that it shows that what appears to

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1 be a relatively minor exposure, similar to what  
2 was discussed with the malaria cases, this  
3 individual was not assigned to Tallil. He  
4 actually worked down in Al Jaber and worked on  
5 convoy duty and took trucks up and overnight,  
6 because there wasn't enough time to safely return  
7 to his home station, they would remain in the  
8 local area there. That means those individuals  
9 who don't have a tent assignment and they don't  
10 have some of the other equipment maybe that they  
11 should have, so he was sleeping in the back of  
12 the truck in a sleeping bag, took off most of his  
13 uniform because it was hot, and woke up and found  
14 that his arm had not remained inside the sleeping  
15 bag, it was outside, and he had lots of bites on  
16 it.

17 The other thing that's a little bit  
18 interesting on these two cases is that they show  
19 a rather short incubation period, although I'm  
20 not entirely confident on the data on when these  
21 people came into the theater, but we'll see some  
22 other numbers from the Army experience shortly to  
23 expand that range a bit.

24 (Slide)

25 So, if you look at the total numbers -

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1 - and I'll have to say here a bit of a  
2 disclaimer, there is an article going to be  
3 submitted to MMWR, and we hope published in the  
4 near future, and the numbers don't exactly match  
5 up. And this is often the case early on. As  
6 we've said, we're trying to track down cases,  
7 they may not have all been confirmed yet, and so  
8 my numbers are slightly higher than what's  
9 showing up -- 10 is what's going to be reported  
10 in the MMWR article, covering May of '02 through  
11 the end of August '03.

12 I have heard of several other cases,  
13 and that would bring my total up to 17 as opposed  
14 to 10, and so we'll sort through that and we can  
15 let you know later. But most of them had been  
16 from Tallil, most of them had been in the Army.  
17 And the only other things that are different is  
18 that the time in-theater reported in the MMWR  
19 article is a median of 52 days with a range of 20  
20 to 100-and-something. So, certainly, the  
21 traditional findings have been incubation periods  
22 on the order of a few weeks to a few months, but  
23 in a number of these cases they seem to have been  
24 remarkably short, such as one week, but our main  
25 concern was that many of these would show up

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1 later in the States.

2           They have all been L. major so far,  
3 the ones that have been speciated, and that  
4 luckily does not usually involve any visceral  
5 involvement. However, in the local area, they  
6 are known to have other species of leishmania  
7 which are associated with visceral, and so that's  
8 probably our greatest concern, is that people  
9 will redeploy to the States and it won't be  
10 diagnosed in a timely fashion.

11           I'll modify the note. When I made  
12 these slides originally, I only had access to the  
13 article that's referenced at the bottom there.  
14 There was a follow-up article by the then Cdr.  
15 Hiams (phonetic) in 1995, where they had  
16 identified one additional visceral case which  
17 actually didn't even manifest until greater than  
18 two years after having returned to the States,  
19 and then there were two more cutaneous cases, so  
20 the total should be 19 and 12 there.

21           (Slide)

22           So, what were we worried about? Well,  
23 we've talked about most of that already. A lot  
24 of it has to do with personal protective  
25 equipment, the logistics, making sure it's there,

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1 making sure command emphasis is correct, and  
2 somehow overcoming humans' capacity to accept  
3 rather than the credible people from the public  
4 health preventive medicine staff that are talking  
5 to you locally, they are far more willing to  
6 accept the incredible source of information. So,  
7 at Tallil, there was from some individual a story  
8 about if you use your bednets, you trap the sand  
9 flies in with you and you get lots more bites.  
10 So, many of those people refused to use their  
11 bednets even if they had them. So, again, you  
12 have to be fighting the risk communication game  
13 and working through these issues.

14 Two things that I didn't put up here -  
15 - I actually thought about it some more -- the  
16 reason we should probably be more worried -- a  
17 lot of people say, "Well, in Desert Storm you  
18 only found the 19 cases, the 12 cases, et  
19 cetera". But the big difference to me is that  
20 here we have a lot more urban exposure, and the  
21 previous operations were pretty much secluded in  
22 desert climates and away from the urban areas,  
23 and so there wasn't as much likelihood of seeing  
24 the sand fly. And even then we had that number  
25 of cases.

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1           And the other big difference is that  
2 Desert Storm/Desert Shield, most of the people  
3 were not there in the active period of time.  
4 This time, we're spanning the complete active  
5 season, which is April through November. So we  
6 might actually worrisomely see a significant  
7 number of these cases. And the big thing was to  
8 make sure, especially for Guard and Reserve that  
9 come back and our VA colleagues who aren't here  
10 to know that we were thinking about them, is that  
11 we wanted to make sure physicians would be ready  
12 to pick these up.

13           (Slide)

14           So, some actions were taken, and most  
15 of them in the education area, and all of those  
16 are underway. The medical alert is due out of  
17 Health Affairs shortly. The MMWR article has  
18 been written and is in coordination right now  
19 prior to submission. The risk communication  
20 products are under development as well, and will  
21 be posted on the PD site that was mentioned  
22 earlier today. And so there's a lot of work done  
23 to try and stay ahead of this and make sure that  
24 we capture these as early as possible, and that  
25 it doesn't turn into the pictures of disfigured

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1 individuals on the media and how we didn't  
2 protect our troops.

3 That's the end of the briefing, if  
4 there are any quick questions or comments.

5 DR. OSTROFF: Thanks very much.  
6 Comments and questions? Let's start with Jackie,  
7 and then John Herbold.

8 DR. CATTANI: Jackie Cattani. Just a  
9 question about whether the bednets are treated  
10 with premetherine (phonetic).

11 COL. COX: They are supposed to be.  
12 Again, lapses do occur. So, yes, the materials  
13 are there, and that is the training. One of the  
14 areas we found that was a problem is that some of  
15 the people who even had it didn't necessarily get  
16 shown how to use it properly before they left.  
17 So there's been a number of re-education attempts  
18 made, and the briefings that people get before  
19 they go have been refocused to enhance that and  
20 make sure that the people know how to use it.

21 Turns out some of the things we do  
22 make it difficult. In trying to make life better  
23 for people in the field, we often, as quickly as  
24 we can -- or at least on the Air Force side,  
25 since we're fond of the more comfortable

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1 accommodations, of course, than our other more  
2 serious service members here -- but we take cots  
3 away and replace them with beds, or sometimes  
4 bunkbeds, and then there is no way to use the  
5 available poles and bednets, and so they are not  
6 designed to fit on that kind of structure, so  
7 that's one reason. And there's hope that maybe  
8 because they are in air conditioned tents it's  
9 not such a big deal, but as you noticed even in  
10 the air conditioned tents they were capturing  
11 sand flies because you still have to open up the  
12 flap and come in. And, no, it's not so cold that  
13 they become dormant, which was one of the rumors,  
14 too -- if you had an air conditioned tent, the  
15 sand flies would all go to sleep when they came  
16 in.

17 DR. CATTANI: To respond about the  
18 adaptability of using bednets without structures  
19 to attach them, the Africans really have been  
20 very clever in putting posts up at the end of  
21 beds and stringing nets over them. And the  
22 concept of trapping mosquitoes or sand flies  
23 inside an untreated bed, especially when you get  
24 in and out or if it has a hole in it, is really  
25 true, and that's the whole point of impregnated

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1 nets reduce or eliminate that entirely because it  
2 kills them. So, it's an important factor.

3 COL. COX: It is stressed in all the  
4 services that they should treat their bednets,  
5 but it definitely wasn't happening all the time.

6 DR. HERBOLD: Do you know if there are  
7 a large number of military working dogs in the  
8 theater, and are they experiencing any problems  
9 of this nature?

