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ARMED FORCES EPIDEMIOLOGICAL BOARD

SPRING 2005 MEETING

COHOSTED BY THE  
ARMED FORCES MEDICAL INTELLIGENCE CENTER (AFMIC)  
AND  
THE U.S. ARMY MEDICAL RESEARCH INSTITUTE OF  
INFECTIOUS DISEASES (USAMRIID)

DAY TWO

Dalrymple Conference Room (1425)  
The U.S. Army Medical Research Institute of  
Infectious Diseases (USAMRIID)  
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1 P R O C E E D I N G S

2 (8:10 a.m.)

3 CAPTAIN FUJIMOTO: Good morning. My  
4 name is Captain Fujimoto, and I'm here to give a  
5 briefing on the Department of Defense influenza  
6 surveillance program, including findings for the  
7 2004-2005 influenza season, as well as program  
8 accomplishments this year.

9 First, I'll just give a brief overview  
10 of influenza surveillance. In the DOD, it is  
11 largely funded and supervised by the Global  
12 Emerging Infectious Systems Group at Walter Reed,  
13 GEIS. Underneath GEIS are two main components of  
14 the DOD Influenza Surveillance Program. The first  
15 is population-based recruit and trainee  
16 surveillance, and that's conducted by the Naval  
17 Health Research Center in San Diego. The second  
18 half is the Worldwide Sentinel Surveyor, and so in  
19 other words, non-recruit sites, and that's managed  
20 by AFIOH at Brooks City Base.

21 I'll also briefly mention that the  
22 Army -- outside of the GEIS program, the Army also

1 compiles their own respiratory virus report, and  
2 that is done at Landstuhl Regional Medical Center,  
3 and they cover mainly the main Army Medical  
4 centers.

5 Just to go over our program methodology  
6 really quickly, this summarizes in text format,  
7 but I am going to go over to the diagrams, which  
8 show the same information but is probably a little  
9 easier to understand in a presentation like this.  
10 So again, we'll start at the top with GEIS, with  
11 the overall funding and guidance. This  
12 methodology shows AFIOH. But NHRC works in a very  
13 similar manner, with an additional step that NHRC  
14 is actually able to calculate rates like the AFIOH  
15 portion, because they have denominator data from  
16 their recruit populations.

17 So it could be best for AFIOH and NHRC  
18 to divide it into the two halves. There's the  
19 laboratory half and there's the epidemiology half.  
20 In terms of our interactions with the Sentinel  
21 Sites, the Epi Services Branch gives the sites  
22 program guidance. For instance, at the beginning

1 of the influenza season each year, we will send  
2 out a PowerPoint presentation to the public health  
3 officers at the bases just explaining what the  
4 program is and what we expect with their  
5 participation as a Sentinel Site. We will also  
6 distribute -- every week we generate a weekly  
7 influenza surveillance report that just summarizes  
8 the findings for that week across the whole DOD  
9 Influenza Surveillance Program. These are  
10 distributed every week to the Public Health  
11 Officers at the bases, as well as GEIS, MAJCOMs,  
12 Health Affairs and other important agencies.

13 On the laboratory side, the laboratory  
14 gives the providers at the Sentinel Site, clinics  
15 and MTFs, respiratory collection kits. Providers  
16 at the Sentinel Sites will collect specimens from  
17 patients who meet the case definition for  
18 influenza-like illness, that being a temperature  
19 of 100.5 or greater and a cough or sore throat.  
20 These respiratory specimens are then sent back to  
21 the laboratory which subsequently diagnoses  
22 influenza through either conventional or molecular

1 laboratory methods. And currently, the bulk of  
2 the diagnosis is still done through viral culture  
3 or shell vial staining.

4           Once flu is isolated, the Sentinel sites  
5 are reported results, again basically on two  
6 levels. On the laboratory side, the laboratory  
7 will transmit individual patient results to the  
8 Sentinel site laboratories. Again, this would be  
9 individual information, so it is transmitted via  
10 secured methods. And this is for the benefit of  
11 the clinicians who could look up the individual  
12 patient results.

13           On the Epi Services side, we will send  
14 in a summary of the base's findings, all the flu  
15 findings for that week, to the Public Health  
16 officer, and this is again on the surveillance  
17 side, so there's no personal identifiers for that  
18 information. And this is in addition, as I  
19 mentioned before, to the weekly overall reports  
20 that we generate for the Public Health Officers.

21           Besides feedback within the Department  
22 of Defense, we also have available relationship

1 with the CDC, and really, the type of data that we  
2 share with the CDC is through four different  
3 means. First of all, all of our laboratory  
4 results are transferred to the CDC's own Public  
5 Health Laboratory Information System and becomes  
6 part of their greater database. Secondly, the  
7 molecular sequencing that our molecular laboratory  
8 does is also similarly shared with the CDC and  
9 becomes part of their sequencing database. The  
10 third way is that often the CDC will request that  
11 the specimens we collect themselves be forwarded  
12 to the CDC's laboratory for further analysis and  
13 workup by them. These are typically overseas  
14 specimens and especially specimens from places  
15 such as Iraq, the Middle East, Southeast Asia,  
16 where it might be otherwise hard for the CDC to  
17 get specimens through other surveillance networks.  
18 Lastly, and this is new this year, the CDC asked  
19 permission to post those weekly flu reports that  
20 we generate that I mentioned earlier onto the  
21 CDC's Epi-X website for access by Public Health  
22 officials. We gave them the okay after clearing

1       it with our base.

2                   In addition to our relationship with the  
3       CDC, we also send in a representative from our  
4       program to the annual VERPAC meeting when they  
5       discuss the recommendations for the influenza  
6       vaccine composition for the next year's season.  
7       We give a presentation about what we have found in  
8       our own surveillance system during that meeting,  
9       and hopefully the information we provide will be  
10      useful to the VERPAC committee as well.

11                  This slide just shows the 2004-2005  
12      Sentinel sites, and we are a worldwide program.  
13      Within the United States, all regions of the  
14      United States are covered by military bases as  
15      well as many military bases overseas, including  
16      Europe, Asia, especially Japan and Korea. And  
17      currently we are trying to get more and more sites  
18      in the Middle East and Central Asia -- in other  
19      words, deployed sites -- aboard our surveillance  
20      system, including ones in Iraq, Qatar, Kyrgyzstan,  
21      which is next to Afghanistan, and recently we have  
22      been trying to get some sites in Kuwait as well.

1 We have also had a valuable partnership with two  
2 overseas military laboratories. The first is the  
3 Naval Medical Research Center in Peru, which  
4 gathers specimens from the South American region  
5 to forward to us. The second is an  
6 Army-affiliated overseas laboratory, the Armed  
7 Forces Research Institute for Medical Science.  
8 That is based in Bangkok, and they gather  
9 specimens from Thailand and they are trying to  
10 expand to other Southeast Asian countries as well  
11 to send specimens to us. These are valuable  
12 partners in our surveillance program, because they  
13 allow us to get specimens from places we would not  
14 otherwise receive because we have no permanent  
15 military bases there.

16 One last thing on methodology. A new  
17 thing that we have emphasized this year is further  
18 development of PCR screening for specimens in  
19 addition to the more conventional laboratory  
20 diagnostic methods I mentioned earlier. That is  
21 one reason, on the AFIOH side of things, that we  
22 have tried to encourage the submission of nasal

1 washes this year over throat swabs which have been  
2 traditionally sent in to our laboratory. The main  
3 reason is that we found that PCR with nasal washes  
4 have generally been more sensitive than throat  
5 swabs. This just illustrates one of those  
6 studies. As you can see, 92 percent of nasal wash  
7 influenza specimens were detected by our PCR  
8 versus 56 percent of throat swabs. Both NHRC and  
9 AFIOH have developed chimeras for different flus  
10 such as universal influenza, the type A including  
11 H-1 and H-3 sub-types, Type B, and H-5 avian  
12 influenza. One of the main reasons we are trying  
13 to really encourage development of this and  
14 emphasizing it this year is that basically, PCR  
15 gives quicker results compared to conventional  
16 laboratory methods. And obviously this can be  
17 very important if you are trying to rule in or  
18 rule out a suspected avian influenza specimen.

19 Another factor into this is that it is  
20 easier to train other sites to do PCR screening as  
21 opposed to other more conventional laboratory  
22 methods. This spring we are hoping to send out a

1 lab person from AFIOH to that Bangkok laboratory I  
2 mentioned earlier to train them to do PCR  
3 screening in Bangkok for flu, including avian  
4 influenza. The NHRC has already trained ten ships  
5 in the Pacific region to do onboard PCR screening  
6 in order to more quickly diagnose shipboard  
7 outbreaks that may occur. This is especially  
8 important for ships in the Pacific region, because  
9 they are continually docked at Asian and Pacific  
10 ports, so they are already engaging in PCR  
11 screening.

12 This last item is further out. It  
13 hasn't been developed or validated yet. But we  
14 hope to eventually develop lyophilized reagents  
15 for use in portable PCR machines. The idea here  
16 is that if there is, say, an outbreak in a remote  
17 section of Cambodia, we are able to use a  
18 lyophilized reagents, meaning dry reagents, with a  
19 portable PCR machine -- send a team out there to  
20 that remote location in Cambodia to do on-site PCR  
21 screening to, say, rule out avian Influenza. But  
22 that is a future development.

1           I'll move now to our 2004-2005 season  
2 results. This is last year's 2003-2004 season,  
3 just as a comparison. As you can see last year,  
4 Influenza-A, especially the H-3 and -2 subtype,  
5 predominated. We basically saw the same thing  
6 that the CDC Surveillance System saw -- an early  
7 peak in November and December.

8           In contrast, this season seems to be  
9 more mild with a later peak in January and  
10 February compared to last year. Influenza-A, H-3  
11 and -2, for us also has predominated this year,  
12 similar to the CDC. We have seen a slightly  
13 greater frequency of Bs though this year compared  
14 to last year.

15           If we look at individual sites -- first,  
16 I'll show you the U.S. sites -- we have got a  
17 large number of influenza positives from places  
18 like Scott Air Force Base in Illinois, McGuire Air  
19 Force Base in New Jersey, and the Air Force  
20 Academy in Colorado. To summarize the overall  
21 trends as far as the U.S. military bases, they  
22 basically mirrored what the CDC has seen. For

1 instance, many of our initial influenza positives  
2 came from Fort Drum in New York and McGuire Air  
3 Force Base in New Jersey, which is similar to the  
4 early influenza positives that the CDC saw in the  
5 New York region. Moving on to overseas military  
6 bases, we have received a lot of influenza  
7 positives from Lakenheath in the U.K., from  
8 Landstuhl Regional Medical Center in Germany, and  
9 this year we have also got a batch of influenza  
10 positives from our overseas military lab in Peru  
11 as well.

12 The other interesting thing to note is  
13 for our Asia sites, specifically Tripler and our  
14 Japan bases, we have seen a relatively greater  
15 proportion of influenza B's there compared to the  
16 rest of the world. Again, this seems to mirror  
17 what Japan's own civilian influenza surveillance  
18 system has seen, in that they have also see a  
19 greater -- relatively greater proportion of B's as  
20 well.

21 If we move on to the subtyping we have  
22 done this year, for influenza A it seems to be,

1 well, it's all H3 our own program has found. We  
2 have not subtyped an H1 yet this year. As far as  
3 influenza B, for us we have seen mostly the  
4 Shanghai.

5 NHRC has not seen much through this  
6 year, probably because the recruits this year have  
7 been well covered by FluMist. They were one of  
8 the first priorities when the flu vaccine shortage  
9 hit. Also, adenovirus also typically is more  
10 numerous in recruits. So they have not seen much  
11 flu this year.

12 In terms of the PCR screening they do  
13 for influenza, they picked up three shipboard  
14 outbreaks this year. The interesting thing to  
15 note here is of all those three, it turned out  
16 that influenza A, H-3 and -2 turned out to be the  
17 culprit. But in the first two outbreaks, when  
18 NHRC did further sequencing, they found that was a  
19 Fujian-like strain. In contrast, this last  
20 outbreak, which occurred on a Coast Guard cutter  
21 from Oregon to San Diego in February, when they  
22 did the sequencing, they found it to be more akin

1 to the California-like strain which has recently  
2 also emerged in the U.S. Another notable thing is  
3 that the 40 crew were vaccinated and nearly half  
4 of them became ill. However, there were no  
5 hospitalizations or deaths in this outbreak. This  
6 is just an example of the screening that NHRC  
7 does, and it just illustrates that with that  
8 recent outbreak on the Coast Guard ship -- not  
9 only that, but the recent sequencing they have  
10 also done with recruits and also border  
11 surveillance on the San Diego-Mexican border --  
12 other recent sequencing again akin to what the CDC  
13 is seeing has been more related to the California  
14 strain as opposed to the Fujian strain.

15           The other type of data surveillance that  
16 AFIOH does is we do syndromics surveillance using  
17 the GEIS Essence System which tracks the rates of  
18 influenza-like illness. But in general, with this  
19 type of data surveillance, we have also again --  
20 it's mirrored what we've seen on the laboratory  
21 side, in that we do see the peak again in the  
22 January and February months.

1           This is an example of -- we're trying to  
2 put more and more of the data I've presented onto  
3 the website so that public health officers at  
4 these Sentinel bases and any other military  
5 customers can look at the data any time they want.  
6 And we've sort of set up the website with the  
7 ability to look up your individual results, maybe  
8 from your bases or from the States in your bases.

9           I'll move on quickly to other topics,  
10 because I want to make sure I finish in time for  
11 questions. The first topic is avian influenza,  
12 which has been a big concern recently, and  
13 basically the preparations that the DOD Influenza  
14 Program has done this year. I've already talked  
15 about -- a lot of it centers around the  
16 development and validation of PCR screening, not  
17 only for the H5 primers, but validating the  
18 influenza A and influenza B primers as well,  
19 because in a way it's as important to rule in an  
20 influenza A or B from a suspected specimen that  
21 comes from our Bangkok lab as it is to rule out  
22 avian influenza.

1           The second thing is: continue to  
2           strengthen our ties with our Asian sites. And  
3           again, this relates to the training we hope to  
4           give to AFRIMS laboratory personnel, hopefully  
5           this spring, on how to do PCR screening. As I  
6           mentioned, NHRC has already implemented a PCR  
7           screening aboard ships in the Pacific region as  
8           well. Other than that, we also monitor every week  
9           other surveillance systems -- for instance, the  
10          CDC and WHO websites.

11           An issue that came up this year was the  
12          wider use of the live intranasal vaccine due to  
13          the inactive vaccine shortage. Perhaps a question  
14          that inevitably came up from this is that, say, if  
15          you vaccinate someone and then you subsequently  
16          test them, and they become positive for a flu, how  
17          do you know if that's from the vaccination as  
18          opposed to an actual infection? Fortunately, both  
19          NHRC and AFIOH have the vaccine sequence on file,  
20          and so through sequencing, both AFIOH and NHRC are  
21          able to differentiate between vaccine positive  
22          wild-type or actual infection positive.

1           The other message we tried to get out to  
2           the public health officers and providers on this  
3           issue is to kind of use clinical common sense when  
4           testing patients who have received the vaccine.  
5           When they first approved live vaccine for use in  
6           the studies they did, they found no statistically  
7           significant increase in rates of fever, especially  
8           high fever with the vaccine group as opposed to  
9           the placebo group. So the message we've tried to  
10          get out is that if you vaccinate someone and he  
11          subsequently develops a fever, especially a fever  
12          over 100.5, go ahead and test him, because a  
13          positive flu will likely be from actual wild-type  
14          virus. However, if someone is vaccinated and they  
15          suddenly get a runny nose, maybe some with a sore  
16          throat, but no fever, then we say don't test them,  
17          because if they get a positive flu, that will  
18          likely be from the vaccine. Fortunately, this has  
19          not become as much of an issue as we thought it  
20          might be at the beginning of the season when they  
21          first expanded the use of the vaccine.

22                            Another thing, the type of data that we

1 monitor is vaccine breakthroughs, which is  
2 basically defined as someone diagnosed with  
3 influenza who received a vaccination 14 days or  
4 greater prior to the diagnosis of influenza. So  
5 basically it could be thought of as a breakthrough  
6 infection or a type of vaccine failure. AFIOH  
7 were able to kind of monitor this because we have  
8 access to the Air Force database. This type of  
9 data surveillance could be thought of more as a  
10 way to look for warning flags, for instance, if  
11 there is a high number of vaccine breakthroughs a  
12 particular week or a couple of weeks, or if  
13 there's a disproportionate number of vaccine  
14 breakthroughs that's associated with, for  
15 instance, a particular lot number of vaccinations  
16 or a particular provider, that may warrant further  
17 investigation.

18 While it really can't be interpreted as  
19 a reliable indicator of vaccine effectiveness, as  
20 you can see here, 90 percent of all influenza  
21 positives were vaccine breakthroughs this year  
22 compared to last year. That's probably

1 predominately because many people don't get  
2 vaccinated until late in the season, and of  
3 course, if you haven't been vaccinated, you are  
4 not susceptible to a vaccine breakthrough.  
5 Therefore, that number is probably artificially  
6 low. For a more accurate calculation or  
7 estimation of vaccine effectiveness, we actually  
8 have a study. This is a continuation of a study  
9 we started last year. Again, the methodology is  
10 the same. People who have been identified as  
11 having positive influenza, we do telephone  
12 interviews or -- interviews and find out other  
13 household contacts, how many have been vaccinated  
14 and how many have come down with influenza-like  
15 illness. We are then able to calculate the  
16 secondary attack rates between vaccinated and  
17 unvaccinated household contacts and from there  
18 give an estimation of vaccine effectiveness. I  
19 don't have results for you yet. We're still doing  
20 the study. But we hope to have all the surveys  
21 complete and data analysis complete by the end of  
22 the flu season and certainly by the time of the

1 annual Department of Defense influenza meeting on  
2 June 1st. Hopefully, if the results are solid  
3 enough, we also hope to get this published in a  
4 peer review journal. And in the future, if  
5 everything goes well, we hope to make this vaccine  
6 effectiveness study a permanent part of our  
7 program as well so we will have an estimation  
8 every year of vaccine effectiveness.

9           The other interesting issue that some of  
10 our customers have brought up is whether we are  
11 able to compare the effectiveness of live versus  
12 an inactive vaccine. We'll just have to see what  
13 our sample size is and if the subgroups are big  
14 enough to do an subanalysis like that. The last  
15 issue I would like to quickly go over is the  
16 unusual occurrence last summer of an outbreak in  
17 Nepal. I'm kind of presenting this vignette  
18 because I believe it kind of illustrates one of  
19 the unique strengths of the DOD influenza program.  
20 What this was was an influenza-like outbreak that  
21 occurred the end of June, the beginning of July of  
22 last year at a Bhutanese refugee camp in Nepal

1 that was investigated by AFRIMS, the overseas  
2 laboratory that's based in Bangkok. They managed  
3 to get specimens back to us very rapidly so that  
4 we got good results from what they gave to us.  
5 Sixty-six percent of the specimens collected  
6 turned out to be positive with influenza A, H3 and  
7 2. Of course, one of the things we wanted to make  
8 sure was that this was that this was influenza A  
9 and B and not another type.

10 What was interesting was that when we  
11 did further sequencing on these specimens, we  
12 found out it was not the Fujian strain that was  
13 predominant the previous season. What we found  
14 from sequencing is that we found -- and they would  
15 be letters in red -- these are four antibody sites  
16 where we found amino acid changes that differ  
17 between the Nepal specimens and the Fujian strain.  
18 What we didn't know at the time but we now know is  
19 that these four amino acid changes are identical  
20 to what we are now seeing in the California  
21 strain. Now, these Nepal specimens are not the  
22 same as the California strain. The California

1 strain has gone further antigenic drift since  
2 then. But what it seems to be is maybe one of the  
3 first indications that this drift was occurring  
4 back last summer.

5 I believe this kind of illustrates one  
6 of the strengths in the program, because we do  
7 have the ability to go to these remote  
8 locations -- for instance, Nepal -- because of the  
9 partnership we have with our Bangkok lab overseas,  
10 or places like Iraq, the Middle East, Central  
11 Asia, because we are a Department of Defense  
12 influenza surveillance program -- to get these  
13 specimens from these remote locations for further  
14 analysis. And in this case it looks like we did  
15 pick up a new strain last summer, which now  
16 appears to be related to the California strain  
17 that is emerging in the United States right now.