10 COL. COX: I haven't heard anything  
11 about military working dogs, and whether they go  
12 into that theater or not. I mean, certainly, all  
13 of our permanent installations have military  
14 working dogs, but I'm not aware of them  
15 necessarily being deployed. I can say that there  
16 was a lot of trouble with the local reservoir.  
17 They had lots of the feral dogs in the area, and  
18 they have reduced that population significantly,  
19 which is also great for exposure in the media,  
20 but they can't fully eliminate them and there's  
21 still a lot of them there, and they definitely  
22 are carriers.

23 DR. CLINE: With this density of  
24 exposure to sand flies, I wonder if there's any  
25 evidence of other sand fly transmitted diseases

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1 such as sand fly fever?

2 COL. COX: Sand fly fever hasn't  
3 broken out as an individual diagnosis that we've  
4 made. I mean, at this point all we have is  
5 cutaneous leishmaniasis that we've found. We  
6 certainly have heard a lot of stories in the  
7 local population and talking to the local medical  
8 people, and one of the problems is we don't have  
9 the greatest data from the Iraqi public health  
10 system right now, the infrastructure has been  
11 disrupted for a couple of years. They haven't  
12 reported to the WHO in recent years, but prior to  
13 that time they had thousands of cases annually,  
14 of course. The story is that there are no  
15 children to be seen anymore in those surrounding  
16 communities because they have all developed  
17 visceral leishmaniasis and didn't have treatment  
18 available. And so all you see are adults and very  
19 young infants. But, again, how much of that is  
20 anecdote and how much is fact is very hard to  
21 sort out at this point.

22 DR. OSTROFF: We're going to have to  
23 move on. I will point out that leishmaniasis  
24 does call eosinophilia, so I'm curious as to  
25 whether anybody has actually looked at the

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1 eosinophil counts. Something to think about.

2 We have two more presentations from  
3 Preventive Medicine update. Sharon Ludwig, from  
4 the Coast Guard. And I am told that the slides  
5 that are in the briefing book are not the right  
6 slides, so ignore them.

7 CDR. LUDWIG: Right. You have the  
8 wrong slides. I must have pointed and clicked  
9 too rapidly, and subconsciously I wanted you to  
10 have the handouts from the meeting that I missed  
11 in February because of the snow. In any case,  
12 I'm going to go rapidly through a few slides.  
13 I'm going to talk basically about respiratory  
14 illness issues in the Coast Guard.

15 (Slide)

16 In mid July we had a report of  
17 influenza in Ketchikan, Alaska. Civilians had it  
18 and we had a positive or a confirmed test.  
19 Ketchikan is along the Pacific Northwest Coast.  
20 It's basically along the coast of Canada. This  
21 incident led to the establishment of this as a  
22 sentinel surveillance site for the DOD, what used  
23 to be Air Force Project Gargle. So now we'll be  
24 sending in specimens from Ketchikan.

25 (Slide)

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1           A report of 10 pneumonia cases on a  
2 cutter of probably about 150 people that was  
3 supposedly just back from a deployment possibly  
4 to Asia might be Legionnaire's. This is how it  
5 was reported to me as I was called off of leave  
6 to do an outbreak investigation. Turned out to  
7 be, after several phone calls, 6 cases of febrile  
8 respiratory illness, of which 2 were pneumonia.  
9 One was treated as an outpatient, the other was  
10 hospitalized briefly, and the cutter had actually  
11 recently returned from Mexico, and the diagnosis  
12 was mycoplasma pneumonia. It's not surprising,  
13 but hysteria can usually be taken care of, or  
14 often be taken care of with a couple of well-  
15 pointed questions.

16           (Slide)

17           I'm going to skip this slide, it's  
18 just respiratory illness at Cape May experience  
19 over several years.

20           (Slide)

21           The Department of Homeland Security is  
22 involved in the SARS CON plan that was mentioned  
23 and discussed by LtCol. Gibson. The main issue  
24 for the Coast Guard involves the quarantine  
25 issue. We have legal authority to enforce

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1 quarantine but, as I mentioned in my last report  
2 at the last meeting, it had not been formally  
3 worked out, at least in recent memory.

4 This SARS plan, one should understand,  
5 was requested by the White House. The meetings  
6 that I've been to there's been unanimous  
7 agreement that it should not just focus on SARS,  
8 however, the immediate document, the immediate  
9 product had to just address SARS and that in the  
10 future this will be broadened to cover other  
11 disease, communicable diseases.

12 And I'm going to stop there. If there  
13 are any questions, I'd be happy to answer them.

14 DR. OSTROFF: Thanks very much.  
15 Comments or questions?

16 (No response.)

17 If not, why don't we move along.  
18 Thanks. And we're looking forward to the  
19 afternoon. Sharon, one question.

20 DR. POLAND: Do we know what type the  
21 influenza isolate was?

22 CDR. LUDWIG: It was Type A, but I  
23 don't know what the strain was.

24 DR. OSTROFF: And I don't know either,  
25 it's the first I've heard of it, but it would be

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1 interesting to know.

2 Our next presentation is from our  
3 colleagues to the North, who have also had a very  
4 busy infectious disease year, and we have Dr.  
5 Zamorski.

6 DR. ZAMORSKI: Thank you, everybody.  
7 I'm going to aim for about 15 minutes of  
8 discussion per Col. Riddle's recommendation.

9 (Slide)

10 So, thanks to a few people, important  
11 people.

12 (Slide)

13 We all know that after certain  
14 deployments, our members -- CF being Canadian  
15 Forces -- do have an increased risk of mental  
16 distress and diagnosable illness, these medically  
17 unexplained physical symptoms. And we've tried a  
18 number of different things, as have you, to try  
19 to prevent these, but we accept that there will  
20 be times that they fail.

21 (Slide)

22 And we believe that intervening early  
23 rather than late is probably a good idea.  
24 Whether this works or not is uncertain to some  
25 extent. It's reasonably clear that screening and

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1 early intervention for depression, and probably  
2 problem drinking are better than usual care, at  
3 least in some randomized trials. And for PTSD  
4 and medically unexplained physical symptoms, lots  
5 of reason to think it might be the case, lots of  
6 suggested evidence here and there, but never  
7 really convincing and proven. At best, we  
8 accept, though, that if there are potential  
9 benefits here, they are likely to be modest. And  
10 harm is also a possibility for many screening  
11 programs.

12 (Slide)

13 So in response to previous  
14 deficiencies in our own post-deployment care,  
15 about 4 to 6 months after return from deployment  
16 to Afghanistan, the members completed a survey  
17 booklet, which took around 20 minutes. A mental  
18 health staff member interviewed the member for  
19 about 40 minutes -- this is a fairly time-  
20 intensive process. They made recommendations.  
21 The member completed an anonymous evaluation  
22 form, if they chose, and if the member consented,  
23 data was sent to my office anonymously.

24 (Slide)

25 Six or eight weeks later we followed

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1 up to make sure that people who had had follow-up  
2 recommended actually had done so. And this was a  
3 clinical process with a voluntary research  
4 element, this was not a research project.

5 (Slide)

6 So, here is our sample -- 95 percent  
7 male, average 34 -- so different from your  
8 deployments -- a nice balanced similar breakdown  
9 to our forces, which also makes us a little bit  
10 unique in that this is a tri-service analysis of  
11 the aggregate deployment experiences -- average  
12 number of years in the forces, 14; previous  
13 deployment 2.6, on average, and they were  
14 interviewed on an average of 156 days after  
15 return. The Army members were actually  
16 interviewed earlier, which may have an effect on  
17 the results we'll show you here.