18 So in summary, for the results we have  
19 seen this year, again, influenza A, the H3 and 2,  
20 we have seen has been predominant again, similar  
21 to what the CDC has seen. We have seen a peak  
22 later in the season this year compared to last

1 season. But in another sense, the later peak is  
2 more consistent with previous seasons. In that  
3 sense, last season was unusual, in that it peaked  
4 unusually early. We have seen a relatively  
5 greater frequency of B in the Asia and Pacific  
6 regions. Again, as I mentioned, we also saw this  
7 antigenic drift in the outbreak that we  
8 investigated last year in Nepal.

9 For our accomplishments this season, we  
10 are really trying to get more surveillance sites  
11 aboard our surveillance program, especially  
12 deployed sites in the Middle East and Central  
13 Asia. We are continuing to develop primers for  
14 PCR screening to enhance our ability to more  
15 quickly detect avian influenza. We are continuing  
16 to develop influenza sequencing capabilities and  
17 this became particularly important this year when  
18 the issue of detecting the difference between live  
19 vaccine and actual infections came up. We are  
20 continuing our vaccine effectiveness study and  
21 hope to make that a permanent part of the program.  
22 We continue to monitor trends, for instance such

1 as breakthrough infections and genetic drift  
2 through our sequencing capacities.

3 One last note. We will have our annual  
4 Department of Defense Influenza Program meeting  
5 this year, June 1 in San Antonio. We have a  
6 meeting every year. During this meeting, all the  
7 key players in the Influenza Program such as GEIS,  
8 NHRC, AFIOH, Health Affairs, and others meet to  
9 discuss important goals for next year, including  
10 what new Sentinel sites you may want to add to our  
11 network, special studies including continuation of  
12 vaccine effectiveness studies, better surveillance  
13 for avian influenza, and we invite the CDC to this  
14 meeting as well, because we want to make sure that  
15 we coordinate our surveillance activities with the  
16 CDC's so that we complement each other and we  
17 don't overlap resources.

18 This concludes my briefing for the  
19 Influenza Surveillance Program. Are there any  
20 questions?

21 DR. OSTROFF: Thanks very much. Let me  
22 open it up to board members for questions and

1 comments. First Dr. Gardner and then Dr. Gray.

2 DR. GARDNER: Hi. Pierce Gardner. That  
3 was a very nice presentation. I was particularly  
4 impressed by the ability to calculate vaccine  
5 effectiveness, one of the big questions every  
6 year, how good was our guess regarding the vaccine  
7 and what actually happened? We had a poor  
8 vaccine, I think in 1997, that was based on a test  
9 that didn't turn out to be correct. So this is an  
10 important contribution.

11 The other comment I have would be when  
12 you are going to expand your sites, I would  
13 encourage you to look harder at South America.  
14 You had one South American site in your list that  
15 was a fairly major contributor. It has always  
16 surprised me that we haven't paid more attention  
17 to South America. That's an area where  
18 surveillance, I think, needs to be improved.

19 CAPTAIN FUJIMOTO: Just to comment on  
20 that, we are actually fortunate that we have these  
21 partnerships with these overseas laboratories. I  
22 should point out that the laboratory crew in

1 Bangkok aren't the only military laboratories that  
2 the Department of Defense has. We also have a  
3 laboratory in Cairo and one in Jakarta and one in  
4 Kenya as well. However, the reason they don't  
5 send specimens to us is that all these  
6 laboratories, they need agreement from the host  
7 countries in order to participate in our program.  
8 And in those other cases, the host countries have  
9 been more comfortable with the specimens being  
10 sent to the WHO as opposed to directly to the  
11 Department of Defense. So we truly try to nurture  
12 and make sure everything runs smoothly with the  
13 ones we already have.

14 DR. GRAY: Well done, Captain. It's  
15 very interesting. I'm wondering how the threat  
16 that you might import the B03H5N1 into San Antonio  
17 has changed the way you folks have done business.

18 CAPTAIN FUJIMOTO: Again, that's one of  
19 the reasons we are trying to train, for instance,  
20 that laboratory in Bangkok to do their own PCR  
21 screening. Because obviously, having all these  
22 specimens being shipped where some of them could

1 be avian influenza across the globe to San Antonio  
2 would be a concern. So that would be the reason  
3 that GEIS has really pushed for us to further  
4 develop and validate these PCR screenings --  
5 again, so we could train more and more of these  
6 sites, especially in our Asia sites, to do PCR  
7 screening onsite there as opposed to shipping it  
8 to us.

9 I should also note that we're still  
10 working out the protocols on how we would  
11 actually, in San Antonio, screen for avian  
12 influenza, what type of tests. We need to  
13 validate a lot of those tests, still. That's  
14 another reason we're sending out a person to the  
15 backup laboratory, is that would be another  
16 opportunity to validate these primers, because  
17 obviously we want everything almost 100 percent,  
18 if we are thinking about ruling out avian  
19 influenza at a B cell 3 condition and dropping  
20 down and relying on those tests to tell us whether  
21 we can drop down out of B cell conditions.

22 DR. OSTROFF: Commander Ludwig and then

1 Dr. Ennis.

2 COMMANDER LUDWIG: This is Sharon  
3 Ludwig. Hi.

4 In retrospect, you may have had some  
5 evidence that the California-like strain or  
6 something like the California-like strain was  
7 coming into play early on. Would this information  
8 in conjunction with any WHO information or any  
9 other organization around the world have any  
10 effect, do you think, on the composition of the  
11 influenza vaccine?

12 I guess what I'm getting at is, in a  
13 retrospective look, you can almost always find  
14 something that does precede what's happening now.  
15 But how do you envision that process affecting the  
16 composition of the vaccine? Did you just note  
17 that it had happened? Or do you imagine that at  
18 some point you would have some quality of data  
19 that would affect the composition?

20 CAPTAIN FUJIMOTO: I think that's the  
21 reason why we send in our sequencing information  
22 to the CDC, because we are only one portion of

1 overall influenza surveillance. We send it in to  
2 CDC because they still have all these other  
3 sources of sequencing they get from the United  
4 States and overseas as well.

5 We can't really judge. I mean, back  
6 then we had no idea that, obviously, this strain  
7 would be related to the California strain now.  
8 What we do is we send it to the CDC, and they have  
9 a better overall picture as to what's happening.  
10 They in turn present that to the VERPAC, and the  
11 VERPAC looks at the CDC, including the specimens  
12 that we provide to them as to the overall  
13 determination.

14 So from our own, the specimens we get  
15 alone, it's probably just not a complete enough  
16 picture to make any definite recommendations for  
17 this composition.

18 DR. OSTROFF: Dr. Ennis?

19 DR. ENNIS: Thank you for your  
20 presentation. The AFRIMS lab I have had in-depth  
21 experience with, and I can vouch for their high  
22 level of technical ability in PCRs and their

1 careful attention to quality control. They  
2 haven't used these primers, but I think things  
3 should go very smoothly, and we've worked with  
4 them for a number of years.

5 I had a question that's a more generic  
6 one regarding the overseas labs. When they are  
7 asked to participate in an activity such as this  
8 and get training and have a technician involved,  
9 are there funds provided for this, or is this  
10 coming out of their traditional operating budgets?

11 CAPTAIN FUJIMOTO: Right now,  
12 specifically for -- because these labs, they do  
13 much than just influenza -- but for influenza  
14 activities, some of it is supported through GEIS  
15 funding. And recently the CDC has also provided  
16 funding as well to some of these sites, because  
17 the CDC has also realized that these sites are  
18 valuable parts of the worldwide surveillance for  
19 influenza.

20 DR. OSTROFF: Dr. Klein?

21 DR. KLEIN: In overseas labs, could you  
22 give us a little better sense of what populations

1 are actually covered? For example, in Peru, we  
2 saw quite a large number. Probably it went far  
3 beyond the employees or the people actively  
4 involved in the lab. In Nepal, it was an  
5 outbreak, apparently, that was recognized.

6 But could you give us a little better  
7 sense of what populations are actually screened?  
8 Thank you.

9 CAPTAIN FUJIMOTO: Yes. For the  
10 overseas laboratories it usually is -- for  
11 instance, Nepal Lab, their usual satellite clinic  
12 there is a travel clinic. So it's usually still  
13 civilian, U.S. civilian, such as overseas  
14 diplomats or -- not too much military, because  
15 these aren't really military bases. It usually is  
16 more civilians, U.S. civilians, than the natives  
17 living there, I believe.

18 DR. CLINE: I think, knowing something  
19 about the studies in Peru that the Navy is doing,  
20 I would imagine that they are part of a  
21 prospective study dealing with dengue, and  
22 probably people come in with fever or children

1       come in with fever and they have respiratory  
2       symptoms that are sampled. I would imagine they  
3       are picked up as part of that prospective study.

4               DR. GRAY: This is Greg Gray. I happen  
5       to work with Tony Sanchez, who set up the South  
6       American surveillance. They actually do not do  
7       this among Americans. It's actually done in  
8       various clinics throughout a number of different  
9       countries in South America, and it's the same kind  
10      of case definition. If they meet a fever of 100.5  
11      or the equivalent and one or more signs, then they  
12      collect the swabs and deliver them.

13             DR. OSTROFF: I'm just going to ask one  
14      or two quick questions before we move on to the  
15      next presentation. One of them is that I'm very  
16      curious about who chose the name of your website.  
17      My second relates to one of your slides at the  
18      beginning that indicates that the Army also  
19      compiles their own respiratory virus report. When  
20      you say "also," does that mean they do it  
21      separately from your system or they do it in  
22      addition to their system?

1           If the former is the case, what  
2           difficulties does that introduce in terms of  
3           getting a comprehensive picture of what's going on  
4           with respiratory disease surveillance among the  
5           Services? Is there an effort underway to try to  
6           better incorporate the Army into this surveillance  
7           network?

8           CAPTAIN FUJIMOTO: Yes, sir. As far as  
9           the first question, I'll have to ask the web geeks  
10          that are at AFIOH, because I'm not sure why they  
11          came up with that, other than it's memorable.

12          As far as your second question, our  
13          interaction with the Army as such is a little  
14          complex. The respiratory reports that I mentioned  
15          are outside of the actual GEIS program. However,  
16          Tripler and Landstuhl, at least, also send in  
17          specimens after they diagnose just influenza A or  
18          influenza B at their medical centers. They will  
19          actually send in a subset of specimens to us for  
20          further subtyping and sequencing. So it's a  
21          little complex, our interactions with the Army.  
22          They do some of them.

1 DR. OSTROFF: Why?

2 CAPTAIN FUJIMOTO: Well, for a long time  
3 we tried to get them more integrated into our own  
4 influenza system, but I'm not quite sure what the  
5 difficulties were in the past. Perhaps, I guess,  
6 Linda or Colonel McCall or Dr. Gaydos could give  
7 us some history.

8 DR. OSTROFF: Maybe Colonel Stanek.

9 LIEUTENANT COMMANDER STANEK: I don't  
10 know the historical information behind that  
11 answer. We'll find out.

12 DR. OSTROFF: Can I suggest that maybe  
13 this is something that needs to be fixed, because  
14 there ought to be a unified surveillance system  
15 for the military. This is too important an issue  
16 to have fragmented individual systems.

17 CAPTAIN FUJIMOTO: One of the issues  
18 that we did discuss during last year's influenza  
19 meeting was trying to get the Army more involved  
20 with our own program.

21 We have gotten more Army sites involved  
22 this year. For instance, Fort Drum in New York

1 has sent us plenty of specimens, and we may make  
2 them a Sentinel site next year. So we are aware  
3 of the program and are trying to incorporate them  
4 more into our program.

5 DR. OSTROFF: I would request that maybe  
6 for next season that we get an update of efforts  
7 to better integrate these systems.

8 The only other thing that I'll mention  
9 is that I am quite intrigued by the data from the  
10 recruit settings about the virtual absence of  
11 influenza. I think it is an indication of  
12 actually how good FluMist is as an influenza  
13 vaccine. There are other data out there to  
14 suggest that this is quite a robust vaccine. I  
15 think it's another -- based on the comments that I  
16 made yesterday, it's another reason that I think  
17 it's important for the military to diversify their  
18 flu vaccine acquisition, because this is a really  
19 good vaccine. I think the more it can be used,  
20 the better the impact is.

21 COL. COX: This is Kenneth Cox. I just  
22 wanted to follow your statement up by saying that

1       although FluMist certainly can make a significant  
2       impact, we have several seasons of data that have  
3       shown this same pattern. The recruits always have  
4       very few influenza specimens. There certainly has  
5       to be a fairly significant impact on the  
6       prevalence of adenovirus and how many things they  
7       can get sick with simultaneously, I guess, in a  
8       6-week period. So we do have a fair amount of  
9       background information that shows that this  
10      persisted prior to the institution of FluMist.

11               DR. GRAY: This is Greg Gray. I think  
12      in Vaccine, just recently, NHRC published an  
13      efficacy study. Last season, was it 98 percent  
14      effectiveness?

15               SPEAKER: It was over 98.

16               DR. GRAY: So pretty impressive. I  
17      don't know if they used FluMist for that.

18               SPEAKER: That was injectible.

19               DR. GRAY: So 98 percent with the  
20      injectible.

21               DR. OSTROFF: Thanks very much.

22               Why don't we move on to our next set of

1 presentations? The Board members may recall that  
2 we had some presentations back in San Antonio  
3 regarding a very complicated and difficult issue  
4 which arose regarding the use of the drug  
5 Mefloquine and its possible associations with  
6 vestibular dysfunction. We have a series of  
7 updates regarding some additional work that's been  
8 done related to that issue. The first presenter  
9 is LCDR Dennis Faix, and he is going to discuss  
10 the status of the investigation. And all of the  
11 slides for the three presentations that we will be  
12 hearing are in Tab 9.

13 LIEUTENANT COMMANDER FAIX: Thank you,  
14 sir. Good morning. A look at influenza and  
15 Mefloquine in one morning is wonderful. I'm LCDR  
16 Dennis Faix from the Environmental Preventative  
17 Medicine Unit Number 5 in San Diego. I've never  
18 had like a black cloud over me here in medical  
19 school or residency, but it has been raining  
20 everywhere I've been for the last 2 months. It's  
21 amazing. Anyway, hopefully if I leave this  
22 afternoon, it will be a little better here.

1 I'm going to talk about vestibular  
2 dysfunction in folks that have recently returned  
3 from OIF, OEF, this small outbreak or cluster of  
4 cases that we had in San Diego. The background is  
5 that in early 2004, one of the members of a small  
6 Navy Reserve team that had been in Kuwait and Iraq  
7 and had recently returned had been diagnosed with  
8 vestibular dysfunction. Shortly after that, five  
9 other members of his six-man team, which was part  
10 of a larger 33-man unit, were diagnosed with  
11 similar symptoms at the same clinic at Navy  
12 Medical Center San Diego, which resulted in quite  
13 a bit of press, and the lay press linked it to  
14 Mefloquine. That's what they were pointing to as  
15 the cause of their vestibular symptoms.

16 After this, EPMU 5, with the help of  
17 some folks from the CDC Malaria Branch, initiated  
18 an investigation to look at this vestibular  
19 dysfunction among these personnel.

20 So as soon as we started this  
21 investigation, there's six more cases show up out  
22 of that clinic. These ones are not from the same

1 unit. They are from all completely different  
2 units and unrelated, except that they have also  
3 returned from OIF or OEF recently.

4 So when we first started the  
5 investigation, we had these 12 cases, and they  
6 were all identified as being malarian or  
7 Mefloquine toxicity at that time. So the first  
8 thing we did was go ahead and take all of the  
9 clinical information that we had and background  
10 information, blind it, and give it to the expert  
11 there at Navy Medical Center and also consult with  
12 some outside experts and gave the same data to  
13 them blinded, and have them come back with the  
14 salient features of the cases and confirm the  
15 diagnoses and findings and, from that, develop a  
16 case definition.

17 Once we did that with the case  
18 definition, then we are able to say that we  
19 actually only had 10 cases. Two of the original  
20 six cases fell out because they had things such as  
21 a recent history of head trauma or they developed  
22 their dizziness or they didn't actually have

1 vestibular ocular reflex dysfunction visible on  
2 their rotational chair testing. So we did that.

3           Of course, one of the first things you  
4 want to do is figure out, do you actually have a  
5 rate of dizziness or vestibular ocular reflex  
6 dysfunction that's above the background? And in  
7 fact, we still don't really know that, because the  
8 rate in the general population, let alone the  
9 military population, is not established. But we  
10 did have an apparent cluster of four cases in this  
11 one small, 33-member, Navy Tactical Dissemination  
12 Module team, TDM. So we had that, and we had the  
13 idea that all of the folks that we had talked to  
14 that were cases, they all in their history had  
15 exposures to multiple things that are known  
16 vestibular toxic agents such as loud noises. They  
17 had worked near runways in Iraq or Kuwait. They  
18 had been exposed to jet fuel and various other  
19 things, environmental exposures that could result  
20 in vestibular toxicity.

21           So what we did was, we developed a case  
22 control study looking at all the exposures that we

1       could think of, all the known exposures,  
2       deployments and those types of things. We  
3       developed a 188-question survey that was  
4       investigator-administered -- it was scripted over  
5       the telephone -- that we did. We basically  
6       surveyed that entire 33-member team that the first  
7       four cases came from. Then we were also able to  
8       find units, an Army unit, Army 286 air defense  
9       artillery brigade, that was stationed at the same  
10      base, the Ali el Salam Air Base, that's the big  
11      acronym there which takes up too much room on the  
12      slide. They were at the same base at the same  
13      place at the same time, so we thought that that  
14      was a good comparative group. It was the best one  
15      we could find.

16                Also, as part of this case control  
17      study, we went ahead and did a medical review of  
18      the entire record, not just the relevant ENT  
19      records, of all the cases that we could get the  
20      entire record from, so that was 9 of those 12.  
21      Then we also, as a confirmation of Mefloquine  
22      status or reported Mefloquine status, we requested

1 serum from everybody in the study from the Army  
2 medical surveillance, from the DOD serum  
3 repository. We were able to get serum and go  
4 ahead and test that if it was close to when they  
5 reportedly took Mefloquine. Additionally, we went  
6 ahead and we were able to get ahold of some  
7 Mefloquine tablets from the folks that were part  
8 of the study group, and they still had some  
9 Mefloquine tablets left over. So we were able to  
10 get some of those and look to have that analyzed  
11 by the FDA to look for any abnormalities there.  
12 We were also asked to review the mobilization  
13 process at the base and clinic that they went out  
14 of. So those were the things that we did.

15 I should note -- this is relatively  
16 important -- we had that 33-member team initially  
17 in which we had 4 cases out of. When we picked  
18 this control unit, we interviewed 18 people over  
19 the phone and we actually ended up with 4 folks  
20 that fit our case definition just from symptoms  
21 out of that 18. We did vestibular ocular reflex  
22 testing or rotational chair testing on those

1 folks, and only two of them had the VOR  
2 abnormality that we said was defining a case. So  
3 actually, in our control group we ended up with  
4 two more cases, which made it a little more  
5 difficult to do the analysis. So you will see  
6 later as I present the data, you will see that  
7 there's these 4 cases versus the 29 controls here,  
8 and then we combine these cases and compare them  
9 against the 16 controls, and then we group these 2  
10 others as cases, since they met our case  
11 definition.

12           The Navy unit was a Reserve unit, so  
13 those members were active duty Reservists and  
14 tended to be a bit older than the second control  
15 group, which was the Army Air Defense Battery. So  
16 the Army folks that were our second comparative  
17 group tended to be younger on active duty. But  
18 other than that, no real significant differences  
19 between cases and controls.

20           Again, no real significant difference in  
21 medical history. The cases had a slightly higher  
22 rate of past medical history of motion sickness,

1 but our survey didn't actually differentiate  
2 between recent motion sickness and these guys all  
3 complaining of dizziness and distant past medical  
4 history of motion sickness as a child. So I can't  
5 really draw too many conclusions from that.

6 One other thing we found was that cases  
7 did tend to be deployed longer than controls, but  
8 there wasn't a significant difference there  
9 either.