18 (Slide)

19 So what did they do? Our land forces  
20 were on the ground in Kandahar, and these were  
21 the first ground forces combat mission since the  
22 Korean War for Canada, so this is a big deal.  
23 This got a lot of attention locally in the media.  
24 And there was, of course, the tragic "friendly  
25 fire" incident which caused the first combat

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1 fatality since the Korean War. Again, this was a  
2 major sort of thing. Rustic conditions. The sea  
3 elements, maritime forces were part of the  
4 maritime blockade in the Persian Gulf and Arabian  
5 Gulf, and the air forces contributed strategic  
6 and tactical airlift.

7 (Slide)

8 Instruments we used. We used the SF-  
9 36. We used a subset of the Prime-MD, and we  
10 also used -- this was forced upon me and proved  
11 not to be valid -- but this sort of doctored  
12 version of the Mississippi Scale, about which I  
13 will say nothing further.

14 (Slide)

15 How many of you are vaguely familiar  
16 with the SF-36?

17 (Hands)

18 This is the most widely used  
19 instrument for health-related quality of life,  
20 and it measures 8 different attributes of  
21 physical and mental health, and those scales on  
22 the left here reflect largely physical, on the  
23 right mental health, and in the middle they  
24 reflect both mental and physical health. The  
25 scales, of course, go from 0 to 100. Note the

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1 scale is truncated there, which will exaggerate  
2 the differences you are about to see.

3 (Slide)

4 And bad scores are low scores, and  
5 good scores are high scores.

6 (Slide)

7 So these are the results. This is in  
8 red. The SF-36 score profile for the Canadian  
9 general population of the same age and sex of our  
10 Op. Apollo sample, and this is the Op. Apollo  
11 group. As you can see, there are 6 statistically  
12 significant differences. Let's go through them.

13 There's no limitation in specific  
14 physical tasks. This is the physical functioning  
15 scale. These are questions like can you climb  
16 stairs? Can you bend over and stoop? Can you  
17 dress yourself, et cetera. So there's no  
18 differences there. However, they believe that  
19 they have physical health problems that interfere  
20 with their life. The questions on the role  
21 physical scale RP, have physical health problems  
22 interfered with your activities, with daily  
23 activities, I guess -- work and other daily  
24 activities, is what it says.

25 They have more pain complains. This

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1 measures both the amount of pain and the extent  
2 to which it interferes. Impaired health  
3 perception, markedly decreased vitality and  
4 energy. So these reflect impaired physical well  
5 being.

6 (Slide)

7 On the emotional well being side, they  
8 have somewhat impaired mental health. This  
9 principally measures anxiety and depression. But  
10 a 3 point decline, which happens to be by  
11 coincidence what we see there, is about equal to  
12 the acute effect of being fired or laid off from  
13 your job, so a 3 point decline is probably a  
14 meaningful change or difference in mental health.

15 However, the emotional problems do not limit  
16 their work or other daily activities, which is  
17 interesting. So, if they are having impaired  
18 mental health, they do not perceive it to be  
19 interfering. They do, however, believe that they  
20 have impaired social functioning with friends,  
21 families, and others. So these reflect impaired  
22 emotional well being.

23 (Slide)

24 This is a comparison between our  
25 ground forces, which had a different deployment

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1 experience, and those of everybody else -- so Air  
2 Force and Navy. The purple line on the bottom is  
3 actually the ground forces and, as you can see,  
4 there are some statistically significant  
5 differences there. The vitality rating there for  
6 the ground forces is equivalent to that of the  
7 average 60-year-old American diabetic. They have  
8 more pain complaints and poor emotional well  
9 being.

10 (Slide)

11 The Canadian general population is  
12 clearly not the same -- even of the same age and  
13 sex, is not the same as our military members, so  
14 we're going to look to see how they compare to  
15 other military members.

16 (Slide)

17 And as you can see -- this is U.S.  
18 Gulf War veterans six years post-conflict. This  
19 is from the Iowa study. And as you can see, the  
20 pattern and degree of impaired physical well  
21 being is strikingly similar to U.S. Gulf War  
22 veterans. I couldn't have picked the data any  
23 better if I had chosen to. And as you can see,  
24 the emotional well being and functioning are  
25 worse than U.S. Gulf War veterans, which is also

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1 concerning.

2 (Slide)

3 And at this point, the Minister of  
4 Defense said, "We don't know what these people  
5 were like before they deployed", and he's  
6 absolutely right, but -- interesting. So there  
7 are a few sort of glimpses we have into this  
8 question. One is there is a health transition  
9 item on the SF-36 and it says "Compared to one  
10 year ago, how would you rate your health in  
11 general now?" And as you can see, there's a  
12 disproportionate number of people who said that  
13 their health was somewhat worse. This is more  
14 than would be expected by aging one year at  
15 average of 34 to average of 34.

16 (Slide)

17 Other reasons to believe it. We have  
18 a lot of data from other surveys, and this is  
19 most curious. When we first started seeing  
20 evidence of this in our Gulf War work in the late  
21 '90s, we sort of discarded it. We had evidence  
22 that the health of our members was poorer than  
23 that of the general Canadian population, and we  
24 said, well, there must be some statistical freak  
25 here, or whatever. And we did several other

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1 studies, and it's a very consistent effect. But  
2 the magnitude of those differences is smaller --  
3 much, much smaller than the ones that we saw.  
4 And at least for the ground forces, the  
5 deployment experiences that these people had were  
6 of the sort expected to cause problems. If we  
7 saw absolutely no mental health morbidity after  
8 those deployment experiences, I would smell a  
9 rat, as we all would.

10 (Slide)

11 So, if we think that at least some of  
12 those are due to deployment, another question is  
13 are these differences we're seeing equivalent to  
14 the health deficit of having a hang-nail or the  
15 common cold, or of having cancer? So, this slide  
16 tries to address that issue.

17 So, just to simplify things, you can  
18 actually collapse the SF-36 scores into a mental  
19 summary score and a physical summary score, and  
20 you'll see those represented here. Here are some  
21 various conditions. First is Op. Apollo, and  
22 this will be the difference between Op. Apollo  
23 and the age and sex match the Canadian general  
24 population. Land Forces is land forces only  
25 versus Canadian general population, and then

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1 there is allergies, diabetes, depression, heart  
2 attack, and arthritis.

3 And these are the differences in the  
4 score that are due to the unique effect of the  
5 condition. And the difference is the scale is  
6 negative because these conditions have a negative  
7 effect on health.

8 (Slide)

9 So, this is looking at a minor  
10 physical illness. Allergies, first. As you can  
11 see, there's a small decrement in physical health  
12 and an infinitesimal decrement in mental health.  
13 This makes sense.

14 Diabetes, as you'd expect, significant  
15 effect on physical health, less effect on mental  
16 health. It's a bummer, but it's not that big of  
17 a bummer to have diabetes.

18 It is a bummer to have depression,  
19 although it doesn't affect your physical health  
20 much. And it's sort of a bit of a bummer to have  
21 a heart attack, which affects both your mental  
22 and physical health score. And the fact that  
23 these things line up in accordance with our  
24 common-sense notions reflects the substantial  
25 validation that's gone into the SF-36.

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1           And arthritis, again, modest effect on  
2 your physical health, less effect on mental  
3 health.

4           (Slide)

5           And these are the findings for the Op.  
6 Apollo group and, as you can see, the unique  
7 effect of Op. Apollo, or at least the different  
8 between the Op. Apollo and the Canadian general  
9 population of the same age and sex is greater  
10 than that of many serious conditions, and both  
11 the mental and physical health are significantly  
12 affected. And look at the other conditions to  
13 reference this. Most of them have an effect on  
14 either one or the other, not both.

15           (Slide)

16           I'm going to skip this complicated  
17 graph here in the interest of time, although  
18 don't you like the animation?

19           (Laughter.)

20           Wow. Do they give Academy Awards  
21 here?

22           (Slide)

23           Physical symptom data I'm not going to  
24 belabor in part because we really don't have very  
25 good comparison data, but this looks at a bunch

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1 of physical symptoms and whether people -- I'm  
2 just looking here at whether people are bothered  
3 a lot. And these are symptoms that happen to be  
4 common among distressed people, in particular,  
5 and that's the percent bothered a lot. This is  
6 the Op. Apollo group.

7 (Slide)

8 And this is the comparison population,  
9 which happens to be -- as you can see, the  
10 pattern of symptoms is similar, albeit at a lower  
11 rate in the Op. Apollo group. For example, if  
12 there were a deployment-related illness caused by  
13 "fill in the blank" that was characterized by  
14 shortness of breath, bowel problems and fatigue,  
15 you'd see that those are disproportionately  
16 elevated compared to the comparison group.

17 So, we're not seeing from this data  
18 evidence of some new particular syndrome or  
19 illness yet. My theory is that as these people  
20 start surveilling their health because they have  
21 impaired health perception and fatigue, et  
22 cetera, they are going to start noticing more  
23 symptoms. That's just my thinking.

24 The comparison group is a primary care  
25 population, or the doctor's waiting room, and

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1 about half of those people would be sick or  
2 symptomatic. We don't know what the rate of  
3 symptoms would be before deployment or in a  
4 nondeployed population, so it's a bit difficult  
5 to look at this except to say it doesn't appear  
6 as there are any particular new syndrome of  
7 symptoms. And in the ground forces, or the PPCLI  
8 Battle Group -- that's the Princess Patricia's  
9 Canadian Light Infantry. Only in Canada would  
10 you have an infantry named after a princess, but  
11 in Canada a very proud group of people stationed  
12 at Edmonton and Winnipeg. So there were a few  
13 of the symptoms that were a bit more common.

14 (Slide)

15 This is looking at the mental health  
16 diagnoses from the prime MD patient health  
17 questionnaire. I'm colorblind -- is that green  
18 or yellow?

19 VOICE: Yellow.

20 DR. ZAMORSKI: Thank you.

21 DR. OSTROFF: That's yellow?

22 DR. ZAMORSKI: The rate of mental  
23 illness, we see here, these are symptoms  
24 suggested for mental illness. The prime MD does  
25 map reasonably well to actual diagnoses. And

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1 this is just looking at land forces versus  
2 others. And as you can see, rates of depression  
3 are 3.5 to 5 percent; minor depression perhaps 4  
4 to 6 percent; panic attacks, panic disorder, et  
5 cetera, you can see there. And the last bar is  
6 significant, which is that of those in the Navy  
7 and the Air Force, about 15 percent had at least  
8 one of these diagnoses whereas in the land forces  
9 almost twice that, or close to 30 percent, had  
10 one of those diagnoses which, of course, is  
11 concordant with the fact. You may recollect that  
12 their SF-36 mental component summary scores were  
13 lower in the land forces. This makes perfect  
14 sense. And those are the statistically  
15 significant differences, not a big surprise.

16 And if you look at the group as a  
17 whole, about 80 percent had no mental health  
18 diagnosis. Doesn't mean necessarily that they  
19 were well, but at least they didn't meet  
20 criteria.

21 We don't have any survey data on PTSD  
22 again because the instrument was not --

23 COL. RIDDLE: How do you define  
24 alcohol abuse, Mark?

25 DR. ZAMORSKI: Well, there's a

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1 criteria under the prime MD, and there are 5  
2 different questions about problem drinking  
3 behaviors, including operating a motor vehicle  
4 under the influence, and drinking while taking  
5 care of other people, or various other sorts of  
6 problem drinking things.

7 As it happened, it didn't provide us  
8 very much precision, and so we actually switched  
9 using the audit which is a much more precise  
10 estimate.

11 (Slide)

12 The other sorts of data we have on  
13 mental health are the interviewers' concerns. At  
14 the end of the interview, the interviewer filled  
15 out a little disposition form, and this is the  
16 percentage of members in which interviewers  
17 identified concerns at either a major level or a  
18 minor level. These are not diagnoses, but they  
19 are concerns about symptoms. And as you can see,  
20 in purple, those are the minor concerns, and in  
21 that other color, that's the major concerns -- to  
22 me it looks kind of gray. Concerns cover a  
23 number of different areas, there's not any  
24 particular area that predominates except there's  
25 a lot of minor physical health issues which you

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1 would expect to see, and minor concerns outnumber  
2 major concerns. About 23 percent of everybody  
3 who went through this program were for follow-up  
4 and about half of those had at least one major  
5 problem. About one-third of the referrals were  
6 urgent. And of the major concerns, 60 percent  
7 were psychosocial only, 20 percent physical  
8 concerns only, and 20 percent had both.

9 (Slide)

10 I'm not going to show you the data.  
11 Last February I showed you the data for the  
12 evaluations but, surprisingly, our participants,  
13 the members, found the process to be  
14 comprehensive, sensitive and helpful, which was a  
15 bit of a surprise. Well, people going into this,  
16 especially in the Army, they said, "Our guys  
17 aren't going to want to talk to you about this  
18 stuff", and, in fact, they did.

19 (Slide)

20 These are the exposure concerns. I  
21 asked a question on the evaluation form that said  
22 this -- can you read it -- and what we found was  
23 about 18 percent had these concerns.

24 (Slide)

25 There are certain limitations. It's a

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1 preliminary analysis. Only about 72 percent out  
2 of the first 2,000 gave me permission to use  
3 their data. We have data from a single point in  
4 time. We don't have pre-deployment data,  
5 although we do have pre-deployment data on our  
6 next group going back to Afghanistan that is  
7 interesting. We don't have anymore data on PTSD.  
8 It's based on self-reported symptoms in the  
9 context of a post-deployment examination in which  
10 we believe people may be over-reporting, in a  
11 sense, because of all the biases that they have.

12 The magnitude of that effect is difficult to  
13 estimate. If anyone has any data, rather than  
14 just conjecture, about the size of that bias or  
15 the extent to which people will under-report  
16 physical problems pre-deployment, I would love to  
17 see it. And we don't have data on final  
18 diagnoses.

19 (Slide)

20 So the key findings were that this was  
21 successful in identifying members with problems,  
22 and that the people with problems have been  
23 referred for individualized care, and that the  
24 members evaluated this program very favourably.  
25 See, I've learned how to spell like a Canadian

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1 already.

2 (Slide)

3 Compared to the general population,  
4 there are significantly and globally reduced  
5 physical and mental well being. There is likely  
6 a somewhat higher rate of diagnosable mental  
7 illness. I didn't show you the data, but that's  
8 probably true if you look at other Canadian data.

9 And some, but not all, of this difference is  
10 likely a deployment effect. And so our current  
11 countermeasures have not been as effective as we  
12 had hoped.

13 (Slide)

14 And the physical and mental health  
15 status is similar to or worse than U.S. Gulf War  
16 veterans. Health of Army participants is worse  
17 than others. And we don't see evidence of a new  
18 symptom syndrome or illness yet. And so the  
19 findings are consistent with typical post-  
20 deployment health effects, as we might have seen  
21 from other deployments.

22 (Slide)

23 That should have printed better in  
24 your thing, but for some reason the color is not  
25 showing up well here. There are Web links on the

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1 bottom to sort of a preliminary report that gives  
2 a lot more detail.

3 (Slide)

4 And the other thing that got cut off,  
5 but I believe it is in your handouts, we recently  
6 completed a big mental health survey in Canada as  
7 a whole, which is real interesting. Statistics  
8 Canada just released this about a week and a half  
9 ago, and it's sort of like our equivalent of the  
10 National Co-Morbidity Survey or the  
11 Epidemiological Catchment Area Study, and perhaps  
12 not quite as detailed but epidemiologically  
13 rigorous, and they over-sampled the Canadian  
14 Forces for about 5,000 regular force members and  
15 3,000 reserve force members, to try to get some  
16 sense of the mental health of those. And I've  
17 given you some links to find out information  
18 about that, and the principal person involved,  
19 Col. Randy Boddam, was our chief psychiatrist.