10 This is a time line of the deployers.  
11 You can see the green here. These are those two  
12 cases that came from the Army control unit. These  
13 are the four original cases from the Navy unit.  
14 So you can see, the blue bar is when they were  
15 deployed. They were all in Kuwait, all at the Ali  
16 el Salam Air Base. The yellow bar is when they  
17 took Mefloquine or if they took Mefloquine. And  
18 the red bar is when they had symptoms. So what's  
19 interesting is you can see that four out of the  
20 six did take Mefloquine. You can see that five  
21 out of the six, the onset of symptoms was actually  
22 after they redeployed. In four of the cases, it

1 was immediately upon redeployment that they  
2 started feeling symptoms. In one case over here,  
3 it took about 6 months before symptoms were onset.  
4 Of the four that took Mefloquine, only one of them  
5 took it actually as prescribed and took the whole  
6 4 weeks after redeploying.

7 Although all these folks were in Kuwait  
8 the whole time, these four folks had a 2-week trip  
9 up where they did a road trip, a convoy up to  
10 Baghdad and back where they did some work up there  
11 for a week, and then came back. That was a  
12 relatively intense combat experience that they had  
13 riding on that convoy.

14 DR. OSTROFF: Can I ask you one quick  
15 question on that slide?

16 LIEUTENANT COMMANDER FAIX: Yes, sir.

17 DR. OSTROFF: The ones that are blue on  
18 the Y axis versus yellow, are those the Navy  
19 versus the Army?

20 LIEUTENANT COMMANDER FAIX: Yes, sir.  
21 These are the Navy folks and those are the Army  
22 folks. These are from our second control unit and

1 these are the original first four cases.

2 DR. OSTROFF: So the Army did not use  
3 Mefloquine, is that right?

4 LIEUTENANT COMMANDER FAIX: That is  
5 correct, sir. We can go into that more later if  
6 you'd like.

7 So we have a whole bunch of results,  
8 obviously. I'm just going to show you some of the  
9 ones that seem relevant. This is, again, the Navy  
10 group here. So this is the Navy control group  
11 with those original four cases versus those  
12 controls. The highlighted ones are the ones that  
13 are statistically significant. But the point here  
14 is that really overall, we see a general trend  
15 where any time we look at these type of things,  
16 it's extreme stress, intense fear, engaging in  
17 direct combat, we see that basically the cases had  
18 higher rates of exposure than the controls.

19 Here, these are not exposures but actual  
20 symptoms. These three right here actually are  
21 part of the case definitions. We expect those to  
22 be higher. But when you get down here, little

1 interest in doing things, feeling down, hurting  
2 oneself, these types of things are associated with  
3 anxiety or post-traumatic stress, something like  
4 that. Here again, we tend to have the cases  
5 having higher rates than the controls. This is  
6 again for that Navy group. It's repeated here for  
7 the Army control group, although from the lack of  
8 (inaudible) it's not quite as significant, but  
9 again, relatively more as a general trend.

10 In terms of malaria chemoprophylaxis,  
11 and again, this is only for the Navy -- the Army  
12 did not take any malaria chemoprophylaxis while  
13 they were at Ali el Salam Air Base, so there is  
14 really no comparison to be made in this case --  
15 but we have the difference of taking any  
16 anti-malarial and then the difference in  
17 Mefloquine. So it's 100 percent versus 50 percent  
18 as the difference, but again, not a statistic that  
19 we can draw any significant conclusions from.

20 In the records review that we did, we  
21 had documentation of pre-deployment health  
22 assessments in only three of the nine records that

1 we have reviewed. Of those that have taken  
2 Mefloquine, none had any documented counseling or  
3 screening prior to the issuance of Mefloquine.  
4 Now, we realize that all those folks deployed  
5 before the DOD memo came out on force health  
6 protection, prescription products requires that  
7 kind of thing, but it's not in the record here.  
8 Postdeployment health assessments were in six out  
9 of the nine charts. The next thing we did was the  
10 Mefloquine tablet testing that we sent these  
11 tablets to the FDA. They were compared to  
12 off-the-shelf warehouse controls, and there were  
13 no differences between the control tablets and the  
14 tablets that have been issued, deployed over to  
15 Kuwait or Iraq, have been in the individual's hand  
16 for 6 months and then come back. The pills were  
17 the exact same.

18 Certainly, there were many limitations  
19 in this study. We had very small numbers. This  
20 was supposed to be a pilot study just to kind of  
21 generate hypotheses for a further look. Potential  
22 biases, certainly. Selection bias, the cases, at

1       least the first four were self-selected and  
2       strongly motivated to seek out care and  
3       specifically to seek out rotational chair testing  
4       at Navy Medical Center San Diego. They were  
5       really instructed to do so by the guy, the initial  
6       index case. He was the OIC of that group while  
7       they were at Ali el Salam Air Base, and he's the  
8       one who is a very vocal proponent of the link with  
9       Mefloquine, and he strongly encouraged all the  
10      folks which he had been deployed with, if they had  
11      taken Mefloquine, to seek out this care.

12                On the other hand, we do know that there  
13      is an acute neurotoxicity of Mefloquine. Anxiety  
14      and dizziness are known as acute side effects,  
15      although there's not been any evidence in  
16      controlled studies of longterm effects from  
17      Mefloquine. There are recent articles looking at  
18      physiologic possible effects or ways that  
19      Mefloquine could be causing the mechanisms of  
20      acute neurotoxicity of Mefloquine. We do know  
21      that there's an association between anxiety  
22      disorders and vestibular dysfunction. So if you

1 have Mefloquine that causes short-term anxiety in  
2 some folks and possibly you have combat stress and  
3 anxiety, could there somehow be an interaction?  
4 Certainly we can't rule that out. What we can  
5 conclude is that the vestibular abnormalities  
6 exhibited by our cases were not the same as  
7 peripheral vestibular abnormalities that are  
8 normally seen with ototoxicity that you would  
9 expect from drug toxicity or exposure to loud  
10 noises, that kind of thing. They were similar to  
11 central vestibular toxicity which you normally see  
12 related to migraine and anxiety-related dizziness.  
13 The rate of balance disorders and dizziness among  
14 these subjects is within the reported normal range  
15 in the general population, which is actually huge,  
16 from like .8 to 24 percent. So it is not well  
17 known, and it's hard to say whether in an active  
18 duty population you might expect the rate to be  
19 higher or lower. You might expect military-unique  
20 exposures such as deployment battle to cause  
21 higher rates of dizziness, or you might expect a  
22 healthy soldier or healthy deployer type of thing

1 would keep folks having lower rates of dizziness.

2 From this study, there's not evidence  
3 that any known vestibular toxic agent was  
4 associated. Of all the vestibular toxic agents  
5 that we looked at, none was associated with being  
6 a case in this study, nor was taking Mefloquine  
7 which, again, was not a known vestibular toxic  
8 agent.

9 We did have higher levels of combat  
10 stress and neuro-psych symptoms as compared to  
11 controls in these cases, possibly suggesting that  
12 combat-related stress may be associated with  
13 vestibular dysfunction. You can't rule out some  
14 kind of interaction there. Certainly we conclude  
15 that documentation of predeployment health  
16 assessments and appropriate Mefloquine screening  
17 was not found in the medical records reviewed at  
18 the time, indicating that either it wasn't done  
19 or -- hopefully it was done and just not  
20 documented.

21 So further study into the possible  
22 interaction between Mefloquine and vestibular

1 dysfunction and combat stress is warranted.  
2 Certainly, exploiting existing databases is --  
3 we'll hear it from Tim Wells soon -- is an  
4 excellent way to go. Other alternatives are a  
5 selected survey of redeploying personnel such as  
6 Dr. Holmes' group at Walter Reed. Army research  
7 has been doing and explaining that to look a  
8 little more closely at the Mefloquine question.  
9 DOD-wide case finding for a larger case control  
10 study would increase the numbers and maybe give us  
11 some more statistical power for repeating this  
12 same study. We are working on establishing a  
13 baseline of dizziness and vestibular ocular reflex  
14 abnormality rates among active duty personnel  
15 right now at Navy Medical Center San Diego. So we  
16 are recruiting folks into that study as we speak.  
17 And to reemphasize current DOD guidance regarding  
18 predeployment medical screening, documenting  
19 appropriate medical screening, and excluding folks  
20 that don't meet prescription requirements, and  
21 doing the predeployment health assessments.

22 I would be happy to take any questions.

1 I just want to acknowledge NHRC for their support,  
2 the DOD Serum Repository from AMSA, the FDA for  
3 doing the testing, and the wonderful folks at the  
4 CDC Malaria Branch that helped us out with this  
5 investigation.

6 DR. OSTROFF: Thank you, Commander.  
7 That was a terrific presentation. Congratulations  
8 in a very difficult circumstance.

9 Let me first turn to Dr. Blazer and then  
10 Dr. Brown.

11 DR. BLAZER: Yes, I would agree that I  
12 think you have done a very, very thorough job.  
13 The caution I would make, though, is I have a lot  
14 of difficulty labeling this a case-controlled  
15 study, given all the difficulties in identifying  
16 controls and all the potential biases. I have  
17 some difficulty in presenting statistics tests  
18 because of all the potential biases as well. To  
19 me, this is a qualitative study. When you've got  
20 a few individuals who exhibit some symptoms I  
21 think you have done a very thorough job of trying  
22 to explore victim potential hypotheses.

1           But just from my perspective, I'd be  
2           very careful about presenting the statistical  
3           data, because I'm just not sure that that really  
4           is going to tell you anything. I would just be  
5           very, very careful about doing that, because I  
6           think there's just too much here that renders too  
7           much bias. I think if this were presented as a  
8           case control study, I think it really puts you up  
9           for a lot of criticism in terms of your  
10          methodologies that you really don't want to. I  
11          think you can say what you've done, and I think  
12          that's probably enough.

13                   LIEUTENANT COMMANDER FAIX: Point taken,  
14           sir.

15                   DR. BROWN: Mark Brown. I would, I  
16           guess, echo Dr. Blazer's points there. I mean,  
17           this data that you presented, I know why you got  
18           involved with this. You had to respond to the  
19           situation. But the data, it seems sort of  
20           confusing. I mean, you have the vestibular  
21           abnormalities in the group of half a dozen  
22           individuals and the allegation that it might be

1 associated with Mefloquine, taking Mefloquine.  
2 But then when you look at the data, some of the  
3 individuals weren't even taking Mefloquine. Then  
4 I thought you made a pretty good case that there's  
5 the possibility that this is associated with some  
6 kind of a psychiatric component to some degree.

7 Putting it all together, it's kind of  
8 hard to make any conclusions. I guess you kind of  
9 answered that point, though. Further studies will  
10 be required to really nail this down, to get an  
11 answer about what's going on with this, right?

12 LIEUTENANT COMMANDER FAIX: Yes, sir.

13 DR. OSTROFF: Well, I would say you  
14 might want to listen to the rest of the  
15 presentation to be able to put it into better  
16 context.

17 DR. BROWN: Fair enough.

18 DR. OSTROFF: Dr. Lauder?

19 DR. LAUDER: This is Tamara Lauder. I  
20 just had a quick question. When you were  
21 comparing your two groups, you said overall, your  
22 control group, there was no clinical significance

1 between the ages between the control group in your  
2 case control group.

3 What do you mean by "clinical  
4 significance?"

5 LIEUTENANT COMMANDER FAIX: The only  
6 difference in ages was, again, between the two  
7 groups, the Navy group and the Army group. The  
8 Army group was younger in active duty by a couple  
9 of years. I don't have the actual data here,  
10 because it's a highlighted presentation. But  
11 between cases in the control groups, there was not  
12 a difference, particularly --

13 DR. LAUDER: I would just look at that  
14 maybe closely because I think with the age  
15 vestibular dysfunction does -- I mean, there is a  
16 correlation there.

17 LIEUTENANT COMMANDER FAIX: There is  
18 over a certain age. But all of our folks were  
19 under the normal age where you consider the  
20 vestibular function decreases or you have a sharp  
21 increase in VOR abnormalities.

22 DR. OSTROFF: First Dr. Cattani and then

1 Dr. Gardner.

2 DR. CATTANI: Jackie Cattani. I'm  
3 actually more interested in how you are going to  
4 do surveillance or follow-up on this in the future  
5 in terms of the case definition. How important is  
6 the rotational chair going to be, and are you  
7 satisfied that you have a precise enough case  
8 definition that the data collected in the future  
9 is going to be more easily interpreted?

10 LIEUTENANT COMMANDER FAIX: That's a  
11 very good question. This is something we have  
12 struggled with, because at first when these cases  
13 were presented to us, it was explained to us in  
14 such a way that rotational chair testing was  
15 something very important and concrete -- you could  
16 hang your hat on it. But after investigating this  
17 quite a bit, that's not the case.

18 So is rotational chair testing  
19 important? Possibly in a subset of patients. But  
20 if you were going to do a larger study, the  
21 logistics and expense to go ahead and test  
22 everyone is probably prohibitive. So we would

1 have to look at changing that.

2 DR. OSTROFF: Dr. Gardner.

3 DR. GARDNER: My question is a  
4 follow-up. How reproducible is the vestibular  
5 ocular testing? Again, I gather all the cases  
6 were tested, but it seems to me the obvious study  
7 to do is people before they start their Mefloquine  
8 and after they have had it, because it seems to me  
9 our biggest problem here is sorting out the  
10 subjective complaints led by a particular  
11 individual, apparently, who is encouraging people  
12 to go after this versus what can you objectively  
13 hang your hat on. It sounds to me as if you have  
14 some doubts as to whether you've got a test that  
15 really nails this.

16 LIEUTENANT COMMANDER FAIX: That's  
17 correct, sir. I do have some doubts.

18 Now, there's literature to show that  
19 there is good reproducibility. You do it in the  
20 same lab with the same person running the chair  
21 and you can get good reproducible results. You  
22 also have to have a willing and compliant and

1 cooperative patient.

2 DR. CATTANI: Well, it seems to me,  
3 then, that you would need to take individuals who  
4 volunteer and test them and give them their  
5 Mefloquine and test them again.

6 I gather there are no animal models or  
7 anything like that that could help us here, is  
8 that right?

9 LIEUTENANT COMMANDER FAIX: Not at this  
10 time.

11 DR. OSTROFF: I have a couple of quick  
12 questions. This Board has grappled over the last  
13 year or two with issues related to malaria  
14 chemoprophylaxis. I know it continues to be a  
15 difficult and challenging issue. But when you see  
16 a circumstance where you have two units basically  
17 serving right next to each other, one unit is  
18 taking malaria chemoprophylaxis and the other one  
19 apparently isn't --

20 LIEUTENANT COMMANDER FAIX: Sir, I can  
21 address that.

22 DR. OSTROFF: Good. It's confusing, to

1 say the least.

2           LIEUTENANT COMMANDER FAIX: Definitely.  
3 And again, this is in the retro-spectroscope  
4 looking back. But in my opinion, the Navy group  
5 that went out was a small Reserve unit. They were  
6 activated out of China Lake. When they were  
7 activated and being sent into the theater, they  
8 had no idea where they were going to end up. All  
9 they knew was that they were going into the  
10 theater in CENTCOM. So at that time the medical  
11 personnel at China Lake said, well, we don't know  
12 where you are going; we are going to give you  
13 Mefloquine, because that will cover you in the  
14 whole area, and off you go.

15           So they ended up spending most of their  
16 time there in Kuwait, and they were actually --  
17 again there's no documentation of this, but the  
18 medical personnel say they told them, here's your  
19 Mefloquine; when you get in the theater, ask your  
20 local medical folks. But they started taking it  
21 before they left and took it while they were  
22 there. Whereas the Army unit was going into

1 Kuwait, knew they were only going to go into  
2 Kuwait, and that malaria chemoprophylaxis was not  
3 necessary.

4 That's my interpretation of how it  
5 happened that you had two units right next to each  
6 other, one taking Mefloquine and one not.

7 DR. OSTROFF: Thanks. My second  
8 question is, have the results of this particular  
9 study been discussed or provided to those units or  
10 the personnel that are most concerned about this,  
11 and what sort of feedback have you gotten?

12 LIEUTENANT COMMANDER FAIX: The results  
13 of this study have not been given out to these  
14 personnel involved yet. We will be doing that.  
15 We're basically getting ready to disseminate the  
16 report. It hasn't been disseminated yet.

17 DR. OSTROFF: Be careful how you do  
18 that.

19 LIEUTENANT COMMANDER FAIX: Thank you,  
20 sir. I hope to be in Iraq at that time.

21 DR. EMBREY: I have a question. Did all  
22 of these people have anthrax and smallpox shots?

1                   LIEUTENANT COMMANDER FAIX:  Yes, ma'am,  
2                   they did.

3                   DR. EMBREY:  Aha, so there's the cause,  
4                   huh?

5                   DR. OSTROFF:  Thank you very much.  Dr.  
6                   Oxman, one more question.

7                   DR. OXMAN:  Just a quick question,  
8                   because obviously the reality of this and whether  
9                   there's anatomic damage or not is important.  
10                  Anybody have any data on a PET-scan before or  
11                  after the Mefloquine or in these subjects, in  
12                  these patients?

13                  LIEUTENANT COMMANDER FAIX:  I certainly  
14                  don't have any data on that, no.

15                  DR. OXMAN:  Yes, I'm sure there wouldn't  
16                  be beforehand.  So whether there is afterwards, I  
17                  don't know if there was any indication in the  
18                  records.

19                  LIEUTENANT COMMANDER FAIX:  No, sir.

20                  DR. EMBREY:  How early in the fight was  
21                  this?  What's the time frame?

22                  LIEUTENANT COMMANDER FAIX:  This was

1 very early. This was in the beginning of 2003  
2 when the team deployed, basically in January and  
3 February of 2003. And then in that April is when  
4 they made the trip up to Baghdad and back, which  
5 was basically as soon as the hostilities were such  
6 that they could drive up there and back. It was  
7 still relatively intense.

8 COLONEL GIBSON: Dr. Oxman, this is  
9 Colonel Gibson. Was your question relative to the  
10 literature with respect to PET scans, not  
11 necessarily just these folks?

12 DR. OXMAN: I reviewed this literature  
13 pretty deeply over the last year and a half.  
14 There are just a handful of case reports that have  
15 had MR and in a couple of cases PET scans, but  
16 there's not very deep literature on that type of  
17 follow-up for cases. Most of those were related  
18 to other types of psychological problems  
19 associated with or potentially associated with  
20 Mefloquine.

21 DR. OSTROFF: Thanks. We're going to  
22 move on. Thank you again. Our next presenter is

1 Colonel Wells from NHRC, and he's going to discuss  
2 a study that was done on Mefloquine-related  
3 hospitalization.

4 COL. WELLS: Thank you, Dr. Ostroff.

5 Ms. Embrey, Dr. Ostroff, other members  
6 of the Board and invited guests, I'm Tim Wells,  
7 and on behalf of the team at NHRC, I'd like to  
8 brief today the study that we conducted looking at  
9 Mefloquine prescriptions and their association  
10 with potential hospitalizations among our active  
11 duty force.

12 As most of you know, malaria has been  
13 historically a big problem for our military. It  
14 dates back to prior to Guadalcanal. But in  
15 Guadalcanal, the attack rate was actually higher  
16 than the number of forces in the operation. Sixty  
17 years later in Liberia, we still had 80 out of 290  
18 U.S. military personnel contract malaria, so there  
19 was a breakdown in prevention. Malaria prevention  
20 can be broken down into two categories: Basically  
21 prevent the bites from the mosquito and the other  
22 is to use a chemoprophylaxis. The one that we're

1 going to talk about in this study is Mefloquine,  
2 which was approved by the FDA in 1989 under the  
3 trade name Larium.

4 I've got a number of slides on  
5 background. I'll try to go through those quickly.  
6 Basically, most of the research has been done in  
7 civilian populations in Europe, and so we've got  
8 travelers and those -- so Mefloquine is being used  
9 for a different scenario than it is in our  
10 military population, where these folks are  
11 travelers, and our military population is often  
12 going into harm's way.

13 The other thing that you will see  
14 different between the military studies and the  
15 studies among military populations is that a lot  
16 of the civilian studies were confounded by up to  
17 30 percent of individuals were using recreational  
18 drugs also. So that complicates how you interpret  
19 the results. But it's basically believed that  
20 Mefloquine is generally considered well-tolerated  
21 in military populations, but the studies have had  
22 mixed results. So what I present now is just

1 three randomized clinical trials, one using  
2 Indonesian soldiers and the other two using U.S.  
3 Service members. In all three of those, the  
4 individuals that were randomized to Mefloquine did  
5 have higher rates of adverse mental disorders than  
6 did those who were on other anti-malarials.