20 DR. OSTROFF: Thanks very much, that  
21 was a terrific presentation. Before I open it up  
22 to questions, I did have one quick question. You  
23 didn't talk about the gender demographics and  
24 whether there were any differences in gender  
25 demographics. I don't know what types of forces

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1 were deployed to Afghanistan from Canada.

2 DR. ZAMORSKI: Of the sample, there  
3 were about 5 percent women both in my sample and  
4 in our aggregate data for the deployment as a  
5 whole. The sample is reasonably representative  
6 of the deployment as a whole, at least with  
7 respect to demographic characteristics.

8 We haven't done all of the multi-  
9 variate models to try to sort those out.  
10 Superficially, just to look at the uni-variate,  
11 sex did not appear to be a major factor in any of  
12 the principal outcomes. The number of women,  
13 however, overall, out of a sample of 1500 people  
14 or so, was not huge.

15 DR. OSTROFF: Dan.

16 DR. BLAZER: Excellent presentation.  
17 I have just a couple of questions. First, what  
18 was the total number of people who went through  
19 this process post-deployment?

20 DR. ZAMORSKI: Well, there were about  
21 3,400 people who were in our first rotation,  
22 which was our population of interest. We had  
23 completed, as of the time I started analyzing  
24 this data, about 2,000 of those, and of those I  
25 have data on around I think about 15 -- well, 72

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1 percent of 2,000.

2 DR. BLAZER: And what is, on the  
3 average -- I know this is probably a spin, but  
4 you can give me something about the spin, too,  
5 for the time that they actually returned to  
6 Canada and the time they actually go through this  
7 process?

8 DR. ZAMORSKI: It was about 156 days,  
9 on average. We were aiming for 4 to 6 months.  
10 The Army was interviewed about 45 days earlier.  
11 And so some of the differences in their health  
12 status may be due to the fact that they were  
13 still readjusting. Nevertheless, they were still  
14 home around four months, so it wasn't like we  
15 caught them the first week off the boat, or  
16 anything.

17 DR. BLAZER: Now, you have a plan for  
18 referral. Is there any plan to follow up whether  
19 they actually do go for referral, and to actually  
20 maybe resurvey these individuals at a later point  
21 in time?

22 DR. ZAMORSKI: We are following up --  
23 well, the sites were supposed to go back and  
24 follow up to make sure that people kept their  
25 follow-up appointments. And the reason that was

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1 done was not actually for research, but because  
2 the data from the primary care setting suggests  
3 that screening for depression is effective if and  
4 only if it is associated with implementation of  
5 appropriate treatment -- duh -- and systematic  
6 attempts at follow-up and referral. So I have to  
7 say earlier returns are disappointing in the  
8 extent to which that happens, and I suspect that  
9 they will have to be persuaded in order to look  
10 at that, but we are doing that.

11 We are also planning on doing a little  
12 random sample of 100 charts, to try to look to  
13 see if the people followed up, if the issues  
14 addressed during that follow-up visit were,  
15 indeed, as a consequence of this rather than  
16 something else.

17 DR. BLAZER: Just out of curiosity, of  
18 that 1500, what are the chances that you will be  
19 able to resurvey them just, for example, with the  
20 SF-36?

21 DR. ZAMORSKI: Well, it's not clear.  
22 We're thinking of instituting the SF-36 for  
23 everybody as part of their routine health  
24 appraisal, their periodic health appraisal. And,  
25 if so, it depends on when we actually get that

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1 together, and how many people still stay in the  
2 service. But I think that it would be unlikely I  
3 would get a huge response if I tried to resurvey  
4 these people. We had to fully anonymize the  
5 data, so I have no way of linking these up ever  
6 again, which was a stipulation of our  
7 extraordinarily stringent privacy requirements.

8 DR. OSTROFF: Thanks very much.  
9 Unfortunately, we're going to have to move on or  
10 else we'll disrupt the afternoon activities.  
11 That was a terrific presentation, and I'm sure  
12 we're looking forward to hearing more.

13 We have one additional presentation,  
14 and that is from Cdr. Craig Mallak, from the  
15 Office of the Armed Forces Medical Examiner, and  
16 I'm really pleased that you are here. This is an  
17 important presentation. I was a former member of  
18 the Scientific Advisory Board of the AFIP, so I  
19 know you folks quite well.

20 And one other comment before you get  
21 started is that in light of the discussions  
22 yesterday, what I would like to do -- we decided  
23 to have a ballot on the issue of the fourth  
24 meeting among the Board members, in case there  
25 were individuals who did not necessarily want to

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1 vote in favor of a fourth meeting, for one reason  
2 or another. I didn't want them to feel that they  
3 could not express their desires. And so we have a  
4 ballot that will circulate during this  
5 presentation, if you could fill it out -- oh,  
6 they are done already? I didn't do it. I'm  
7 sorry. Forget it. Go ahead.

8 CDR. MALLAK: Thank you, sir. I'm  
9 Craig Mallak. I'm the Armed Forces Medical  
10 Examiner. And Capt. Kilbane, who you met a  
11 little earlier, is actually also a forensic  
12 pathologist in a prior life and was one of my  
13 mentors, so he brings a lot to the table for us.

14 (Slide)

15 One of the things about our office  
16 that's unique in the last few years is that we  
17 have a new law passed. We don't have primary  
18 jurisdiction in most of the deaths in the  
19 military, they fall under the jurisdiction of the  
20 local coroner or medical examiner, but now we  
21 have secondary jurisdiction. So if we feel the  
22 local medical examiner or coroner has not done a  
23 full examination or investigation, we can step in  
24 after they have released jurisdiction. This  
25 allows us to get a lot of information for a body

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1 such as yourself, as to the cause or manner of  
2 death and some other contributing factors.

3 (Slide)

4 We're stationed around the world, and  
5 right now we need to be.

6 (Slide)

7 This isn't showing up very well, but  
8 this is what we do. What's in the background  
9 there is an F-18 that crashed in Port Lucy,  
10 Florida, at 700 knots, hitting vertically. And  
11 this gives you an idea of some of the problems we  
12 have gathering the data after sifting 53 tons of  
13 dirt, we recovered less than 4 ounces of bone of  
14 a 180-pound pilot. So to this date, we don't  
15 know what happened to this F-18 and why it fell  
16 off the screen and went into the ground there.

17 (Slide)

18 Been a little busy this year,  
19 unfortunately. Starting February 1st, the space  
20 shuttle crashed. We can't talk too much about it  
21 yet. We've got some interesting data and I'd be  
22 glad to come back. We're allowed to talk about  
23 it 12 months after this happened, so next spring  
24 sometime if you want to know about the data that  
25 we gathered from the space shuttle and what

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1 happens to the human body at 200,000 feet and how  
2 that may apply in the future, I'll be glad to  
3 come back.

4 We've been over to the Middle East  
5 eight times doing enemy prisoner-of-war  
6 investigations. This is the tibia from Ude, and  
7 that's the plate it was on that we made the ID  
8 with.

9 That's our morgue. It's pretty rustic.  
10 It's tough to get good data working in the  
11 middle of the desert. We also went over and  
12 looked for Capt. Spiker. We haven't found him.  
13 We've had crashes in Italy, crashes in Puerto  
14 Rico, all kinds of cases in Germany, two CIA  
15 planes that have gone down in Bogota, had two  
16 Army officers fall off this mountain in La Paz,  
17 and we've also been to Afghanistan several times.

18 The president of the country has said "We do not  
19 torture prisoners", so every time we have an EPW  
20 death, we have to go and do an investigation to  
21 uphold that. So we've done over ten cases of  
22 that also, in gathering this data.