7           However, in observational studies, most  
8 recently in Australian soldiers that were in East  
9 Timor, although 6.5 percent of them withdrew from  
10 Mefloquine, those that stayed on Mefloquine, when  
11 it was asked, "Would you take this again," 94  
12 percent of them said that they would compared to  
13 89 percent of those who were on doxycycline.

14           So the objectives of our study were to  
15 describe morbidity potentially associated with  
16 Mefloquine use as measured by objective electronic  
17 data on prescriptions and hospitalizations, and  
18 then to use this study as a foundation for other  
19 Mefloquine research.

20           The study population that we chose was  
21 active duty individuals who were on active duty in  
22 the year 2002. They could not have had an

1 anti-malarial prescription during October 1, 2001  
2 through the end of the year. And our  
3 Mefloquine-prescribed group was defined as  
4 individuals having a minimum of seven Mefloquine  
5 tablets and a deployment that overlapped to some  
6 degree with that Mefloquine prescription.

7 We decided to use two referent  
8 populations. The first one, we wanted to have  
9 what we would consider to be a fairly healthy  
10 population but with no chance of having been  
11 prescribed for an anti-malarial during the study  
12 period. So we opted to used individuals with duty  
13 zip codes of Europe or Japan, because individuals  
14 who live overseas are generally healthier than  
15 those who stay back here in the United States.  
16 They have been through a screening process. We  
17 also restricted it to those who had no deployment  
18 history and no history of Mefloquine anti-malarial  
19 use.

20 We also wanted another referent group,  
21 and so we opted for individuals who had been  
22 identified as being deployed but didn't have

1 prescriptions for any anti-malarials.

2 We got our deployment status from the  
3 DMDC pay files, whether or not they had had the  
4 combat zone tax exclusion or imminent danger pay,  
5 and the Mefloquine prescriptions were obtained  
6 from the Pharmacy Data Transaction Service. If  
7 there was more than one qualifying Mefloquine  
8 deployment combination, we chose the first one as  
9 our exposure event for this study.  
10 Hospitalizations came from the standard inpatient  
11 data record in the health care service record.  
12 And we broke it into different ICD-9 categories.  
13 We looked at an any cause category. Then we  
14 looked at 14 broad ICD-9 categories. Then a group  
15 of mental disorders that we got from a paper  
16 published by Dr. Engel, and then we looked at  
17 hospitalizations of specific interests that came  
18 up from the Naval Medical Center San Diego study.

19 Statistical analyses included  
20 descriptive analyses, and we used Cox Proportional  
21 Hazards with adjusting for age, sex, military  
22 rank, Service branch, race, ethnicity, marital

1 status, prior hospitalizations for any cause, and  
2 then occupation, which was broken down to combat  
3 and other.

4 The follow-up period for the  
5 Mefloquine-prescribed group and the other deployed  
6 was very similar. We started following them upon  
7 return from deployment, and then the goal was to  
8 follow them for 12 months. However, if they  
9 separated from Service, began a new deployment or  
10 a new anti-malarial prescription, had a  
11 hospitalization of interest or hit the end of the  
12 study period which was March 31, 2004, we would  
13 stop follow-up at that time. The Europe-Japan  
14 group was a little bit different in that we  
15 started their follow-up -- if their duty Zip code  
16 was Europe or Japan at the beginning of the study,  
17 we started following them for the point during  
18 2002 in which their duty Zip code became Europe or  
19 Japan. We followed them basically the same as the  
20 other two groups except for if their duty Zip  
21 ended, then we would stop follow-up at that time  
22 also. We had a requirement that we had to follow

1       them for a minimum of 2 months. So I'll brief our  
2       results with that.

3                 Although these differences are  
4       statistically significant, the proportions are  
5       basically the same across the category for these  
6       four variables. You'll note that we had about  
7       9,000 individuals in our Mefloquine group, 156,000  
8       in our Europe and Japan group, and the other  
9       deployed reference group, 232,000.

10                We did have some interesting findings or  
11       differences when we look at Service. You will  
12       notice that 79 percent of our Mefloquine group  
13       were in the Army, compared to only 39 percent in  
14       the Europe and Japan group or 25 percent in the  
15       other deployed reference group. The other thing  
16       of interest in the occupational categories is that  
17       our Mefloquine-prescribed group was 37 percent in  
18       infantry, gun crews and seamen, and it tapered off  
19       for the Europe-Japan group, but it was once again  
20       about 26 percent for the other deployed groups.  
21       So there were some differences there.

22                Here's looking at our Cox Proportional

1 Hazards Analysis, looking at the broad categories.  
2 What you will see is that we do have some that are  
3 statistically significant, but they are all within  
4 the Europe and Japan reference group. But you  
5 will notice that they are all less than 1.0.

6 The other thing that's interesting of  
7 the comparisons, it appears that there's some type  
8 of a systematic bias there, because most of the  
9 hazard ratios are less than 1.0. In comparison  
10 with the other deployed reference group, you will  
11 notice that we have quite a bit of dispersion  
12 about 1.0, but none of the hazard ratios are  
13 statistically significant.

14 When we looked at specific mental  
15 disorder categories, once again we see with the  
16 Europe and Japan group a similar trend as we did  
17 in the previous slide and with the other deployed  
18 group also. You will notice that under  
19 "vertiginous syndromes" down near the bottom, we  
20 do see some elevated hazard ratios. This is based  
21 on one individual in our Mefloquine-prescribed  
22 group, four individuals in the Europe-Japan group,

1 and six individuals in the other deployed group.  
2 So it's pretty small numbers.

3           When we compared the Europe and Japan  
4 reference group, we did find some statistically  
5 significantly lowered risk in those four different  
6 categories. We think there could be a selection  
7 bias where those who deploy are still healthier  
8 than those with duty Zip codes overseas. There  
9 may be differences in the reporting of medical  
10 encounters between overseas and within the U.S.,  
11 or it may be an artifact of multiple comparisons.

12           When compared to the other deployed  
13 reference group, we didn't find any statistically  
14 significant differences. These findings may  
15 reflect that Mefloquine is unlikely to be  
16 associated with hospitalizations over a broad  
17 range of outcomes. But we do have some  
18 differences in the groups. The  
19 Mefloquine-prescribed group was primarily Air  
20 Force and Army. They were more infantry, and when  
21 we dug down deeper into the data, we found that  
22 they were primarily deployed to OEF and OIF. The

1 other deployed reference group seemed to have  
2 random scatter throughout the globe. So there's  
3 probably some differences in the types of  
4 operations that the two groups were performing,  
5 which could also account for differences.

6 We do have some limitations with the  
7 data. I think the biggest one is using the  
8 Mefloquine prescriptions. The problems that we  
9 have is that those individuals who were prescribed  
10 Mefloquine, we don't know for sure that they took  
11 it. Conversely, in our other deployed reference  
12 group, we don't know that individuals who got  
13 overseas weren't given Mefloquine once they got  
14 there. So we are concerned about that.

15 Using the inpatient hospitalization data  
16 or those ICD-9 outcomes, we are only looking at  
17 very severe, significant outcomes that required  
18 hospitalization. Then we did conduct a large  
19 number of analyses, which increases the likelihood  
20 of statistically significant findings.

21 The strength is, we did have a large  
22 sample size. We used two healthy reference

1 populations to try to overcome the limitations  
2 that each one presented and that the use of  
3 objective data eliminated the possibility of  
4 recall bias.

5 So overall, Mefloquine-prescribed active  
6 duty Service members were not at increased risk  
7 for hospitalizations over a broad range of  
8 outcomes in this study. And this is our team back  
9 at NHRC.

10 So I'll be happy to entertain any  
11 questions.

12 DR. OSTROFF: Thanks very much. Another  
13 really very nice effort. Thanks for presenting  
14 this.

15 Let me open it up for the Board members.  
16 Dr. Brown first.

17 DR. BROWN: I agree. That was a very  
18 useful study, I think, to try and answer some of  
19 the questions about Larium health effects.

20 You mentioned under your study of  
21 limitations the issue that you were just looking  
22 at inpatient data. It struck me as you were

1 talking about this that that's probably a good  
2 point. I know when VA looks at health care  
3 utilization of Service members who served in Iraq  
4 or Afghanistan and then came back and separated  
5 from military service and are therefore eligible  
6 for health care, if you look at that population  
7 who come to Virginia for any help, we are seeing  
8 tens of thousands of individuals who come to VA  
9 for health care. But it's almost all -- more than  
10 99 percent of it is on an outpatient basis. We  
11 are only seeing a very tiny handful of individuals  
12 on an inpatient basis.

13 So I'm wondering if, A, could you look  
14 at outpatient data? Do you have access to that?  
15 If you do, you know --

16 COL. WELLS: Why didn't we do it? The  
17 hospitalization data is much more mature. It's  
18 been around approximately 10 years longer than the  
19 ambulatory data. The ambulatory data, we have  
20 some concerns about the accuracy of the diagnoses,  
21 and then from the preliminary investigations that  
22 we've done, there's also some systematic

1 differences when we are looking at the reporting  
2 from the overseas areas. For example, in October  
3 through December of 2001, all of a sudden there  
4 was just a very noticeable increase in the number  
5 of ambulatory visits or outpatient visits that  
6 were reported, and then they drop off. So there's  
7 some limitations in the ambulatory data that we  
8 don't have a good handle on yet. That's one of  
9 the biggest reasons that we haven't used that.

10 Yes, you're right, when you look at the  
11 number of outcomes, there's a lot more available.  
12 For example, with the mental disorders, there's  
13 only a total of 37 individuals in our  
14 Mefloquine-prescribed group that had a mental  
15 disorder hospitalization diagnosis. But there's  
16 thousands and that's relative to the other  
17 groups -- it's not just that group. But there's  
18 so much more ambulatory data. But we're, number  
19 one, worried about the reliability of the  
20 diagnoses, and then there's some inconsistencies  
21 that we really haven't worked out well yet.

22 DR. OSTROFF: Dr. Herbold?

1 DR. HERBOLD: John Herbold. When we had  
2 a subcommittee meeting in D.C. last year, we  
3 received some information on the pharmacy database  
4 so that it was the policy for units to be  
5 prescribed the Mefloquine so that they had it  
6 onboard. And then they were told that when they  
7 got in theater, depending on where they went, to  
8 make a decision whether they were going to take it  
9 or not. Before this information is released, I  
10 would think that whether they took the Mefloquine  
11 or not needs to be validated. That was an issue  
12 that was brought up by the pharmacy people to us.

13 COL. WELLS: That would require  
14 considerable resources.

15 DR. HERBOLD: That's an excellent point,  
16 but using the electronic data sets without  
17 validating that the people actually took the drug  
18 would result in significant misclassification  
19 error.

20 DR. OSTROFF: You might not have to do  
21 9,000, but just 100 or so to get a feel of how  
22 accurate that assumption was.

1 COL. WELLS: We thought about doing that  
2 with trying to link. Well, we could link our  
3 cohort to the postdeployment health questionnaire  
4 with the database that AMSA has. There is a  
5 question number 5 on there that's a laundry list  
6 of, did you take any of these? One is  
7 anti-malarial pills. So we thought about looking  
8 at the correlation between the prescription data  
9 and that question number 5 on the postdeployment  
10 health questionnaire as at least a surrogate for  
11 doing personal interviews, which we know from the  
12 Liberia experience may not be accurate.

13 DR. OSTROFF: Dr. LeMasters?

14 DR. LEMASTERS: Grace LeMasters. I just  
15 had one question. Is there any difference in  
16 length of follow-up of the three groups? It could  
17 be as short as 2 months and as long as 12 months.  
18 I was wondering, what was the average length for  
19 your three groups? That could affect the  
20 opportunity for hospitalization if the length of  
21 follow-up was significantly different among your  
22 groups.

1 COL. WELLS: I don't have those numbers  
2 in front of me, but I think it was fairly  
3 comparable between the Mefloquine-prescribed group  
4 and the other deployed referent group. But it was  
5 actually longer for the other, for the  
6 Europe-Japan reference group, because they are a  
7 little bit more stable a population than were the  
8 other two.

9 We tried to take into account we're  
10 using the Cox Proportional Hazards, which does  
11 take into account the time of follow-up also.

12 DR. OSTROFF: I have a couple of brief  
13 comments and questions. One is that I think that  
14 this is a wonderful effort. While I think all of  
15 us would agree that this isn't definitive  
16 information, it is certainly reassuring  
17 information in terms of there being nothing  
18 overtly obvious that's going on in terms of severe  
19 morbidity associated with Mefloquine.

20 I actually am struck by the relatively  
21 small number of individuals that were prescribed  
22 Mefloquine, given the large numbers of individuals

1 that have deployed to the region in which the  
2 policy has been to have malaria chemoprophylaxis.  
3 Is this number fairly consistent with what the  
4 general gestalt is in terms of the proportion of  
5 deployed individuals that were prescribed  
6 Mefloquine?

7 COL. WELLS: Sir, we don't have a good  
8 feeling for that. Using the definition that they  
9 had to have a minimum of seven tablets probably  
10 eliminated some individuals. Well, it did  
11 eliminate individuals who were prescribed  
12 Mefloquine. The reason we went with the seven  
13 tablets was because we thought that would be a  
14 2-week predeployment. They'd have to be deployed  
15 for at least 1 week, so that's three tablets.  
16 Then they are supposed to take it for 4 weeks  
17 afterwards. So that's why we use the seven tablet  
18 definition.

19 But I don't have a good answer to your  
20 question.

21 DR. OSTROFF: And then my second  
22 question gets back to this issue of looking at

1 hospitalizations versus outpatient. In terms of  
2 what prompted all of this with these individuals  
3 with the vestibular dysfunction, does anybody  
4 know, were any of them actually hospitalized?

5 COL. WELLS: No, sir.

6 DR. OSTROFF: For those who didn't hear,  
7 the answer is no. Any other comments or  
8 questions? Mike Parkinson?

9 DR. PARKINSON: Let me just echo, great  
10 study, and I hope that there's some systematic way  
11 to pull together all these multiple studies in a  
12 crisp communication summary to preventive medicine  
13 officers, military public health officers, line  
14 commanders. I mean, we typically fall down after  
15 we do the research, and the communication strategy  
16 is there, so maybe you can comment on that, first  
17 point.

18 Second point, we are going to be  
19 reviewing the final draft on this serum repository  
20 periodic surveillance issue. If there ever was a  
21 good use for that serum, it is to do exactly the  
22 study that you just said -- for a cohort of people

1 who just got back who answered yes on  
2 questionnaire number 5 on the postdeployment  
3 survey, if they have had a serum bank collection  
4 done in X period of time, just cross-hatch them.  
5 What proportion of people who said they did  
6 actually had positive serum result at times  
7 certain after deployment? They are supposed to be  
8 taking it during the full deployment. Do a range  
9 of those things. In other words, proactively use  
10 that database and the serums to get at these  
11 reliability issues.

12 COL. WELLS: We haven't made any  
13 definite plans.

14 DR. PARKINSON: Good. You could make  
15 those things and then run some trial tests to see  
16 whether or not the deployment database that says  
17 that people were in Qatar corresponds to what the  
18 serum said and whether or not question number 5 on  
19 the postdeployment -- in other words, pull that  
20 all together in a way that makes sense, you know.  
21 So just two thoughts there. But the first one on  
22 the communication of these results, because I for

1       one -- I mean, in 1992 we were here chasing  
2       Mefloquine side effects. Maybe the study here is  
3       never pilot a drug in the Scandinavians. I don't  
4       know. But somewhere here we've got to stop  
5       putting good resources maybe after a resource  
6       could be better spent elsewhere. I just don't  
7       know how to get ahead of this. Any thoughts are  
8       welcome.

9               COL. WELLS: The goal is to publish the  
10       Naval Medical Center San Diego study and this  
11       study hopefully side by side in the same journal.  
12       Not a lot of military commanders are probably  
13       reading our professional journals. We'll have to  
14       get the word out some way other than the  
15       peer-reviewed literature. But that's that goal,  
16       to get in the peer-reviewed literature.

17              DR. OSTROFF: Colonel Phillips and then  
18       Dr. Halperin.

19              COL. PHILLIPS: Just one quick comment  
20       for those that are new on the Board. The study  
21       that the National Health Research Center has done  
22       is actually just the first part of a study that

1 was recommended by the AFEB last year at this  
2 meeting in terms of start with a descriptive study  
3 and then use that as your basis for doing a more  
4 in-depth case-controlled type retrospective study  
5 to look for specific adverse events and try to  
6 tease out what's the attributable risk to an  
7 anti-malarial versus some other factor, or is  
8 there an interaction between deployment and taking  
9 an anti-malarial, those sorts of things. So  
10 there's work that's going to be ongoing. This is  
11 by no means the definitive end-of-the-line study.  
12 This is just kind of opening the door to explore  
13 and the work that was done by the net mu  
14 (phonetic) in San Diego has contributed to what  
15 they have been able to do here and will further  
16 educate the additional studies that will go from  
17 here.

18 DR. OSTROFF: Last comment, Dr.  
19 Halperin, and then we are going to have to move on  
20 to the next presentation.

21 DR. HALPERIN: Thank you. You know,  
22 once an epidemiologist, one's always in awe of

1 completion of a large study, so congratulations.  
2 This is really a question about our role as AFTB,  
3 really more than about the study. I think in this  
4 study and the prior study, there were things that  
5 happened as the study evolved that were a bit of a  
6 surprise. The perhaps healthy worker effect in  
7 this study and then the prior study, perhaps the  
8 finding of cases amongst the controls, raising  
9 questions of can controls be cases and all of  
10 those things we love to discuss.

11 And I'm wondering whether we have a role  
12 in the peer review of the protocols for studies or  
13 whether we are available in the midst of studies  
14 for consultation. Or is our role really to kind  
15 of stand back at a distance and only see them when  
16 they are done, which is a hell of a time to say,  
17 why didn't you do this or that kind of thing?

18 So it's really more of a question about  
19 what our role is.

20 DR. OSTROFF: Well, our role is any of  
21 the above. And there have been circumstances  
22 where we have requested that before a study goes

1 forward, that we take a look at the protocols and  
2 the questionnaires to be able to provide some  
3 feedback. Certainly there have been times where  
4 we have been asked to provide that type of input.  
5 So it's variable. Generally, we do tend to  
6 provide feedback on completed studies, so there's  
7 no set rule.

8 Thanks very much. Let's move on to the  
9 last presentation in this series. This is  
10 somebody who has come before the Board on a number  
11 of occasions and we welcome her back. This is  
12 Major Pearse from AFIP. She has been looking at  
13 the issue of Mefloquine and suicides.

14 MAJ. PEARSE: Good morning. I have been  
15 hounded a few times to make sure that I make it  
16 clear to everyone that these are my opinions and  
17 not those of the AFIP or anyone else.

18 DR. OSTROFF: Even though Dr. Molluck is  
19 not here today.

20 MAJ. PEARSE: I'm coming to you from the  
21 Armed Forces Medical Examiner's Office, and I was  
22 asked to look at the descriptive study that Dr.

1 Phillips was just mentioning. You all asked for  
2 the opportunity to comment on a study before it's  
3 completed. Here's your opportunity. This is not  
4 a completed study. We are still in a data  
5 collection phase. This is truly an update of  
6 where we are on the descriptive study. The  
7 descriptive study is to identify the risk factors  
8 DOD-wide for suicide. Once those risk factors are  
9 identified, we intend to progress into the case  
10 control study.

11 Right now the descriptive study  
12 population is 1,032. For inclusion, we are taking  
13 all suicides between 1998 into 2003. We're taking  
14 all four Services, regular active duty as well as  
15 activated Reservists. We are not taking  
16 Reservists that are in an inactive status, because  
17 we have no visibility over them, nor are we taking  
18 folks that have retired or veterans after they  
19 leave service.

20 We are taking a very broad approach to  
21 this. We are looking at demographics, Service,  
22 deployment, looking at substance abuse, mental

1 health, prescription data information, and other  
2 known risk factors that we can get on  
3 interpersonal, family -- you can read these legal  
4 sorts of issues.

5           We're looking at a lot of different data  
6 sources. Most of them are electronic data  
7 sources. The first one is ourselves, the DOD  
8 mortality registry, suicide event reports from  
9 each Service, criminal investigative reports, and  
10 then a variety of medical databases that are out  
11 there. I'm going to go through each of these in a  
12 little bit more detail.

13           The mortality registry, which is how I  
14 got involved in this, will answer all of our  
15 fundamental questions of demographics, what  
16 Service they are in, the basics of the who, the  
17 when, the how and the where. It doesn't help us  
18 very much at all with the why.

19           Suicide event reports are designed to  
20 answer the why. They are done by each Service.  
21 Let's start with the Air Force. The Air Force,  
22 what's interesting about them is that they use the

1       investigative agencies to complete these reports,  
2       so they are essentially filled out by cops. The  
3       Navy has the commanding officer. They have line  
4       officers filling out these reports. The Army  
5       doesn't fill them out at all. They had an ASER  
6       program. They had no compliance whatsoever. So  
7       prior to 2004, there are no ASER reports  
8       available. We had been doing psychological  
9       autopsies before 2001, and we do have the  
10      psychological autopsies that had been done. But a  
11      policy was instituted which changed the focus of  
12      the psychological autopsies so that it is only  
13      done in cases where the manner is not clear. If  
14      somebody comes off of a bridge and we're not sure  
15      whether they jumped, whether they fell or they  
16      were pushed, that would be an indication for a  
17      psychological autopsy. So instead of having them  
18      on every case, which had been routine, they are  
19      really only available in a few of our cases.

20                    We have been trying to extract data from  
21      CID investigative reports which are completed on  
22      their suicides. That is hideously time-consuming,

1 and that's primary data extraction. Right now we  
2 are at about 73, almost 75 percent.

3 Deployment history. In our more recent  
4 cases, any time there's a suicide we call the unit  
5 to find out if they deployed, when and where.  
6 There are systematic ways to get that information.  
7 The PERSTEMPO database has some significant  
8 limitations. Nineteen percent of our deaths that  
9 occurred in theater were listed in the PERSTEMPO  
10 database as never having deployed at all. So  
11 we're relying on the contingency tracking system,  
12 which is significantly better. It's a combination  
13 of personnel records and hazardous fire pay.

14 The denominators for rates will be using  
15 DIOR, and that's the Washington Headquarters  
16 service. Those are the official denominators.

17 The Reserve/Guard, we have struggled  
18 with. Anybody out there who has a good way of  
19 doing this, I would love to hear it. We have not  
20 been able to factor in time, the time at risk for  
21 the Reserve and Guard. Deployment we will be  
22 getting out of the Contingency Tracking System.

1           Postmortem toxicology. This is a good  
2 news source, because that's done actually  
3 in-house. For OIF and OEF fatalities, we are  
4 doing full autopsies on every one of those cases.  
5 We have forensic toxicology available for those  
6 cases. So all of our deployed cases will have  
7 been checked for Mefloquine and have complete  
8 toxicology.

9           For cases that occur in civilian  
10 jurisdictions, those are more difficult. Some  
11 civilian jurisdictions will only test for alcohol.  
12 Others only test for drugs of abuse. None of them  
13 test for Mefloquine. We had been calling in cases  
14 of postdeployment, just calling up the local  
15 coroner or ME, asking them to please send us some  
16 blood so that we can test it for Mefloquine. We  
17 had some unfortunate media events that the  
18 military is worried about Mefloquine because they  
19 are trying to get this blood. So we have been  
20 less aggressive about trying to get the blood from  
21 the civilians to test it.

22           Altogether, we have forensic

1 toxicological or objective testing for drugs on 71  
2 percent of our suicides.

3 Prescription history, that's another  
4 source that we have been looking at. We have the  
5 Uniformed Services Prescription Database that is  
6 available to us. That has since been replaced by  
7 the pharmacy data transaction service. We are  
8 awaiting access for that. We do not have it yet.  
9 Part of that M2 database is the seder-insider  
10 (phonetic) records, and we are also awaiting  
11 clearance for our civilian contractor to get  
12 access to that database.

13 Military drug testing files. These are  
14 all the folks that have random urinalysis. We do  
15 have access to that, and that is complete.

16 Family advocacy program. That tracks  
17 domestic violence. We do have access to that, and  
18 that is available to us.

19 DIVRS (phonetic). Now this is a legal  
20 program, and it is designed to track contacts with  
21 the legal system, particularly in homicides. But  
22 since suicides are also investigated, we had hoped

1 to get data from there. We struck out. There was  
2 not a single suicide that was in the DIVRS  
3 database. That's being addressed in a different  
4 forum.

5 This is just a summary site of the  
6 places where we have looked for information and  
7 data and where we are with that right now. As you  
8 can see, this is not a complete effort.

9 That's it. I do have some preliminary  
10 data. Please take in mind that this is  
11 preliminary. What I'm going to show you is  
12 predominately demographics, things that I have  
13 in-house and the complete data sources, the ones  
14 that we have gotten full records on and we are  
15 good to go on.

16 From my world, the mortality registry,  
17 what you can see is that we have had an increase  
18 in deaths since the '98 to 2002 5-year block.  
19 Recently 2003, 2004, up to over 1,800 deaths from  
20 the baseline of 1,000. These are  
21 disproportionately in the Army and the Marines,  
22 and this is why. The distribution of deaths has

1 changed fairly markedly to calendar year '04.  
2 Thirty-nine percent of all deaths in DOD were  
3 directly due to combat.

4           These are just counts of suicides. The  
5 yellow line is Reserve/Guard. The green is  
6 regular. The reason I put that out without a rate  
7 is that it gives an overall look at the suicides.  
8 What we don't see is this really steep ramping up  
9 over the last 5 years. We do see some spikes.  
10 These are small numbers. They're fairly brittle  
11 and there's variability. With the exception of an  
12 increase in spikes towards the end in the Reserve  
13 and National Guard, and we do know there was an  
14 increase in denominator there, there really has  
15 not been an obvious trend.

16           The calendar year '04 is blocked out  
17 because we have about 40 cases for which the  
18 manner of death is still pending determination.  
19 We are still waiting for legal closure on those  
20 cases. But what we do see is the distribution of  
21 Reserve in proportion to regular runs, about 13  
22 percent. We were looking for a sudden increase in

1 '03 and '04 with the activations for the war, and  
2 we really have not seen it. There is an increase  
3 in '03, but '04 is a little too early to say, but  
4 it really stays fairly stable.

5 We can look at rates for the regular  
6 components, and we have. What we do not see is a  
7 huge jump in '03 or yet in '04. I do encourage  
8 extreme caution in looking at anything in '04 at  
9 this point. The Army does rise a little bit. It  
10 does not rise beyond the levels of calendar year  
11 '98 and '99. The Marine Corps is smaller and  
12 therefore more brittle, but '04 does look like  
13 it's going to be high. This is that same data  
14 presented graphically.

15 We wanted to compare our rates for the  
16 regular component with the U.S. rates overall.  
17 What we found is that in males between the ages of  
18 17 and 44, the DOD rate is statistically less than  
19 the male suicide rate in the civilian sector in  
20 those same age groups. In the other strata, our  
21 numbers are really too small to do a balanced  
22 statistical comparison.

1           We looked at ourselves with a crude rate  
2           and an age-adjusted rate compared to the U.S. rate  
3           in the same age group. Adjusted, it is even lower  
4           in comparison. When you adjust indirectly, it  
5           still stays lower. We wanted to look at ourselves  
6           in '98 to '02, and then we wanted to separate out  
7           '03, because that's when we really started seeing  
8           deployments and we were looking for changes with  
9           those deployments in '03. As our comparison  
10          population is going across, we have the DOD  
11          population for fiscal year '02, the U.S. suicides,  
12          and then the U.S. population because the DOD  
13          population is somewhat different than the U.S.  
14          Population as a whole. What we see is that our  
15          DOD suicides are higher in the 17 to 24 age group  
16          in the U.S. population. So the distribution of  
17          suicides within the Department of Defense is  
18          different than the distribution of suicides in the  
19          civilian sector. But that's fairly well explained  
20          by the difference in the DOD population structure.

21                 Male versus female. Again, DOD is more  
22          male than the civilian sector, but suicides are

1 more male still. Race, ethnicity, suicides appear  
2 to be disproportionately white compared to the DOD  
3 population and the U.S. population. Marital  
4 status, they were a little bit less likely to be  
5 married when we have suicides. Pay grade -- and  
6 this goes along with the age being lower in '03 --  
7 the pay grade for the folks that commit suicide in  
8 E-1 to E-3 is disproportionately represented.

9 This is incomplete data, but '03 seems  
10 to be more likely to be present for duty and more  
11 likely to occur in the residence or quarters.  
12 Method of suicide compared to the United States,  
13 we are more likely to use firearms. I think  
14 that's probably because we are more likely to be  
15 male. Males tend to use firearms for suicides.  
16 Females tend to use drugs.

17 This is a little bit of a sidebar. We  
18 also have data on our accidental overdose deaths.  
19 If you look at accidental overdose deaths, these  
20 are very toxic substances. These are folks using  
21 recreational drugs. They die by accident. They  
22 are using heroin and methadone. For the folks

1 that are deliberately committing suicide with  
2 drugs for an overdose, diphenhydramine in  
3 non-narcotic analgesics tends to use much less  
4 toxic agents.

5 Postmortem, alcohol runs about a  
6 quarter, and this is toxicological evidence.  
7 Looking at all our toxicological evidence, we  
8 found 4 percent positive for illicit drugs. We  
9 found less than 1 percent positive for Mefloquine.  
10 And we found 9 percent positive for  
11 psychotherapeutic agents, suggesting that they had  
12 been under some sort of care for mental health  
13 issues. That 9 percent compares with prescription  
14 data where 21 percent of the folks who had  
15 committed suicides had had a prescription in the  
16 previous year for a psychotherapeutic agent. So  
17 fewer people actually had it on board than had  
18 been prescribed the drug. Again, only 15 had been  
19 prescribed Mefloquine. These are fairly small  
20 numbers, smaller than I had expected.

21 Positive drug tests. These are random  
22 urinalysis tests. Folks that committed suicide on

1 active duty are more likely to have had a positive  
2 drug screen for illicit drugs in the previous  
3 year.

4           Among the married Service members who  
5 committed suicide, they are approximately three  
6 times more likely to have had a family advocacy  
7 contact than otherwise, other couples, other  
8 married people within DOD. Family advocacy  
9 contact can be either as an abuser or as an  
10 abusee; it does not differentiate which.

11           In summary, the rate among DOD folks is  
12 lower than the U.S. civilian population. They are  
13 disproportionately male, white and of a lower pay  
14 grade, which goes with -- compared to the rest of  
15 DOD, as opposed to the U.S. population. About a  
16 quarter of DOD suicides involved alcohol acutely.  
17 And they are more likely to have had a drug screen  
18 or family advocacy contact than the rest of DOD.

19           I wanted to look at deployed suicides  
20 specifically, because that's a question that has  
21 come up over and over and over again, is what's  
22 different with our deployed folks? And there are

1 differences. Across the top we have OIF and OEF  
2 suicides. We have DOD suicides in general, as a  
3 whole. Deployed population, and this is coming  
4 from the contingency tracking system. We've got  
5 some demographics for who has been deployed in the  
6 total DOD population. What we find is that in  
7 deployed suicides, they are more likely to be  
8 regular component than who's actually deployed.  
9 About 32 percent of the folks who have been  
10 deployed are Reservists, but only 20 percent of  
11 the in-theater suicides have been Reservists.

12 Pay grade. The deployed suicides are  
13 much more likely to be in the very lowest pay  
14 grade than the nondeployed DOD suicides. That  
15 goes with age. The 17 to 24-year old age group is  
16 more likely to have committed suicide within OIF  
17 than the other age groups, and that is both  
18 compared to who has been deployed as well as the  
19 rest of DOD.

20 Ethnicity. We do not know the  
21 proportions of who has been deployed, but we see  
22 more Hispanics than we expected to see, compared

1 to suicides as a whole within DOD. We took a stab  
2 at rates, and there are issues with these rates.  
3 One of them is that those denominators are not  
4 stable over time. That is absolutely the biggest  
5 limitation here. For calendar year '03, the rates  
6 for deployed are somewhat higher than the overall  
7 DOD rates. For calendar year '04, it's too early  
8 to say for sure. Right now they look lower, but  
9 that may not be accurate when all is said and  
10 done.

11 So the summary for our deployed  
12 suicides, these are occurring disproportionately  
13 in our very youngest, lowest ranking, unmarried  
14 Service members. So it gives us a target for whom  
15 we can aim our suicide prevention efforts in  
16 theater.

17 I'm going to end with a brief discussion  
18 about the suicide event reports. I already told  
19 you that the Army ones are more or less absent.  
20 Each Service has looked at suicide in their own  
21 way. They collect their own data. They present  
22 their own data. This is really the first time we

1 have made an attempt to look across Services to  
2 look at DOD as a whole. One of the issues is the  
3 way the data is collected from the event reports.  
4 For deployment questions, you can see what the  
5 Army is asking. They are actually looking at  
6 location, start and end dates, and they ask  
7 specifically, is this suicide related to a  
8 deployment? For the Navy and the Marine Corps,  
9 they just asked if the unit was deployed, not  
10 necessarily whether the individual was deployed,  
11 and they look at how many deployments, which is  
12 something the Army does not look at. The Air  
13 Force doesn't look at where. They presume all  
14 deployment is the same. Relationship questions,  
15 they're asked differently. Some of them look at  
16 small time chunks. Others just say within the  
17 last year. Bereavement questions, the Army tries  
18 to take a pretty good stab at trying to get a PTSD  
19 source of questions. The Navy and the Air Force  
20 really aren't looking at combat exposure in the  
21 same way.

22 The result of all this is that a working

1 group has been established and is meeting to try  
2 to unify this into one standardized set of core  
3 questions that can be asked across Services. This  
4 is a new effort. It hasn't happened yet, but it  
5 is in progress. That's the good news story of all  
6 this. The bad news is that the data is not  
7 available to look at right now.

8 Subject to your questions, that's what I  
9 have.

10 DR. OSTROFF: Thank you very much for a  
11 wonderful presentation. I can just imagine how  
12 much work it's been to get to the point that you  
13 are at. So thank you on behalf of the Board. I  
14 think Dr. LeMasters is first.

15 DR. LEMASTERS: Grace LeMasters. One  
16 important conclusion of your slide that I did not  
17 see up there, and one big concern, I think, is  
18 that in the under age 34 group, the suicide rate  
19 is 50 to 100 percent higher than in an age-matched  
20 group of the general population. I mean, this is  
21 huge. I'm wondering what's the next step here.

22 MAJ. PEARSE: My initial next step is to

1 be sure of the data. We need to finish this study  
2 and make sure that it is saying what I think it is  
3 saying right now. Beyond that, each of the  
4 Services needs to know that that exists and to  
5 target their suicide prevention on that high-risk  
6 group. They are involved with advising me on this  
7 study, and they are involved with the questions  
8 that we're asking postevent. Pre-event, we need  
9 to be targeting our efforts.

10 DR. OSTROFF: Dr. Blazer?

11 DR. BLAZER: Again, this is an excellent  
12 presentation, and we appreciate your coming back  
13 every year and doing this.

14 The comment I have is simply something  
15 that we actually talked about at the Mefloquine  
16 subcommittee and others. You have already alluded  
17 to this and you recognize the problem, but I just  
18 want to be sure we all are on the same page.  
19 Denominators, when you are looking at cause, are  
20 going to be absolutely critical, and that is your  
21 absolute biggest problem with these data. So I  
22 think that's something that I think you and

1 perhaps we need to stay on top of throughout this,  
2 because I think that the enumerator data and the  
3 prospective denominator, if it's a broad  
4 perspective, it's okay. But when you get down to  
5 the deployed, nondeployed, and postdeployed,  
6 that's where the real questions are going to come,  
7 and that's where those denominator data are going  
8 to be very, very difficult.

9 DR. OSTROFF: Thanks. I know there are  
10 a number of hands up. Dr. Brown, Dr. Shanahan,  
11 Dr. Catanni, Colonel White.

12 DR. BROWN: Thanks. Mark Brown.  
13 Excellent talk. You have done a lot of work.

14 One of the things I think you were  
15 trying to look at, you were trying to investigate,  
16 one of the hypothesis you had initially, was  
17 whether Mefloquine was associated with suicide or  
18 not, and you mentioned that it's difficult to get  
19 blood samples. I can imagine, especially if you  
20 are dealing with postmortem results and so forth.  
21 But I know you have tissue samples from  
22 potentially everyone who is deceased who has been

1       deployed.

2                   Are there protocols, are there methods  
3       to look at tissue samples that would give you  
4       information about Mefloquine? I mean, since you  
5       can't get good blood samples, you need to turn to  
6       some other approach to get at what I think is a  
7       very important question.

8                   MAJ. PEARSE: Yes, sir. Blood and  
9       tissue both work fine. Urine does not. For  
10      toxicological testing, very frequently local  
11      jurisdictions will just get urine. That is  
12      completely worthless for looking at Mefloquine,  
13      because of the long half-life. Any tissue will  
14      do. Liver and spleen are ideal. The problem is  
15      prying that tissue away from the civilian  
16      jurisdiction who has absolutely no obligation to  
17      work with us.

18                  DR. PATRICK: I too would like to  
19      congratulate you for getting into this study. I  
20      think it's a wonderful effort. I think, outside  
21      of the data, you have identified a number of  
22      process problems. I certainly applaud your effort

1 to have a working group to look into the  
2 differences amongst the three Services. In my  
3 experience in doing that, you get the people  
4 together and you can get a high degree of  
5 consensus. But you really have to have some teeth  
6 somewhere in the system, and obviously it has to  
7 be at the DOD level.

8 I think that these issues are important.  
9 They are politically important as well as  
10 important to the Service. I think if you haven't  
11 already, you need to get somebody from DOD on  
12 board that can basically force a consensus among  
13 the group and get the data that's needed so that  
14 these questions can be answered.

15 DR. OSTROFF: I'll let Colonel Phillips  
16 respond to that.

17 COL. PHILLIPS: To comment on that  
18 briefly, what instigated the start of the study  
19 was last year when we were looking at Mefloquine  
20 and what's the attributable risk for Mefloquine in  
21 suicides. What we realized as we started, as it  
22 was presented, was that all Services collect

1 information about suicides in different ways. So  
2 Major Pearse began this. You know, it's just the  
3 first couple of steps of attacking this mountain  
4 of a problem of trying to sort out DOD-wide. Two  
5 weeks ago when she presented this information to  
6 Dr. Winkenwerder of the ASD Health Affairs, it was  
7 in the context of, these are the Mefloquine  
8 studies that you asked for and here's what we've  
9 got. Right away he jumped on the fact that, yeah,  
10 there's an interesting little tidbit about  
11 Mefloquine here, but this is much bigger than just  
12 Mefloquine. In particular, he jumped on the fact  
13 that the Services were collecting information in  
14 different ways, and he has already engaged on  
15 exactly what you said, in terms of having a  
16 DOD-level official say, this needs to be brought  
17 to bear so that in the future we will be able to  
18 have a better way of assessing this data and  
19 gathering and looking at this.

20 DR. SHANAHAN: This is Dennis Shanahan  
21 again. I think that's great. I think, you know,  
22 in my former life when I was in the military and

1 we were fooling around with this issue at AFIP  
2 coming on 20 years ago now. Nothing substantially  
3 has been done. There's a tremendous opportunity  
4 to do it, but it is a big problem in the military.  
5 It's hit the press a lot. So I certainly applaud  
6 the effort, and I hope you can succeed in getting  
7 the processes straightened out.

8 DR. OSTROFF: Dr. Cattani.

9 DR. CATTANI: Jackie Cattani. Well, I  
10 think this is really a wonderful effort. I'm very  
11 happy that Mefloquine actually triggered it. But  
12 the question I have is how long are we going to  
13 keep investing resources in trying to demonstrate  
14 concrete evidence that Mefloquine is not a good  
15 prophylactic drug? Wouldn't it be better to put  
16 those references into switching over to Malarone  
17 or a drug that is effective and hasn't had  
18 reported side effects?

19 I think no matter what the results of  
20 these studies, the numbers are all so small and  
21 there's so much bias and confounding that you  
22 can't really conclude anything about Mefloquine.

1 Then there's the perception of the people taking  
2 it. If they think it's a bad drug, they are not  
3 going to take it. I don't care how many education  
4 campaigns you put out, if you're honest about the  
5 data, it's not conclusive.

6 So what's the possibility of actually  
7 thinking about switching to another first-line  
8 drug? If you consider the resources that go into  
9 all these studies versus the higher cost of  
10 Malarone, I mean, one does have to ask the  
11 question.