23 We've seen our missions increase,  
24 deployed 55 times already this year and,  
25 unfortunately, it's been a banner year of deaths.

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1 We've had decreasing staff, and that's a  
2 problem.

3 (Slide)

4 OIF. This is the data to-date,  
5 through 5 September, the number of deaths -- 291.

6 This is the breakdown by service.

7 (Slide)

8 This is what they are dying from. The  
9 thing that we're finding interesting is that in  
10 the desert several people are drowning. That  
11 number actually is low. That's primary  
12 drownings. It's about closer to 20 if you add  
13 the vehicles that are going into the water,  
14 vehicles that are flipping over. Soldiers are  
15 not taught to swim. Is that something that we  
16 should look at in the future? Had some Marines  
17 die, and they are supposedly taught how to swim.

18 Some of the pending cases, we've had 4 soldiers  
19 who have basically woken up dead. They are in  
20 their cots. In the morning, they are just dead,  
21 and we don't have explanations for them yet, and  
22 we are working on those. We're continuing to  
23 work on the pneumonia cases with Col. DeFraitess.

24 (Slide)

25 But what I came primarily to talk

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1 about is the exertion-related deaths. This Board  
2 tasked our office to go out and look at the  
3 exertion-related deaths, and also to look at  
4 Sickie Cell Trait. As you can see, we've been a  
5 little busy this year, so we haven't gotten too  
6 far with this, but I'm going to go over some of  
7 the challenges and what we have seen to-date.  
8 Fortunately, we have a Mortality Registry  
9 Division now, Maj. Elisa Pierce, and she is  
10 collecting a lot of data that we can bring  
11 forward to this body.

12 (Slide)

13 Traditionally, 1,000 service members  
14 die each year. It looks like we're going to hit  
15 at least 1400 this year. And you can see the  
16 distribution. The Army has taken the hit along  
17 with the Marines are up, the Navy and the Air  
18 Force are down slightly.

19 (Slide)

20 This is what our military members die  
21 from. In the local medical examiner or coroner's  
22 office, about 50 percent of the cases or more are  
23 due to natural causes. As you see, the vast  
24 majority of our deaths are due to accidents.

25 (Slide)

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1           This is the breakdown of those natural  
2 deaths. You can see 25 percent of all deaths are  
3 natural. Most are cardiovascular, some  
4 neoplastic, and you can see the other breakdown -  
5 - 5.7 percent of these deaths are associated with  
6 exercise or strenuous activity.

7           (Slide)

8           Here is the physical activity deaths  
9 in the last five years, and you can see the  
10 breakdown and the percentages. The average age  
11 is 34.3, and 9.8 percent of the deaths were in  
12 recruits, so they are not overly representative.

13          (Slide)

14          Here is what they are doing when they  
15 are dying from physical activity. Unit PT and  
16 individual PT are the highest. Recreational and  
17 PT testing. We have other activities. We have 1  
18 case of sexual activity when they died, and the  
19 rest of them are different types of activity that  
20 aren't otherwise categorized.

21          (Slide)

22          Most are male Caucasians. Most are  
23 from the Regular Component. We're having a  
24 problem figuring out the rates among the  
25 Reservists because nobody can tell us exactly --

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1 get us a denominator for the number of people  
2 that are activated and the number of days that  
3 they are activated in any real-time sense. The  
4 data is 1 to 2 years old by the time we receive  
5 it, and it makes it difficult to track the  
6 Reserve Components.

7 MS. EMBREY: You can use pay data,  
8 that will get you.

9 CDR. MALLAK: What's that, ma'am?

10 MS. EMBREY: Find out when they were  
11 paid, that will tell you how many days they were  
12 on Active Duty.

13 CDR. MALLAK: We've been working on  
14 that, and we've been working also on the point  
15 system because, if we have voluntary training  
16 units who receive points but no pay, that makes  
17 it difficult also.

18 MS. EMBREY: Especially for the Navy.

19 CDR. MALLAK: Yes. BTUs in the Navy.

20 (Slide)

21 We've identified Sickle Cell in 5  
22 percent of all cases. You can see the most are in  
23 the Army, and the Army does not test for Sickle  
24 Cell Trait in their recruits whereas the Navy and  
25 the Marines do. We don't know if that's

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1 statistically significant yet or not. Seventeen  
2 identified in the last 5 years, the vast majority  
3 were in the Army, 2 were female, 16 were African  
4 American.

5 (Slide)

6 The other point that we were looking  
7 at is the use of ephedrine. As you see,  
8 ephedrine deaths peaked around 2001, and they  
9 dropped off in 2003 with the intervention of  
10 taking the ephedra-containing supplements out of  
11 the Exchanges, and getting the warnings out.

12 When I was in Okinawa in 1999, I had  
13 two deaths. These two deaths were both in  
14 Okinawa. I was the medical examiner.

15 (Slide)

16 Here is the breakdown of those numbers  
17 using ephedra and how they fit into the physical  
18 activity deaths. You can see that the ASCVD is  
19 the highest, as would be expected with a  
20 sympathomimetic. The problem we're going to  
21 start seeing now is that these companies are  
22 adding other substances, other sympathomimetics  
23 to these stimulant -- these bodybuilding  
24 substances.

25 (Slide)

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1           Some more breakdown on the identified  
2 ephedrine use in fatalities. I'm running out of  
3 time so I won't go too deep into this.

4           (Slide)

5           One of our major problems with the  
6 local medical examiner is if you die of a heart  
7 attack, a lot of time they won't even do an  
8 autopsy, they'll just sign you out.

9           We've talked to CID and NCIS because  
10 you've charged us with going out and getting  
11 investigative information about the deaths, and  
12 we need our investigators to help us. So, CID is  
13 Army, that's their Criminal Investigation  
14 Division. NCIS is Naval Criminal Investigative  
15 Services. And we've talked to them and we are  
16 setting up protocols and we're establishing  
17 guidelines and checklists for the investigators  
18 to go out and get the information that we need.

19          (Slide)

20          Out in the community, there's no  
21 standard of care for what to do with these  
22 deaths. If somebody is 40 years old and they  
23 drop dead, a lot of times they are just signed  
24 out as a heart attack. Next case. And that's it.  
25          No autopsy. So currently we're trying to go

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1 after all these cases across the country, around  
2 the world. When the local ME says, "It's a heart  
3 attack, we're done", we're trying to step in and  
4 get these cases. This stuff happens. This is  
5 true. This is kind of the attitude with most of  
6 these cases. I worked in Memphis, Tennessee  
7 while I was a Detailer, and if you didn't have a  
8 bullet in you and it wasn't shot by somebody  
9 else, you didn't get an autopsy. So we're  
10 working with the local authorities, working our  
11 guidelines, and trying to get more locals to  
12 perform the autopsies when we can't get there.

13 (Slide)

14 We're also having problems with the  
15 Air Force. Air Force OSI is their investigative  
16 body. They consider themselves a  
17 counterintelligence group. They investigate  
18 homicides, but they are just not interested in  
19 natural deaths, so we're trying to engage them in  
20 some of these cases to give us a hand.

21 We're also running into a problem with  
22 the DODI for the safety centers. The DODI  
23 currently reads that they can only investigate  
24 those cases that die within one hour of activity  
25 and only those that occur on-duty and on-base. A

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1 lot of these folks are getting sick during this  
2 activity, going home and dying. And so safety  
3 centers can't even participate in these  
4 investigations, to this point. And so we need to  
5 go back and change their instructions so that  
6 they can become engaged. Right now, they can't  
7 even help us. We've talked to them. They want  
8 to be helpful. But we've got to get the  
9 instruction changed.