12 DR. OSTROFF: Thanks for that comment.  
13 I think as probably several other folks around the  
14 table know, we have issued opinions about malaria  
15 chemoprophylaxis. The position of the Board is  
16 that the various options need to remain available  
17 within the department, and that there are specific  
18 situations which should determine which of the  
19 various malaria chemoprophylaxis drugs are used.

20 We certainly would not like to see the  
21 option of the use of Mefloquine lost in DOD  
22 settings, because there are settings which

1 certainly suggest that that is the preferred way  
2 to go. I for one would certainly not like to see  
3 a situation where we lose the availability of  
4 Mefloquine in Department of Defense settings.

5 I think you are absolutely right. None  
6 of these studies are definitive one way or the  
7 other, but they continue to reassure me. I don't  
8 see anything in any of the data presented today to  
9 suggest that there have been significant  
10 documentable problems associated with Mefloquine.  
11 We all know that there are significant public  
12 relations problems associated with Mefloquine.  
13 There are situations where I think all of us would  
14 say it's probably not the best drug to use. But I  
15 certainly wouldn't want to lose it.

16 I think Colonel White and then Dr.  
17 Oxman, and then we are going to take a break.

18 COL. WHITE: David White. I just wanted  
19 to ask Lisa, what is your definition of a  
20 deployment suicide?

21 MAJ. PEARSE: A deployment suicide is  
22 one that occurs in theater.

1 DR. OSTROFF: Dr. Oxman, you have the  
2 last word.

3 DR. OXMAN: Mike Oxman. I wanted to ask  
4 a question, but first of all, I would like to  
5 comment Major Pearse on an enormous amount of  
6 work. It's very obvious. But I wondered if you  
7 could comment on the choice or what your thoughts  
8 are on the significance of the use of analgesics,  
9 and really, I was struck by that difference, which  
10 in my ignorant experience suggests some unanswered  
11 cry for help. I wondered if you are looking at  
12 that and what your thoughts are of the choices of  
13 drugs that are used.

14 MAJ. PEARSE: I think some of it is  
15 simply habit. They grab the Tylenol and the  
16 Motrin that they happen to have on hand.  
17 Diphenhydramine is widely available as a cough  
18 syrup. It's right there. I honestly don't know  
19 beyond that.

20 DR. OSTROFF: Thanks. We are running a  
21 little bit late and I tried not to do that first  
22 thing this morning, but these presentations were

1 really terrific. My congratulations to all of  
2 you. I'm certainly sorry, Major Pearse, that I'm  
3 rotating off the Board so I won't have an  
4 opportunity to hear future presentations, because  
5 that work is just terrific and I'm sure will  
6 provoke some additional discussion during the  
7 break.

8 Let's go ahead and take a 15-minute  
9 break. Then we'll come back and we'll have a  
10 series of presentations about accession settings.  
11 Thanks.

12 (Recess)

13  
14 DR. OSTROFF: This is Colonel Ruscio.  
15 He is going to update us on a subject that has  
16 been a topic of discussion for the Board for a  
17 number of years, certainly as long as I have been  
18 on the Board. That's the RAP or recruit  
19 assessment program.

20 COLONEL RUSCIO: Dr. Ostroff, Ms.  
21 Embrey, AFEB members and guests, on behalf of  
22 Health Affairs, thank you for the opportunity to

1 discuss with you this morning the recruit  
2 assessment program. I'm Lieutenant Colonel Bruce  
3 Ruscio in Health Affairs. And Colonel Ruiz and I  
4 were introduced, I think, 4 or 5 months ago when  
5 we became aware of the SECDEF's directive on  
6 transformation. We have asked him to come to D.C.  
7 multiple times, him and his staff, to have  
8 discussions. I would like to talk to you this  
9 morning about the RAP and the time lines and  
10 directions and where we are at as far as this  
11 instrument that I'm aware that you have high  
12 interest in.

13 I think you are all aware of the purpose  
14 in the program, but very quickly, to collect  
15 baseline health information on new accessions.  
16 This has been a recommendation to DOD by this  
17 committee, the Institutes of Medicine, and most  
18 recently the NDAA, National Defense Authorization  
19 '05, that we will implement such a program within  
20 the next 2 years, and their wording "at the time  
21 of entry into the Armed Forces." So we're headed  
22 toward that direction.

1           I'll give you a little bit of an update  
2       as to where we are at as far as the instrument.  
3       Let me back up a minute, and you will see  
4       different terminologies there. We are all  
5       familiar with the term RAP. Recently there has  
6       been some discussion on the name. One of those  
7       names is Accessions Health Assessment Review Tool,  
8       which is the A-HART, to be in line with the  
9       periodic health assessments throughout a military  
10      member's career. We have had Service subject  
11      matter expertise concurrence on the instrument  
12      over a period of time of review and evaluation.  
13      The current instrument is about 30 minutes in  
14      length. It has 80 questions. We have had it  
15      reviewed externally. It's important, I think, to  
16      identify that the questions on this instrument  
17      have a 71 percent direct match to the periodic  
18      assessment. HERE is probably what you are most  
19      familiar with. About 40 percent of those  
20      questions were derived from other validated  
21      instruments.

22                    Most recently, thanks to the NRHC folks,

1 we have had the instrument placed in the Mark  
2 Sense Form in preparation for implementation. We  
3 are going to probably go through another polishing  
4 and editorial of that form, but it's ready to go.  
5 We have had discussions and review and process  
6 with the Defense Manpower Data Center. All forms  
7 that are tri-Service are required to go through a  
8 certification process at the DOD level. So this  
9 instrument has entered that process. It receives  
10 another peer technical review, evaluation of is it  
11 duplicating, other such collection instruments  
12 that may exist, and multiple legal reviews are  
13 included in that.

14 We have also been working with the PKC  
15 group that have built the couplers, the computer  
16 interface with the HERE, and have been working  
17 with them and working with the RAP to make sure  
18 that that's a similar type of instrument.

19 That's just a snapshot of the instrument  
20 in the scan form. This is what the PKC group has  
21 done as far as automating the instrument. Again,  
22 probably the name will change as we move along

1 here, but I think what's important to point out is  
2 that it looks similar to the HERE. It's something  
3 that a member will see a similar type of form as  
4 we move to a completely computerized process.

5 It's mandatory to have a wiring diagram  
6 in a military briefing, but I wanted to talk about  
7 where we are headed towards as far as  
8 implementation of this instrument. Above the  
9 first dotted green line is the MEPS processing  
10 events that occur in the military member. I also  
11 have gone through the MEPS process, prior  
12 enlisted. You see that you can enter the MEPS  
13 processing in 1 to 2 years prior to entering basic  
14 training. I know Colonel Ruiz and the groups are  
15 trying to make that time shorter, but as far as I  
16 know, that's still the time range. You can go  
17 through the MEPS, the initial MEPS processing,  
18 before you enter basic training.

19 However, in between the two dashed green  
20 lines there, you will see a time where the  
21 individuals come back to the MEPS station for  
22 what's called the inspect. The individuals come

1 back to the MEPS station, have another medical  
2 evaluation, are waiting orders to be cut, leave  
3 the MEPS station, get on a bus and head to basic  
4 training. This is at the point where we are  
5 suggesting that the RAP or A-HART be implemented  
6 at this time. At this time, the individual has  
7 already been accepted, qualified for military  
8 training, and is on his or her way to basic  
9 training.

10 Dr. Ruiz showed this. I just wanted to  
11 emphasize on the far end, we are looking at  
12 implementing this at the MEPS sites. We are  
13 looking at about 260,000 individuals per year, is  
14 still the current number of individuals that enter  
15 military service. There have been some  
16 discussions among the folks in the Services and  
17 the epidemiologists of interest in pushing the RAP  
18 further out to collect further back in the  
19 process. But there's some challenges to doing  
20 that. Right now, as far as the legal authority,  
21 we have gained the OGC review which just occurred,  
22 and that we can implement this at the site at the

1 inspect time, and we have legal authority to do  
2 that, and it's acceptable to implement the RAP at  
3 that time.

4 Very quickly, I already mentioned this.  
5 Colonel Ruiz had it up in his presentation. But  
6 we have a health assessment implemented at the  
7 inspect time prior to individuals getting on the  
8 plane, bus, or whatever to head to basic training.  
9 This data then will be forwarded, fed to DMDC,  
10 CHCS, and CHCS-2.

11 What we identified in our discussions  
12 with Colonel Ruiz and his organizations is a  
13 process that's already in occurrence and an  
14 opportunity to work synergistically to implement a  
15 program and to collaborate in implementing the  
16 SECDEF's directives. As the MEPS move through  
17 their automation process and completely automate  
18 their 65 different sites, we would like to see the  
19 RAP or the health assessment piggyback or move  
20 right along with that process in the MEPS  
21 automation event. We see the data used through  
22 the mirrors, which we can do now, the flat data

1 files as Colonel Ruiz mentioned. And as it moves  
2 to the VIPS system, having access at the Service  
3 population health hubs and storage and evaluation  
4 at the DOD level.

5 This is pretty much a timeline to show  
6 you were we are at and where we are headed. We  
7 have instrument development that has been  
8 complete. We have DMDC review that's ongoing. We  
9 have OGC legal review, complete. We are in the  
10 process of coordinating MEPS site visits, and the  
11 computerized pilot effort which we currently are  
12 planning on doing at the Baltimore MEPS site, that  
13 will be working at one site, the PKC-developed  
14 interface for those individuals to do it automated  
15 at one particular site. At the other sites, we  
16 will be using the SCAN form automated at one  
17 particular site. In the other sites we will be  
18 using the SCAN form tool. Again, we would like to  
19 piggyback onto the MEPS automation and  
20 transformation process. We see data collection  
21 beginning some time in this fall, fall of '05.

22 Some issues in way forward. The

1 question of disclosure certainly is an important  
2 one, one that needs to be addressed. Health  
3 Affairs has been working with the NHRC folks who  
4 have provided a protocol to evaluate a MEPS RAP  
5 comparison study. We are working that into the  
6 process as we move forward. We have been working  
7 on a longitudinal perspective in that the RAP does  
8 not stand alone and that the RAP should have  
9 connectivity with the HERE or whatever you want to  
10 call it, the periodic survey, the end-of-service  
11 survey, and that electronic data through to the  
12 VA. So we are trying to take a large-picture  
13 approach to this. We have been meeting on a  
14 regular basis with the HERE or HART folks and  
15 making sure that we are all in sync and we are all  
16 in coordination on this. This includes,  
17 certainly, the Service representatives.

18 Quality assurance/quality control,  
19 working with the Services and TMA, tri-care  
20 management folks, to look at the quality  
21 assurance, quality control of the data. We have  
22 concurrence, at least verbal concurrence, on the

1 data moving forward to the organization that is  
2 helpful for that evaluation.

3 I mentioned the PKC coupler already.  
4 Long term sustainment, we have funding to get  
5 through this year to implement it, and we are  
6 working on a longer term support in collaboration  
7 with the MEPS command.

8 Sir, if there are any questions, that's  
9 the end of my briefing.

10 DR. OSTROFF: Thank you, Colonel Ruscio.  
11 I have been on my best behavior for this  
12 particular meeting, since it's my last one, and  
13 I'll try to be restrained. But I'm sort of  
14 reminded of the fact that it only took us 10 years  
15 to put a man on the moon. This seems like it has  
16 had about as long a gestation, if not longer. It  
17 sounds to me like we are making progress, but I  
18 need some reassurance that that's actually the  
19 case.

20 When are we actually going to get there?  
21 Because this has been piloted, it's been modified,  
22 it's been changed. We've heard all kinds of

1 discussions about how the data are going to be  
2 collected, how they are going to be entered. I  
3 just want to know, when are we actually there?  
4 When are we going to have a system in place, and  
5 when are we going to lock it in?

6 COLONEL RUSCIO: Sir, as I mentioned in  
7 the one slide, we are looking to have the data  
8 collected by this fall.

9 DR. OSTROFF: No more pilots? That's  
10 it? No more changes?

11 COLONEL RUSCIO: Well, sir, we are  
12 looking to have the data collected by this fall.  
13 As the new accessions access into the military, we  
14 will certainly be looking -- and this presentation  
15 I presented to Dr. Winkenwerder and the ESGs, and  
16 he wanted to be aware of any time slippage on  
17 this. The attention and the focus is there.  
18 That's the timeline, and we are moving forward on  
19 that timeline.

20 DR. OSTROFF: Colonel Gibson, and I have  
21 to be reminded that I think Dr. Atkins is on the  
22 phone and he may have some questions as well.

1 COLONEL GIBSON: Colonel Gibson. I  
2 would remind the Board members and Dr. Patrick in  
3 particular that as we rolled out the RAP, one of  
4 the requirements was to reevaluate, recheck, check  
5 the validity of the questions, and assess new  
6 questions as time goes on.

7 So I think what Colonel Ruscio is saying  
8 is we are done, this is what we are putting out,  
9 but it will evolve over time. There will be  
10 changes to this as this evolves over years, like  
11 it took years to put it in place.

12 DR. OSTROFF: Dr. Brown, and let me just  
13 ask, is David Atkins on the phone?

14 DR. ATKINS: Yes. Can you hear me?

15 DR. OSTROFF: Yes. Let David ask his  
16 question first.

17 DR. ATKINS: I couldn't quite hear what  
18 I thought was Kevin Patrick's question from an  
19 earlier presentation, but I assumed it was about  
20 the connection between the process and the HERE  
21 data for integrating all the data?

22 COLONEL RUSCIO: That's correct.

1 DR. ATKINS: That was my only concern.

2 I didn't have any other questions.

3 DR. OSTROFF: Dr. Brown?

4 DR. BROWN: Okay, thanks. Well, just  
5 following the line of questioning that started up,  
6 in the timeline that you presented for the  
7 implementation of the RAP or whatever it's called  
8 now, I guess it wasn't completely clear to me.  
9 The ultimate goal, I suppose this will be  
10 introduced across all Service branches, for  
11 accession for all Service branches throughout the  
12 military, correct?

13 COLONEL RUSCIO: Across the MEPS  
14 stations.

15 DR. BROWN: So was that point in that  
16 timeline? It wasn't clear to me that, that the  
17 completion point where this is going to be  
18 universally applied throughout the military,  
19 throughout all Services at MEPS, when that's going  
20 to take place. Was that date set?

21 COLONEL RUSCIO: That is fall. That is  
22 fall.

1 DR. BROWN: Okay, I guess I was  
2 confused. I thought that was the Baltimore  
3 program you were talking about, implementing it in  
4 Baltimore.

5 COLONEL RUSCIO: I'm sorry, no.

6 DR. BROWN: This is throughout?

7 COLONEL RUSCIO: Throughout. We will  
8 have one computerized pilot effort in Baltimore.  
9 The other 64 sites will be doing the scan form,  
10 the paper form.

11 DR. BROWN: Okay.

12 DR. OSTROFF: Dr. Parkinson?

13 DR. PARKINSON: I just want to make sure  
14 that I understand the layout of the three  
15 components that really all have to come together  
16 at some point.

17 The first is that -- I assume the intent  
18 of the Board is that this instrument is used for  
19 all accessions, officer and enlisted. So clearly  
20 that's on the worksheet as to how this all gets  
21 done for all of the DODMERB and all the HSPSRs and  
22 everybody coming in, because it's got to be

1 standard. So that's a given, just to get it out  
2 in the open.

3 The second piece is, then, the three  
4 components, being a health questionnaire, the  
5 second being a periodic health examination, the  
6 third being biological specimen collection, be  
7 that your serology or cell, whatever the Board is  
8 going to recommend.

9 So in the case of the enlisted troops,  
10 they've got a physical examination anywhere from 0  
11 to 2 years back based on their initial MEPS. When  
12 they come in for that, just to get the package and  
13 get on the bus trip, they're going to get the  
14 A-HART. Then they get their serology or biologic  
15 specimen, Army, Navy, Air Force, when they first  
16 hit recruit training, or is it at the first time  
17 of their -- in other words, I just want to make  
18 sure that we understand as a Board the windows of  
19 difference. Not that they all have to be the  
20 same, but what outside critics are going to ask  
21 is, you've got your physical exam, you've got your  
22 serology, you've got your questionnaire; what's

1 the rationale for doing them X period of time  
2 apart? So as long as we have good answers as to  
3 how that will model out for each one of the three  
4 Services, so that we don't find ourselves saying,  
5 why did you do it that way?

6 I'm not insisting that all three be done  
7 at the same time. But as long as we are  
8 discussing how that is all going to flow for both  
9 officers and enlisted, because that's -- again, if  
10 you give a window of vulnerability in terms of the  
11 processes that we define, we'll be answering these  
12 same questions 5 years from now about why you have  
13 those differences.

14 So just to put those issues out there  
15 for the record, that those all have to be linked  
16 up in some tactical way that makes sense  
17 clinically.

18 DR. OSTROFF: I'll let Dr. Reese  
19 respond.

20 DR. REESE: Can I go ahead and answer?  
21 I'm Colonel Reese from NAVCOM again. Actually, we  
22 have been looking at this as well, especially in

1 terms of what we call the DODMERB merger, with the  
2 possibility of bringing those officer accessions  
3 through our system. Less about that and more  
4 about the data capture, again. Just so I can be  
5 clear about the process of what they go through  
6 for a physical examination at the MEPS, at one of  
7 the stations in the MEPS, we do draw a serum  
8 sample for HIV currently. That serum sample is in  
9 turn sent to a contract DOD-certified lab. So  
10 potentially we could draw your serum sample then  
11 as well, and that would give you pretty good  
12 surveillance.

13 In fact, if you really want to think  
14 about it in terms of, again, national defense, we  
15 have a near real-time system in development where  
16 we will be able to -- if you had a bio-attack,  
17 let's say -- we would be able to give you fairly  
18 good information on a cohort of about 1,800 to  
19 2,000 people a day, you know, between 17 years old  
20 and 39 years old very quickly. If there was a  
21 spike, we'd know it, because it would be a  
22 centralized process. So we are able to pull that

1 serum sample off, test it for HIV right now, as  
2 well as whatever else you'd like to get tested for  
3 because they did sign a release.

4           Additionally, as far as the officers go,  
5 that is a centralized process. There are 25,000  
6 officer physicals given a year through the  
7 DODMERB, of which they assess some number of  
8 those, whatever the Services require. The process  
9 is slightly different, though the standards are  
10 the same. Those are done at contracted  
11 physicians' offices as things currently stand.  
12 The central point of contact, though, is when that  
13 information is sent by electronic means of a form  
14 that's filled out -- basically it's faxed over to  
15 them -- it goes into an image-based database at  
16 DODMERB where it is centrally reviewed by one of  
17 their DODMERB physicians. There's a staff of  
18 three military officers that review these things.  
19 So potentially, the RAP in its low-tech form as a  
20 Scantron form or a mark sense form would be able  
21 to be faxed to us and they can run it through a  
22 scanner just as easily there. It's about

1 capturing the data.

2 Now, what I had suggested to Bruce is  
3 that we go low-tech first and then develop this  
4 in, especially as PKC continues to refine their  
5 algorithm-directed product, because we're very  
6 interested in doing just that type of work with  
7 our history as well. So we are very interested in  
8 partnering with the folks here at Health Preparers  
9 in trying to develop something.

10 So this is a win-win for everybody. I  
11 mean, the low-tech, we are going to be able to  
12 capture this information fairly quickly.  
13 Basically, I mean, you scan that in, you send it  
14 to a server, and then that server sends it  
15 someplace else.

16 DR. PARKINSON: I guess my point here is  
17 that there's a tendency to compartmentalize these  
18 three integrated facets of comprehensive  
19 surveillance. And if we are not careful, we will  
20 wind up with one over here and one over here and  
21 one over here, and I still can't connect the dots  
22 with the true story, which is the purpose of what

1 was their baseline health status when they entered  
2 the military. Let's define the entry of military  
3 as the case definition time certain, and as a time  
4 certain, we are willing to live with a little  
5 slush on either side. But let's have a document  
6 somewhere in DOD that says why we chose it and how  
7 those three components come together for everybody  
8 in uniform. Because to date, it seems to me like  
9 we are all moving once again on three different  
10 parallel channels. And while we've got it up  
11 here, I don't know that I've got it if I have to  
12 go testify in Congress and give it to somebody up  
13 there saying, well, show me the program as it all  
14 comes together. We are getting the pieces, but I  
15 need a single blueprint.

16 DR. OSTROFF: We are going to have to  
17 move on to our next presentation so we don't get  
18 too far off the schedule. I see Dr. Patrick has  
19 his hand up, and then I have one final comment.

20 DR. PATRICK: Is the next presentation  
21 on this, or do we move to an entirely different  
22 subject? I want to echo Mike's concerns, because

1 I think, again, having been the one who drafted  
2 with the subcommittee the RAP recommendation here,  
3 I think the notion that the RAP is going to evolve  
4 is a strong one. There will be a version 1.0 and  
5 a 1.1 and a 1.2. Each successive version needs to  
6 inherit the characteristics of the ones prior to  
7 that, so in fact we have a meaningful longitudinal  
8 database.

9 But I find this notion of moving the  
10 Recruit Assessment Program from the basic training  
11 sites to a currently untested environment -- I  
12 mean, it's a very impressive presentation and a  
13 vision. Those of us that love electronic data  
14 systems have no problem with the vision thing.  
15 Our problem is that we are often 10 years ahead of  
16 other people on that. And so I'm always reminded  
17 of that by my colleagues. You did mention -- I  
18 believe I heard -- that there were concerns about  
19 quality with respect to what's happening in the  
20 MEPS stations. People having people just sign  
21 forms. Who's filling them out? I think this  
22 raises enormous quality control problems on my

1 research and what it involves in using online  
2 systems that have people answer questions in sites  
3 separate from where I am at the time they are  
4 doing it. Believe me, it's a very complicated  
5 process.

6           So I think building in process measures  
7 that will in fact assure that the quality and  
8 connecting the dots that Mike is talking about is  
9 really going to be key. It is essential when you  
10 have broken apart these processes as you have. It  
11 makes sense to think about breaking them apart,  
12 but it does raise a lot of issues. Again, to my  
13 mind, to think that this is all going to be done  
14 the way we envisioned that it would be done as the  
15 RAP subcommittee that recommended AFEB and the  
16 ultimate recommendation that Steve signed by the  
17 end of this calendar year is, I think, a very  
18 optimistic expectation to pull this off.

19           DR. OSTROFF: Right. I would second  
20 that comment. I can recollect from our previous  
21 meetings how concerned we were about consistency  
22 of application. We had worries about being able

1 to do it consistently the same way, using the same  
2 instrument, using the same entry methods by the  
3 individual that's filling out the form at eight  
4 recruit sites.

5 Now I'm hearing that you are going to  
6 push it back to the MEPS. And again, maybe that's  
7 the absolute right way to do it. But when now you  
8 are talking about 64 different sites or however  
9 many different sites there are in MEPS, I do have  
10 some significant concerns about whether or not you  
11 are going to be able to consistently collect this  
12 information.

13 And in terms of being able to analyze it  
14 comprehensively, it's only as good as the way the  
15 data is being collected, the way this is being  
16 implemented. It's really tough to do that across  
17 that many different sites.

18 DR. EMBREY: This is Ellen Embrey. I  
19 think it's important to recognize that the health  
20 community recognizes the need to get good data  
21 where it can get it and to capture it in a  
22 consistent way. We have committed to doing that

1 by this fall. The integration of that data  
2 capture and the processes by which we use or  
3 modify for the future depend in large part on what  
4 the J-SIS (phonetic) process defines us and we  
5 will morph to meet those requirements so that it  
6 is a single way to capture it as part of the new  
7 business process.

8 But the reality is that Bruce and the  
9 team that has been working this have finally drawn  
10 a line in the sand, said we are going to do it,  
11 defined the process, and we are going to do it.  
12 So I think your concern is noted, as we all are  
13 concerned. But the good news is, A, we have a  
14 process we have defined, and B, we now have a  
15 process that we can integrate into for the future  
16 to make sure that it is well captured as part of  
17 the new process of doing business for the future.  
18 So I don't think they represent two separate  
19 things. They represent the first thing we are  
20 going to do, which we have been long trying to do,  
21 and then the second thing is making sure it fits  
22 into the new process as the line is leading us.

1 DR. OSTROFF: Thank you very much.  
2 Thank you, Colonel Ruscio.

3 Our last presentation is Colonel Cox,  
4 also a regular before the Board from San Antonio,  
5 and he is going to provide us a briefing on a  
6 subject that the Board has repeatedly requested,  
7 which is non-battle injuries. His slides are in  
8 Tab 12.

9 COL. COX: Before I launch into that, I  
10 just have to say, I was interested to see this  
11 name change from the HERE to the HART, the  
12 H-A-R-T. That's been talked about for some time,  
13 that we didn't think the HERE would survive. But  
14 since we are labeling it now with initials in  
15 front of it, we are going to have the accession  
16 HART, which will be the A-HART, and of course the  
17 standard one is the periodic perennial or the  
18 preventive HART, but if you put the P in front of  
19 that, I can guarantee you that most people aren't  
20 going to want to fill out their annual P-HART. We  
21 do have to be careful when we select names for  
22 things, and that's sort of the trouble we got into

1 for the HERE.

2 Now for the dreaded preprandial podium  
3 presentation, first I must apologize for appearing  
4 before you in a relative state of undress, but I  
5 suffered a catastrophic wardrobe malfunction that  
6 prohibits me from wearing my Service jacket. With  
7 your forbearance, we'll go ahead and talk about  
8 injury issues.

9 DR. OSTROFF: You're forgiven.

10 COL. COX: This is just the outline of  
11 where we are going. Some of you saw some portions  
12 of this at a previous presentation. We talked  
13 about surveillance in the deployed setting in  
14 general. It has changed since then, and it's  
15 specifically -- the numbers have changed, although  
16 the methodology is pretty much the same. I think  
17 my other goal with this presentation is to see if  
18 I can finally push Dr. Ostroff clear over the edge  
19 of being disappointed during his last session  
20 here, because we haven't been able to make  
21 substantial progress, except in the area of  
22 delineating the gaps in what we are trying to work

1 with. So I think it's important to recognize  
2 that, so that isn't a total failure.

3 I just want to start out with the  
4 construct of the basic injury pyramid. I realize  
5 all of you are familiar with this, but it helps to  
6 show how some of these things differ in deployed  
7 versus garrison setting, because the theme of this  
8 discussion is going to be the perception of the  
9 need to compare what goes on in deployed settings  
10 with some other setting, and the usual default is  
11 the garrison setting. Things are just not exactly  
12 the same in those two environments and that  
13 presents some real challenges. But in the  
14 standard deployed setting, we have basically  
15 battle versus non-battle injuries as our first cut  
16 point of how we categorize these things.

17 It turns out that the two are just about  
18 running at a 50-50 rate in current operations.  
19 This isn't true on any specific month or if you  
20 look at previous operations. It has a lot to do  
21 with the type of military engagement, what you are  
22 facing, how long you've been there, and many other

1 things. But right now it's running very close.  
2 It's 49 and 51 percent respectively.

3 I also like to look at it, starting to  
4 focus in on this business of the in-theater data  
5 versus what's available in garrison. So for each  
6 of those levels of the pyramid, you will see that  
7 on the in-garrison, left hand side there, we have  
8 pretty close to near total capture of data. I'm  
9 not saying total accuracy of that data, but  
10 certainly near total as far as the events  
11 themselves, especially if we are talking about  
12 active duty military members.

13 On the in-theater side, as we will see  
14 with greater detail, we have very little of that  
15 data available. Certainly for the deaths, which  
16 luckily are smaller than total injuries, we get  
17 much more detailed information, as Major Pearse  
18 has presented it at other sessions. But as we go  
19 down that and move forward past the digital  
20 division divide that was mentioned in a previous  
21 presentation that still exists, and it's a similar  
22 divide in each of the other Services, although not

1 necessarily at the same corresponding level, we  
2 have less and less of electronic information  
3 available. Even written information may be  
4 difficult or missing.

5           So these are some of the specific data  
6 sources that we are working with in these attempts  
7 to analyze the injuries. On the left-hand side  
8 are the garrison items, where we do have extensive  
9 inpatient and outpatient data available  
10 electronically, and we have the so-called  
11 purchased care, what we are farming out because of  
12 exceeding our capacity through contract services.  
13 I put the checkmarks there to show which types of  
14 data we are mostly focusing on, because we are  
15 trying to get some gestalt for the overall  
16 patterns, as opposed to this being a very precise,  
17 detailed, definitive kind of study. In the  
18 deployed setting on the right-hand side, there are  
19 a number of different types of data available, but  
20 in order to have any hope of really making  
21 significant inroads to applying like health and  
22 preventive medicine techniques in order to deal

1 with injury patterns and have an effect that's  
2 beneficial, we need relatively detailed  
3 information about the type and location and cause  
4 of the injury. Most of the reporting at the DNBI  
5 level, the disease/non-battle injury level, is  
6 just ticks on a sheet that says there were 57  
7 people last week who got injured. It may break  
8 them out into types of injuries, like motor  
9 vehicle accidents versus worker training accidents  
10 versus the nebulous "other" category, but you  
11 don't know if those are knees or ankles or sprains  
12 or fractures or whatever the case may be. So we  
13 need individual level data. We often refer to  
14 that by our Electronic Patient Encounter Modules,  
15 the PEMs. There are PEMs for each of the  
16 Services, although I don't check the Navy box,  
17 because theirs primarily functions in the  
18 shipboard setting and isn't used on land  
19 engagements. So that leaves us with the Army and  
20 Air Force ones. But we'll come back to whether  
21 those are widely deployed.

22 The other relatively comprehensive

1 source we have is that related to medical  
2 movements for those cases, whether they be  
3 diseases or injuries that exceed the capabilities  
4 in theater and they must be removed to a higher  
5 level of care. Then there's a laundry list of  
6 new -- it's almost like spring; besides your  
7 grass, you get weeds popping up too. But we have  
8 lots and lots of additional data sources that keep  
9 showing up, sometimes unexpectedly. They are all  
10 in sort of a niche market, and they are capturing  
11 various items to varying degrees. So we have to  
12 keep track of those to see which ones will blossom  
13 and mature to the point where we can gather some  
14 useful information from them. But for the time  
15 being, they haven't made it to that point, so we  
16 are focusing on the PEMs and TRAC2ES.

17 Just to give you an idea again, the  
18 systems aren't used at the same sites. They are  
19 scattered. They are not at all sites. Their  
20 information is transferred over different sets of  
21 communication lines, some of it classified, some  
22 of it unclassified. Then it goes to multiple

1 sites to be analyzed. That's one of the  
2 challenges we face, is trying to bring all these  
3 different streams together and weave those  
4 separate threads into a discernible picture that  
5 we can use to some effect.

6 The medical data is coming through one  
7 set of systems starting on the left-hand side  
8 there. I've put the desert-colored column on the  
9 right that says "occupational environmental data,"  
10 just to illustrate that that is still a separate  
11 data system. So when we are looking to make  
12 relationships between exposures, which is most of  
13 the occupational environmental data, with health  
14 outcomes, we still have to have another system  
15 that ties us together. But our goal has to be to  
16 take data, be able to understand its limitations  
17 and make what conclusions we can based on what's  
18 available, and to have analyzed that and to  
19 disseminate it to people who have some ability,  
20 motivation, and willingness to take action in  
21 order to effect change.

22 So this just shows again that we have

1 many different levels of care we have to deal with  
2 in a deployed setting. So it's far forward where  
3 a individual can get injured in the field with  
4 just a medic available for initial care at  
5 battalion aid stations, and then moving back  
6 through the various levels of more advanced care,  
7 such as combat support hospitals with relatively  
8 full services and then of course to the  
9 out-of-theater sources, level 4 and level 5, such  
10 as Landstuhl or Walter Reed Army Medical Center.  
11 Each of those has different abilities and  
12 different capabilities as far as capturing data  
13 related to health events.

14 So just to talk about the major sources  
15 of data that we are using briefly, they do have  
16 limitations. The MEP TRAC2ES is what we call the  
17 medical movement data for those people that are  
18 removed from theater. The nice thing about it is  
19 that it is egalitarian. It captures any Service,  
20 because any individual, it's their condition that  
21 determines whether they have to actually leave the  
22 theater, so regardless of their Service or

1 component, they are going to come out through that  
2 system.

3 That said, though, a lot of people,  
4 especially in the press, have equated any  
5 individual who is removed from service, removed  
6 from theater, as being seriously ill or injured.  
7 And that isn't the case, because there are things  
8 that are relatively minor such as simple fractures  
9 that can't be handled in theater, because we can't  
10 have an individual with a cast on their arm or  
11 their leg for 6 weeks while they are deployed,  
12 because it presents a risk to themselves and to  
13 their unit fellowship there. So that's why it's  
14 not -- it's a full spectrum of cases across  
15 severity, and we have to be able to sort that out.

16 Unfortunately, and it's not really  
17 unfortunate, the goal of the medical movement  
18 system is to get people out of the theater and to  
19 where they can get the appropriate care without  
20 them becoming any worse in transit. So the system  
21 focuses on those very critical issues like what is  
22 their level of functioning, what special equipment

1 do they need en route, ventilators, do they need a  
2 critical care team? But they are not nearly as  
3 zealous about accurately recording presumed  
4 diagnoses with an ICD code. Much of the data is  
5 being entered by administrative technicians who  
6 are responsible for translating forms written by  
7 doctors under strenuous conditions and putting it  
8 into a database. So that leaves the opportunity  
9 for various accuracy issues to creep in. And as  
10 an example, we don't have an ICD-9 all of the  
11 time. About 25 percent of the time, there isn't  
12 one that's been recorded. But there is textual  
13 information that's being put in in three fields  
14 that can be looked at, but that's rather manual  
15 and it involves some of these fuzzy logic text  
16 parsing systems. So that limits what we can say  
17 sometimes. Whereas the field that identifies who  
18 needs what kind of service, whether they need an  
19 orthopedic evaluation or whatever, that one is  
20 close to 100 percent filled out, because that's so  
21 critical to make sure the person gets to the right  
22 place to accomplish that care. If we use that

1 field, of course, we could just say, well,  
2 orthopedics covers an awful big range of  
3 conditions, and it doesn't help us much with  
4 preventive measures.

5           If we could move to the next levels like  
6 the patient encounter module, you would expect  
7 that you would have a lot better fidelity and  
8 ability to determine these things. But in many  
9 ways it's worse, because that's getting further  
10 forward, and they have a lot of other issues to  
11 distract them from sitting around trying to learn  
12 how to code things which they weren't trained to  
13 do prior to getting to that setting, because most  
14 physicians, medical technicians and even nurses  
15 who may be doing this in theater have never been  
16 trained as coders, and it takes a bit of practice  
17 to be able to make your way through those trees  
18 and come out with something that's reasonable. We  
19 haven't tried to build in at this point some sort  
20 of automated correcting system into these  
21 electronic systems to help them. So that's  
22 certainly one of the things we have to think

1 about.

2 We are getting a lot of records recorded  
3 in these systems now, because they are available  
4 at more and more sites and more individuals are  
5 trying to use them. But in our initial  
6 evaluations in the last couple of months, we found  
7 that there is, as we might have guessed, a fairly  
8 rampant miscoding. So immunizations are getting  
9 coded as diseases and things like that. So there  
10 haven't been several thousand cases of pulmonary  
11 anthrax in theater, but if you just took this data  
12 at face value, you might be led to believe that.  
13 That's why it limits, at this point, our ability  
14 to make any strong statements based on it.

15 This is an example. Because it's been  
16 interesting, there have been many requests to  
17 figure out the differences in gender patterns and  
18 what's coming out. This is using the medical  
19 movement data, and it points out some of the lacks  
20 in that, in that we can't even determine from the  
21 data the gender of 2 percent of the people that  
22 have been recorded. Now, I suspect that it should

1 be available somewhere and they didn't know. It  
2 points out again that this is a gender-neutral  
3 system. It doesn't matter to anybody that's being  
4 taken out whether they are a man or a woman. It  
5 matters what their physical condition is and what  
6 care they need. So you can see why they might not  
7 double-check that always.

8 DR. OSTROFF: Is the title of the slide  
9 incorrect? This is not just female Service member  
10 data.

11 COL. COX: The top 10 diagnoses is for  
12 females. The top one is for total active, but the  
13 second bullet, the top 10 primary diagnoses, based  
14 on ICD-9 codes for those approximately 75 that had  
15 codes, for the time product of 1 January through  
16 May, the end of May 2004, you can see that battle  
17 injuries are figuring prominently as reasons for  
18 removing people from theater, as one would expect,  
19 and that women are at risk, as are men. Then the  
20 other items are pretty much what you'd expect.  
21 Leishmaniasis was fairly common then. If you took  
22 a snapshot now, it would be not in the top ten.

1       Primarily, we feel that is because of strenuous  
2       measures that were taken to improve protective  
3       equipment availability as well as education and  
4       compliance with using it, and the additional  
5       understanding that most of these cases don't  
6       represent an acute medical event that requires  
7       immediate treatment. So the ones that appear  
8       uncomplicated aren't infection, that relatively  
9       are small or already showing signs of improvement  
10      on their own, aren't being evacuated out, whereas  
11      they were initially because of just a decision to  
12      treat all of those very aggressively. So these  
13      things do change over time.

14               Now, the finding of unilateral inguinal  
15      hernia being so high in a female population seems  
16      a bit surprising and makes you wonder about coding  
17      issues as well as the no primary ICD-9 entered.  
18      Again, that's a problem, when you don't have  
19      anything entered. But when you look at a look at  
20      a lot of those, you do find sometimes there was a  
21      tendency for mental health conditions. This  
22      wasn't just in women, but in men too. There was a

1 reluctance to put down an ICD-9 that related to a  
2 mental health condition. Instead there would be  
3 something in the text field, but no code would be  
4 entered. So you end up with these interesting  
5 patterns of behavior.

6 So to look at the non-battle injuries  
7 more specifically, we use the approach of  
8 comparing them to garrison and looking at  
9 outpatient and inpatient visits in garrison and  
10 comparing them with the TRAC2ES data only, not the  
11 PEM data, because it still has too much of an  
12 error rate to handle. Then we wanted to look at  
13 two different methods. One was ICD-9 codes alone,  
14 which of course has more of an anatomic process.  
15 There is also this Barell matrix approach that  
16 gives you some idea of the cause or at least  
17 mechanism of injury, if not specific cause. I  
18 didn't mention it, but the recording of E codes  
19 and D codes is even less consistent and common  
20 than ICD-9 codes are, both in the TRAC2ES system  
21 and in the PEM system in theater.

22 The methodology obviously has some

1 potential flaws. Certainly looking at just the  
2 ICD-9 injury codes, we've modified what has been  
3 done in the past to include beyond the general 800  
4 to 999 range, which is just labeled as  
5 injury/poisonings. There are a number of  
6 conditions that are frequently coded in the 700  
7 muscular/skeletal range which derive almost always  
8 from injuries, but they are not titled an injury  
9 under the ICD-9. So we've tried to include all of  
10 those different ones and have a specific injury  
11 ICD-9 list that has been standardized in the DOD  
12 and is used by our safety community as well as our  
13 medical community.

14 The Barell matrix is based on an  
15 original CDC mapping scheme. It includes  
16 poisonings, which the DOD scheme doesn't, because  
17 we want to focus more specifically on anatomical  
18 injuries. The CDC version doesn't include those  
19 700 series and other ones that frequently do come  
20 from injuries. So we have also modified the  
21 Barell matrix, although not in this particular  
22 data that I'm showing you. It's been modified for

1 future use.

2 We made a prediction because of this  
3 issue of severity that we know that it's not all  
4 severely injured people coming out in the medical  
5 movement system. We said that we would predict it  
6 would be closest to inpatient -- if we are trying  
7 to compare with in garrison, we said it would be  
8 similar to inpatient occurrences in garrison, plus  
9 outpatient fractures in garrison. As I mentioned  
10 earlier, fractures are removed from theater, but  
11 they would normally be treated in an outpatient  
12 setting in most cases. So that was our prediction  
13 going in; it was to look at that and see how well  
14 it matched.