10 And like I said, OSI is not interested  
11 yet, and we're going to try to get them engaged,  
12 and hopefully within six months we'll be able to  
13 start bringing some data back about Sickle Cell  
14 testing, exertional deaths, monitoring for new  
15 substances in bodybuilding supplements, and  
16 hopefully ephedrine will not be an issue anymore.

17 That's kind of a quick runthrough,  
18 sir.

19 DR. OSTROFF: Thank you so much,  
20 that's a really interesting presenting. I just  
21 have one quick question before I open it up.  
22 Have you considered publishing some of these  
23 data? I mean, they are really quite interesting.

24 I think that they would be illustrative.

25 CDR. MALLAK: Yes, sir. We're going

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1 to start publishing when we have time.

2 (Laughter.)

3 Right now -- a lot of this  
4 information, it screams to be published, and we  
5 know that, but right now we're just going 24/7  
6 all over the world. And when things slow down,  
7 we've got the data there, and we're going to  
8 start writing it.

9 DR. OSTROFF: I don't think they are  
10 going to slow down, unfortunately.

11 COL. RIDDLE: You passed by the most  
12 important slide on that. You've accomplished the  
13 greatest number of missions, and that's with all  
14 three of you, the least number of personnel, with  
15 a huge budget at the AFIP. Is it a leadership  
16 issue? I mean, is there a reversal of -- you're  
17 going to do it with two next year?

18 CDR. MALLAK: No. We are actually  
19 plussing up now. There was a nadir where the  
20 forensics was not a big deal in the military.  
21 This is the first time with OIF we've treated  
22 every case as if it's a forensic case. We've  
23 collected every bullet, every piece of shrapnel  
24 that we can get our hands on. We're autopsying  
25 every case. During Desert Storm I, less than

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1 half the cases were autopsied. So we've come  
2 back and we're treating them all as if they are  
3 forensic cases for a couple of reasons. One, the  
4 families expect it. They want to know what  
5 happened to their loved one, and we need to be  
6 able to provide those answers. No. 2, we're also  
7 collecting tissue and building a tissue bank  
8 including muscle, nerve, fat, all the organs. So  
9 we have a tissue bank for Gulf War Syndrome which  
10 is going to come up -- we know it's coming. So  
11 we're building a tissue bank of all the  
12 fatalities so that we have this tissue we can  
13 look at.

14 No. 3, we're picking up friendly fire  
15 incidents. After the first Gulf War, two years  
16 later there were congressional hearings about  
17 friendly fire. We're picking them up at the  
18 autopsy table now, and clearing a lot of them up  
19 right there. It's not good news for the  
20 families, but they'd rather hear it right up  
21 front than down the road.

22 We've got all the shrapnel. We talked  
23 about the depleted uranium. At some point, we  
24 want to send all of that to a metallurgist to  
25 tell us where the shrapnel came from, which of

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1 our troops are at risk from friendly fire  
2 incidents that may involve radioactive materials.

3 So, that's what we're working on.

4 DR. OSTROFF: Comments or questions  
5 from the members? David, and then Paula.

6 DR. ATKINS: Two quick questions.  
7 With all the stuff on your plate, what's the  
8 likelihood that you'll have the resources to get  
9 more information on these exertional-related  
10 deaths occurring outside of theater? And the  
11 second question is, how did you diagnose ephedra-  
12 related deaths? Was that based on toxicology, or  
13 based on information about -- or what patients  
14 had in their lockers or something?

15 CDR. MALLAK: The cases that I showed  
16 here all had positive toxicology. We know  
17 several other cases where we found Ripfuel  
18 (phonetic), Ultimate Orange, hydroxy, all these  
19 different substances, and they were known to take  
20 them, but they are not showing up in their  
21 toxicology. So we're looking into that to see --  
22 we've got eyewitnesses they were taking it right  
23 before they died, and it's negative in their TOX.

24 So we're looking at the testing methods to see  
25 if there's a better way to detect it, also.

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1 DR. ATKINS: And the first question in  
2 terms of --

3 CDR. MALLAK: We've more than doubled  
4 our staff, and we're going to be out there, and I  
5 think we can come forward in six months and have  
6 a good program in place. I don't know if we'll  
7 have all the data yet, but we'll have the program  
8 set up and running.

9 COL. UNDERWOOD: Paula Underwood. I  
10 just want to thank you, Cdr. Mallak, for all the  
11 assistance you gave me when we were looking at  
12 these supposed heat-related deaths. And you  
13 mentioned that the 4 that are still outstanding.  
14 I know there were some tox results pending. Any  
15 idea when you might -- that data might be back on  
16 those 4?

17 CDR. MALLAK: I'm going to check on it  
18 tomorrow when I get back, ma'am.

19 COL. UNDERWOOD: I'll call you.

20 CDR. MALLAK: One of them, we found a  
21 dilated cardiomyopathy, but we want to look at  
22 everything before we make that the bottom-line  
23 call. Does this group look at things  
24 like flak vests and there are -- the troops over  
25 there are abandoning their flak vests as quick as

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1 they can get another vest called an "interceptor"  
2 vest, and we're looking into that and seeing if  
3 it's more effective. Do those types of issues  
4 come before this Board, the effectiveness of  
5 personal protective gear other than things for  
6 microbiologic insults?

7 MS. EMBREY: It comes before my group,  
8 not necessarily this group.

9 COL. RIDDLE: The issues that come  
10 before the Board are those issues that are  
11 brought to the Board by the three Service  
12 Surgeons General and Health Affairs. And if it's  
13 an issue raised to their level where the  
14 expertise can be rendered, yes.

15 DR. OSTROFF: I'm not sure I know much  
16 about flak vests, but -- other comments or  
17 questions? Dr. Haywood, any thoughts about the  
18 exertional-related fatalities?

19 DR. HAYWOOD: We'd certainly like to  
20 know the demographics associated and how they  
21 relate to the specific activities that you  
22 referred to. The Sickle Cell, that we discussed  
23 in a previous meeting. It looks like you have  
24 pretty similar data to what was presented.

25 CDR. MALLAK: Sir, we'll drill down

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1 further on it, as time permits.

2 COL. RIDDLE: Gen. Peak sent a policy  
3 over to the Secretary of the Army to try to  
4 initiate screening in the recruit camp for Sickie  
5 Cell Trait. Is that still just in the Army in-  
6 box?

7 MS. EMBREY: As far as I know -- and  
8 Bob DeFraites can correct me -- I don't think  
9 we're looking at Sickie Cell -- well, let me let  
10 Bob answer that.

11 COL. DeFRAITES: That recommendation  
12 was passed up to the Army Secretariat, but  
13 there's been no action on that recommendation.  
14 I'll say that the recommendation was not that  
15 well accepted within the Secretariat, so until  
16 there is another sort of initiative in that way,  
17 I don't see it going anywhere. And I'll tell  
18 you, the concern was -- it got back to us -- was  
19 the -- I guess the desire for more of a ringing  
20 endorsement by ethicists and experts in the field  
21 that this was indicated in terms of screening.

22 COL. RIDDLE: I think that may be one  
23 of the reasons why that expertise -- a need for  
24 that, and an ethicist being appointed to the  
25 Board. So it may be something we could look at

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1 again as you get additional results from these  
2 latest round of cases.

3 COL. DeFRAITES: That would probably  
4 be helpful, but the history of the Sickle Cell  
5 Trait question has been controversial, to say the  
6 least -- I mean, in terms of getting a unanimous  
7 -- a ringing endorsement, I'm not sure that  
8 that's something that we can expect, though  
9 something from the Board might be indicated.

10 DR. HAYWOOD: That does raise the  
11 issue, though, if recommendations are made and  
12 they are not favorably received, I don't think it  
13 should just be put aside and no response given.  
14 We ought to know what the response has been.

15 COL. RIDDLE: And that's one of the  
16 reasons -- I mean, I have to commend Craig, he  
17 has done a herculean effort since he's been up at  
18 AFIP -- I mean, on the road 24/7 -- and  
19 appreciate him coming here, but part of that was  
20 to give us an update of the status on that and  
21 some of the issues still looking at investigation  
22 of medically related deaths.

23 MS. EMBREY: You might be pleased to  
24 know personally, and for the Board, you might  
25 also be pleased to know, that we were giving Dr.

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1 Winkenwerder a briefing on your activities and  
2 sort of the status of everything, and he says,  
3 "Well, how many people have been working on  
4 this", and we reported to him three, to which he  
5 said, "Make sure they get more people right now".

6 So, you need to know that that's happening.

7 CDR. MALLAK: Thank you, ma'am.

8 DR. OSTROFF: I'm not sure we can  
9 clone you, but hopefully they do have the skill  
10 sets available. I visited the Office of the  
11 Armed Forces Medical Examiner. It was one of the  
12 more interesting places that I have visited, and  
13 you guys do great work.

14 DR. HAYWOOD: One other comment on the  
15 uniformity issue. It would seem to me the  
16 response ought to include some reason why  
17 consistency is not appropriate.

18 DR. OSTROFF: Right. And we may want  
19 to consider making a request that they try to put  
20 something in writing justifying their position  
21 rather than just coming and having a  
22 presentation. So if we could make that request,  
23 that might be helpful.

24 MS. EMBREY: As a matter of process, I  
25 think what the Department does with the advice of

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1 this Board, it's considered and evaluated in the  
2 services, but I think the Department needs to  
3 determine whether it's going to make a policy or  
4 not before we get into who said what to whom. We  
5 need to decide what our policy is, and why, and  
6 then the Department will justify back to you what  
7 our position is and why, not just each service. I  
8 think we need to be collective and represent a  
9 single face to you about our health policy.

10 COL. GARDNER: Didn't the Board  
11 recommend against Sickle Cell Trait screening?

12 COL. RIDDLE: The recommendation was  
13 the lack of evidence makes a definitive  
14 recommendation literally impossible, but given  
15 the evidence that was put before the Board, they  
16 saw no reason why one shouldn't go ahead and  
17 screen. We need to go back and review it. But  
18 as part of a process of one identifying those  
19 individuals, letting them know that they are  
20 potentially at higher risk and, in essence, it's  
21 an ethical obligation to them as opposed to an  
22 excuse for not doing good heat prevention water  
23 and exercise prevention within a training  
24 exercise. So, I think that's where the crux of  
25 the issue comes down to, and Col. DeFraitess hit

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1 it, are we as an entity putting these individuals  
2 at risk because of this particular health issue,  
3 and until we have better evidence, given that the  
4 two services are screening and the data  
5 presented, even though some of the individuals  
6 are being separated, is somewhat convincing,  
7 should those individuals not be aware of that  
8 trait that puts them at a risk. And I think that  
9 was Gen. Peak's argument, if I'm not mistaken.

10 DR. ATKINS: You data on deaths that  
11 have Sickle Cell Trait, is that a complete  
12 estimate? I mean, form the fact that there isn't  
13 routine autopsy, I'm assuming there may be deaths  
14 that we don't know, and since the Army isn't  
15 screening, that's the minimum number, is that  
16 right?

17 CDR. MALLAK: Correct, those are the  
18 ones that we can confirm. Hopefully with this new  
19 protocol we're setting up, we're going to  
20 aggressively go after these cases on a daily  
21 basis, whenever and wherever they occur, and  
22 we'll have more solid numbers for you.

23 DR. OSTROFF: Thanks very much. That  
24 was a terrific presentation. In fact, all the  
25 presentations this morning were just right on the

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1 money. So thank you to all of the presenters for  
2 giving us such a great breadth of interesting  
3 issues to think about.

4 Col. DeFraites, did you want to make -  
5 -

6 COL. DEFRAITES: Just one last point  
7 on the Sickle Cell Trait, just to be clear to the  
8 Board. The policy is for Navy and Marine Corps,  
9 everyone gets screened for Sickle Cell Trait, but  
10 they are not offered discharge from service. The  
11 Air Force screens all recruits, offers voluntary  
12 release from Active Duty for those who so desire  
13 after counseling. The Army Surgeon General's  
14 recommendation was to adopt a program similar to  
15 the Air Force.

16 So the fact that you don't see any  
17 deaths from maybe one Marine, they are not  
18 separated from the service if they are Sickle  
19 Cell Trait positive. So you need to understand  
20 that the Marines and the Navy, they are not  
21 eliminating their Sickle Cell Trait population.  
22 It's unclear exactly why the Army -- because the  
23 Army, Navy and Marines draw from similar  
24 populations and you would expect perhaps similar  
25 numbers to show up among the deaths, all other

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1 things being equal, among the prevention programs  
2 because there is no effort to eliminate Sickle  
3 Cell Trait positive Navy and Marine Corps from  
4 the service-base and the screening. They are not  
5 offered that at all. I think there are some  
6 other issues in that.

7 DR. OSTROFF: One last comment, and  
8 then Rick will give us instructions. We did  
9 pretty well with the time, actually.

10 MS. EMBREY: With respect to the  
11 Canadian presentation, I'd like to point you to  
12 pages 4 and 5 at Tab 8. That is DOD's collective  
13 statistics based on our post-deployment health  
14 assessment forms. There's about 138,000 of those  
15 that have come in, and it's a little snapshot.  
16 It by no means the depth of investigation that  
17 Canada has done with the particular instance  
18 briefed, but we skipped over it in the interest  
19 of time. And I wanted to call your attention to  
20 the fact that we are heavily engaged in gathering  
21 this data, and it's self-explanatory as you read  
22 this information. I just wanted to point that  
23 out for you.

24 LtCOL. GIBSON: I would have liked to  
25 have taken a little more time with that. We

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1 certainly are not to the level of analysis that  
2 the Canadians are, but we are engaged heavily.

3 DR. OSTROFF: Well, we can put it on  
4 the agenda for the next Board meeting, to give us  
5 a fuller update on what's being done by DOD in  
6 terms of looking at some of the same issues. I  
7 wonder what would happen for Canada if they did  
8 the survey after the SARS problem in Toronto,  
9 whether or not some of those scores would get  
10 worse.

11 Rick?

12 COL. RIDDLE: I have new maps -- the  
13 MapQuest directions aren't quite as good as these  
14 directions -- to hand out to those individuals  
15 who are going to drive over. It would be best if  
16 you go ahead and take your materials with you.  
17 If you want them shipped back, if you want to  
18 leave a sticky on it and leave them here, we can  
19 pack them up and I can take them back with me and  
20 mail them back to you.

21 We're going to be eating over at the  
22 Officers Club over at the Coast Guard Academy.  
23 In essence, you just go down here, take a right  
24 on 12, take 95 South, Exit 83 for the Coast Guard  
25 Academy, and it's labeled. And once you get to

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1 the stoplight, you take a left. The Main Gate is  
2 right there on your right. They are expecting  
3 us. If you go right straight through the Main  
4 Gate to Leonard Wood Circle, it's a circle that  
5 just lets folks out right at the front door of  
6 the O-Club. And so if you want to let your  
7 passengers out there and then circle back around,  
8 straight at the end of that road there's a set of  
9 closed gates, and right to the left is a parking  
10 lot. It's right past the recreation building.  
11 And so you can park your cars there and then walk  
12 back up to the Officers Club. We're going to have  
13 a buffet lunch, \$10. They are going to do some  
14 briefings. And then we have the tour of the Eagle  
15 set up after lunch, and a tour of the Coast Guard  
16 Academy.

17 DR. OSTROFF: Good. Thank you,  
18 everybody.

19 (Whereupon, at 12:20 p.m., the meeting  
20 was concluded.)

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