15 We ran into a lot of troubles with both  
16 numerators and denominators, because first of all,  
17 we have a substantial number of people deployed  
18 now. In the past, we didn't usually try to  
19 balance our in-garrison denominators by adjusting  
20 for those who were deployed, because it didn't  
21 make up a significant percentage. We can't make  
22 that statement anymore, so we're trying to balance

1 that. We also have trouble with the enumerator,  
2 because as the people are removed from theater,  
3 they come to some point such as Landstuhl or  
4 Walter Reed and they are then entered, whatever  
5 their condition is, as an entry into the  
6 in-garrison inpatient and outpatient system. So  
7 there's the potential of double-counting these  
8 people on both sides of the fence. You would say,  
9 well, that's easy, you just look at their Social  
10 Security number and then you match it and you take  
11 those people out and you count them only on one  
12 side. Well, that leads to this continuing problem  
13 of having an accurate roster for people that are  
14 deployed. You have heard that from several other  
15 sections today already. I can confirm that it's  
16 still a problem. It is getting better, but it's  
17 just very difficult. It's almost ironic that we  
18 can count M-16s and tanks and planes accurately  
19 and never lose any, but we can't count people.  
20 I'm beginning to think what we need is one of  
21 those embedded signal generators and/or a tattooed  
22 bar code somewhere on our body, and as you walk

1 onto the plane or the ship, you pass through a  
2 portal. It's a gigantic grocery store scanner,  
3 and it just automatically registers you as getting  
4 on the plane, getting off the plane, and we'd know  
5 where everybody was real-time and we'd give up on  
6 all of this. But our current state does not do  
7 that. Every time we think it's getting a lot  
8 better, someone gives us a new roster. I have a  
9 recent one just a week ago from the Army National  
10 Guard that we compared to the official roster from  
11 the personnel center, and there's a difference of  
12 tens of thousands of people that the Army Guard  
13 said they have deployed and the official roster  
14 says are not deployed. That's why we don't do a  
15 lot with rates at this point, because we are just  
16 not sure how to handle that.

17 So that's our big bottom line, that we  
18 are really focusing on continuing to improve that  
19 roster capability. And we are working very  
20 closely with the Defense Military Data Center to  
21 do that.

22 We also have some problems in that we

1 are not allowed to use what we think are the exact  
2 denominators for the in-theater settings, because  
3 most of those are classified until they are quite  
4 old. So instead we use open sources which are out  
5 there on the web and you see the results in the  
6 newspapers and CNN and such, which when we do  
7 comparisons, agree remarkably well with what the  
8 official classified sources are. So we use those  
9 instead, but it seems funny to have to put a  
10 footnote on your table saying that you are using  
11 some open source thing instead of official DOD  
12 data. So that's where we are to keep things  
13 available for the media and to be able to put them  
14 into open settings. We've got to stay out of the  
15 classified realm.

16 So these are the initial results.  
17 Looking at the two theaters, OIF and OEF, and then  
18 these are the comparison values with garrison  
19 inpatient and outpatient fractures, garrison  
20 inpatient only, and garrison outpatient only. I  
21 think if you focus on those annualized rates --  
22 and you can see here, we have all kinds of other

1 difficulties. The periods of time are different  
2 because the inpatient data lags by 30 to 90 days,  
3 and so I can't take it up to the minute like I can  
4 with the deployed data out of TRAC2ES, although  
5 the TRAC2ES data evolves over time and they find  
6 extra records and put them in, and what was a  
7 number yesterday may be a different number when  
8 you check it 2 weeks from now.

9           So we have settled on annualized rates  
10 as being probably the easiest way to try and  
11 average some of these things out and get some  
12 idea. I was actually surprised to have it come  
13 out to this ballpark agreement where OIF and OEF  
14 and the garrison inpatient outpatient are at the  
15 appropriate level, even though they seem like they  
16 are fairly significantly different when you just  
17 look at them grossly. OEF we expect to be higher  
18 because they have a much smaller denominator, and  
19 so all of their rates are much more volatile.  
20 You'll see that on the individual breakouts more  
21 dramatically. The garrison inpatient only, again,  
22 I'm not surprised for that to be less than what we

1 see in OIF, because we know that there's these  
2 other cases that wouldn't normally be hospitalized  
3 coming out of that system. What I think is  
4 intriguing is how high the outpatient injury rate  
5 is in garrison, because I think most people lose  
6 sight of that, but it has been pretty consistent  
7 for several years on the average. And this is for  
8 active duty only. We're not talking about  
9 beneficiaries or Reservists that aren't activated  
10 and things like that. The average is one visit  
11 per year per person for an injury-related case.  
12 All of these were calculated on an incident basis.  
13 It was the first visit for that particular injury,  
14 as opposed to any follow-up visits and PT visits  
15 and things like that.

16 So we do think that's encouraging, but  
17 we don't think it's useful to make any particular  
18 comparisons or take actions based on what we are  
19 seeing at this point, because of these concerns  
20 about whether such a comparison is valid at all.  
21 I really don't think that the environments are  
22 equivalent enough to take numbers like that and

1 match them up head to head. The exposures are  
2 just very different in the deployed setting.  
3 Certainly the availability of data, its accuracy,  
4 completeness and all of that is markedly  
5 different. Then the other parts that are so hard  
6 to figure out are the cultural changes that occur  
7 when people deploy and that their behavior  
8 patterns are markedly different. Unfortunately,  
9 you can argue for it to go in either direction  
10 depending on what's going on. So that makes you  
11 sound like a spin artist when you are trying to  
12 discuss your results with these things. But we  
13 know that there's no incentive to seek care for  
14 minor injuries as there might be in the States.  
15 You are not going to get out of work, you're going  
16 to stay there, so why come in and have it  
17 evaluated? There's less access to care. There is  
18 not as robust a medical infrastructure available,  
19 and so people are less likely to come in for that  
20 as well. So I think all of those things are  
21 factors we have to consider.

22 But just for some interest, I have

1 mapped out some rates using the background we have  
2 talked about for an OIF, OEF, and for the garrison  
3 inpatient, just to see what we might be able to  
4 determine from an anatomical standpoint using the  
5 ICD-9s. The small numbers in dark print, the one,  
6 two, three, four, five, are the rank order based  
7 on these rates. So you can see that the top five  
8 are the same for OIF and OEF, although the border  
9 varies slightly. There's a fair amount of overlap  
10 with the inpatient garrison as well, but some  
11 differences there. If you look at it from the  
12 Barell matrix standpoint, I think that, to me, is  
13 more illuminating, because you do start to get  
14 some idea of the types of injuries as well as the  
15 anatomical location. Now, it's a big disingenuous  
16 to label these as dislocation of the knee, and  
17 that's the label that was given to them by the  
18 people that designed the Barell matrix. Most of  
19 these are just knee troubles, knee pain, something  
20 is wrong with the knee kind of thing, so we expect  
21 that to be fairly common with injuries. If you go  
22 through the rest of the list, the system-wide late

1 effects column, the fourth one over from the left,  
2 .42, is primarily heat-related injuries occurring.  
3 Now, in garrison setting, it's different, as we'll  
4 come to in a separate slide for the primary  
5 motivator for that particular one. However, if  
6 you take some of these where you can see  
7 anatomical sites, like if you put all the hand  
8 things together and there's -- the fracture  
9 hand/wrist as well as the open wound is actually  
10 for hand, although it didn't come out in the chart  
11 label -- and unspecified injury to the wrist/hand,  
12 put all those together and it becomes the number  
13 one, outpacing the knees. That certainly is  
14 something we've seen. There have been a lot of  
15 hand and wrist injuries, and there's been a need  
16 for orthopedic surgeons at Landstuhl to be on  
17 their toes.

18 So this starts to help you with resource  
19 allocation. It gives you general trends without  
20 getting too hung up on specifics.

21 If you compare these Barell matrices  
22 across the operations and inpatient versus

1 outpatient, you can see the expected differences,  
2 that there's lots of fractures and such in  
3 OIF/OEF, whereas in the outpatient it's primarily  
4 sprains and strains and a few fractures. The  
5 garrison inpatient looks a bit different because  
6 of the prominence of traumatic brain injury  
7 showing up, which does not show up nearly as  
8 highly in people being moved out of the theater.

9 I think that this is where we'll end up,  
10 is that in order to make any kind of a reasonably  
11 valid comparison between the garrison setting and  
12 the deployment setting, we're going to have to  
13 focus on fairly specific injury complexes. So we  
14 are going to have to look at the deranged knee, or  
15 we are going to have to look at the fractured  
16 lower leg, or more specifically, maybe it's open  
17 fractures of the tibia or something. That will  
18 probably be the best way to look at this. Now, on  
19 this one, I have left out the outpatient garrison  
20 column because it is so overwhelming, as you will  
21 see on the next one. This allows you to see that  
22 the patterns are not too remarkable when compared

1 to garrison inpatient. When you put in the  
2 outpatient garrison so that you've got to think  
3 there has got to be a lot more access to care, a  
4 lot more willingness to come in, some of those  
5 cultural issues we've talked about. It so dwarfs  
6 anything else that it's hard to see any kind of  
7 pattern at all. So I haven't usually put that in  
8 except for effect.

9 I think the message here that's been  
10 missed by the media, and to some respect Congress,  
11 is that there were accusations that the DOD was  
12 hiding and not reporting non-battle injuries and  
13 even diseases, and that we weren't even tracking  
14 them, maybe. The point, of course, is that we've  
15 always focused on DNVI, because that's the major  
16 detractor from what we do. It's diseases that  
17 outpace non-battle injuries, and in general  
18 non-battle injuries outpace battle injuries,  
19 except for recently in this particular one with  
20 the high insurgency pattern.

21 So the fact is, they have forgotten that  
22 people get injured everywhere. And in our

1 garrison setting, people get injured a lot, and  
2 they come in and they get those injuries taken  
3 care of. But they're not permanent. They're not  
4 disabling. But that issue about disabling has  
5 been very prominent too. So I threw in a couple  
6 of slides on amputations, just to show that we  
7 have tracked that using the movement data and  
8 there have been several hundred people, sadly, who  
9 have been badly injured and had one or more  
10 amputations. There were concerns that it was more  
11 common in Reservists than active and maybe  
12 Reservists were being put in harm's way and that  
13 the active duty people were staying in the cushy  
14 jobs somewhere. That isn't reflected in these  
15 numbers.

16 DR. OSTROFF: Colonel Cox, you have five  
17 more minutes.

18 COL. COX: And that's why this is the  
19 last slide. Except for the summary slide.

20 The amputations were occurring in both  
21 of these theaters in different proportions, as you  
22 would expect. The battle injury amputations are

1 more common in OIF, and it's non-battle injuries  
2 that predominated OEF, because OEF isn't having  
3 the same kind of insurgency, the same kind of  
4 having to deal with improvised explosive devices,  
5 et cetera. These were just sample slides of  
6 things that we can do or ways we can show the  
7 data.

8           The summary slide is that TRAC2ES is an  
9 imperfect surrogate, but it is the best one that  
10 we have. As long as we are open about its  
11 limitations, I think there has been useful  
12 information derived from it. I think it's better  
13 if we focus on rank orders and proportions as  
14 proposed to specific counts and rates until we can  
15 define these very detailed problems with  
16 numerators and denominators and that our way  
17 forward will be greatly enhanced if we can improve  
18 the training, improve the access to computer  
19 systems in theater and have people use them  
20 consistently, and to have behind that an accurate  
21 roster that tells who was where and when they were  
22 there.

1                   That was all that I had hoped to present  
2 today.

3                   DR. OSTROFF: Thank you, Colonel Cox.

4                   Let me open it up for questions and  
5 comments. I'm sure that there are some. Dr.  
6 Lauder.

7                   DR. LAUDER: First of all, you have my  
8 empathy with trying to get people to code  
9 correctly, because most physicians that get paid  
10 on how they code don't code correctly. So to try  
11 to do it with a large group of individuals of  
12 varying places in their life would be a challenge,  
13 to say the least, especially in theater.

14                   One of the questions I have is, we  
15 didn't see an example of what your ICD-9 code  
16 sheet looks like for people to fill out. I guess  
17 I would suggest that perhaps a lot of time and  
18 emphasis should be put on the recording sheet to  
19 make it as user friendly as possible because, I  
20 think, that's an onerous task to begin with, to  
21 code correctly, just to know how to code. Then  
22 secondly, if it's just really not spelled out in

1 plain layman's English, it's hard to understand.  
2 For example, your high rates of dislocation on  
3 meniscal tears is under the large code of  
4 dislocation which accounts for your large numbers,  
5 because that's a common injury, I'm sure. But who  
6 would ever think of a dislocation as a meniscal  
7 injury or a meniscal tear? Perhaps you do have it  
8 very easy to look at and easy to fill out. But if  
9 you don't, that's one area that I would spend a  
10 lot of time on, because that's where it starts.

11 COL. COX: We have done several  
12 different approaches to that. The Air Force,  
13 because they knew their physicians weren't  
14 comfortable or experienced with coding tried an  
15 anatomical cascading tree approach where they can  
16 sort of click on the body and it gave them the set  
17 of things that went with it -- not on the  
18 patient's body, but on the homunculus on the  
19 screen. It produces it. You can work your way  
20 through it. And yet it doesn't seem to be  
21 intuitive and popular with them. It didn't help  
22 that initially, the coding was all wrong behind

1 it. The people that did the software didn't have  
2 the benefit of interfacing with a physician or  
3 someone who understood what it was supposed to be,  
4 and everything was being coded as a HEE and T kind  
5 of thing, even if it was in the foot. But we did  
6 fix that.

7 But that was one approach. In garrison,  
8 they have used the multiple approaches too,  
9 including what they call a super bill where they  
10 have tried to put the most common diagnoses up  
11 front and things like that, and they have used  
12 terms that go with it. We found that even with  
13 that, people will frequently still just default to  
14 the upper left-hand corner, because it's easier  
15 and they don't want to mess with it and they are  
16 just trying to get it off their desk kind of  
17 thing. There has been marked improvement in  
18 in-garrison coding over time. Some of those  
19 systems have helped, if they have been combined  
20 with an aggressive compliance measuring system at  
21 the local unit and interest by the commander as  
22 well as the chief of clinic of hospital services

1 and involving it in their clinical staff meetings  
2 and things.

3 So I think it becomes a generational  
4 issue. It isn't a switch-on-and-off kind of  
5 improvement. But we are looking at a number of  
6 different ways to do that. It's not easy so far  
7 with any of them, or foolproof, I guess is the  
8 better word.

9 DR. OSTROFF: Dr. Baker and then Dr.  
10 Poland.

11 DR. BAKER: Thank you very much for your  
12 presentation and especially for your last three  
13 words saying that we need more --

14 DR. OSTROFF: Dr. Baker, could you use  
15 the microphone? I can't tell if it's on or not.

16 DR. BAKER: And especially for calling  
17 attention to the fact that we need more data on  
18 cause, because in order to do anything on  
19 prevention it's absolutely essential that we have  
20 some idea of the circumstances of injury, both to  
21 develop preventive measures and to prioritize  
22 them. To have information only on an anatomical

1 information, that's fine for medical purposes.  
2 But otherwise it's sort of akin to if we know for  
3 infectious diseases only whether they affect the  
4 lungs or the eyes or the GI tract or whatever,  
5 that would certainly not be acceptable to the  
6 medical community, and I think having no cause  
7 data on injury should be similarly unacceptable.

8           So my question for you is whether you  
9 have any suggestions as to how this particular  
10 absence of data can be corrected. We do not have  
11 data in garrison for the outpatient care. I  
12 gather that for those overseas -- I mean in OIF,  
13 OEF -- we don't have consult data that has been  
14 coded at least for the medivacs or in many cases  
15 for the hospitalized injuries.

16           COL. COX: We have equal concerns and we  
17 have been trumpeting that requirement for a while  
18 now, with some progress, I might add. I didn't  
19 mention that certainly all of these systems  
20 include E codes and D codes. They are there and  
21 available as far as selecting them and putting  
22 them into the electronic record. The TRAC2ES

1 system does get some. As a matter of fact, it has  
2 the opposite problem. There are some cases where  
3 all they have recorded is the E code and they  
4 didn't put any ICD-9 code to go with it, which of  
5 course is of limited value too, and it should  
6 never be listed as a primary diagnosis as an E  
7 code.

8 But our solution in garrison, and I  
9 think it will transfer to the theater in the PEMS  
10 eventually, is that the systems under CHCS-2 are  
11 going to include a trigger window that pops up.  
12 If an injury has been diagnosed and they put an  
13 injury code in but they haven't selected an E code  
14 or a Stanae (phonetic) code, whatever we end up  
15 standardizing on, there will be, before they are  
16 allowed to close out that record, it won't close.  
17 It will pop up a window that says, you selected an  
18 injury. Did you forget to select your causal  
19 code? They will be forced into that habit pattern  
20 of always getting the causal code.

21 That, again, in theory would work in  
22 theater, although the motivation and the

1 importance of the additional coding accuracy is a  
2 little harder sell for physicians if they are in  
3 the middle of a triage situation and bullets are  
4 whizzing overhead. So I think that is an issue  
5 we're going to have to come up with as either very  
6 easy ways -- and they talk about voice  
7 recognition. They talk about picking up your  
8 brain waves and having them turn into computer  
9 screens. I don't think we're there yet. But we  
10 do have to find a way that doesn't put them at  
11 risk and still gives them an environment that they  
12 can get that extra information we need, because we  
13 can't make progress without it.

14 DR. BAKER: Can you tell us at least for  
15 the mortality data what proportion of the  
16 non-battle injury deaths are motor vehicle related  
17 versus other specific circumstances?

18 COL. COX: Well, yes. Major Pearse has  
19 all of that data available. It is clearly  
20 separated into battle and non-battle and motor  
21 vehicle, the cause of accidents for the mortal  
22 cases. It's not as easy on the non-battle injury

1 side to do that right now. But the DNVI tells us  
2 how many motor vehicle injuries there were, but it  
3 doesn't separate them by mortal and non-mortal.

4 So again, all of our pieces are sort of  
5 disconnected and we are bringing them together.  
6 But once they are actually deceased, the AFIP Data  
7 Center is quite complete, and so we rely on that.

8 DR. POLAND: I want to go back to the  
9 Giant grocery store scanner idea, which is only  
10 somewhat tangentially related to your  
11 presentation. It's a bigger issue.

12 After the first Gulf War we had a  
13 similar situation where we couldn't tell who had  
14 been there and where they had been. We said that  
15 wouldn't happen again. I caught and heard vividly  
16 the idea that we still don't know. I  
17 fundamentally don't understand that, why we can't  
18 do it. Even the proposed paragon of inefficiency,  
19 the Post Office, can tell you when your piece of  
20 mail went through the sorter and when it went  
21 through in relation to other pieces. And it has  
22 such a broad reaching inter-digitating effect on

1 so many things, not the least of which is who was  
2 where and when.

3 What is the biggest barrier to having a  
4 chip on the dog tag or whatever the mechanism  
5 would be?

6 COL. COX: That's probably beyond my  
7 ability to answer except to say that certainly the  
8 portable things like chips on cards, they tried  
9 that. The picks, the smarts, all these other cute  
10 names they have had. For technological reasons,  
11 they have often broken down. They haven't been  
12 able to withstand the rigors of the environment  
13 that they're in. Same problems that computers are  
14 having in many of these sites, and why we may not  
15 be able to do as much as we might expect until  
16 some future time.

17 Of course, to the point of putting it  
18 into the people, that brings up a whole other  
19 issue, and I don't think our populace is quite  
20 ready for the embedded scanner yet. But it would  
21 be a lot simpler than what we are dealing with.

22 You know, I have to be careful. I think

1 it is definitely true that we are better than we  
2 were in the first Gulf War. We can count people  
3 far better than we did then. But we're still  
4 amazed, despite all of those improvements, that  
5 there seem to be fairly significant gaps that keep  
6 showing up. It becomes that finger pointing about  
7 whose is right. Everybody says theirs is right.  
8 And epidemiologists or others are stuck trying to  
9 figure that out, and it hasn't been easy. So the  
10 personnel system has worked on this. They are  
11 cross-referencing the financial records. The idea  
12 is that we don't pay money to anybody unless we're  
13 pretty sure they were there. Yet despite all of  
14 those things, we end up with gaps.

15 So the gaps are much narrower than in  
16 1990-91. But there's still room for improvement,  
17 and all of those different people are looking at  
18 it, is the best I can say.

19 DR. OSTROFF: We have time for just a  
20 couple of more brief comments. First Dr. Haywood  
21 and then Dr. Patrick.

22 DR. HAYWOOD: Would you comment a little

1 bit more on heat injury as the primary source?  
2 Does your data indicate when you list it there as  
3 systemic that that is primary injury, or is that a  
4 secondary injury, the fact that they were injured  
5 in some other way?

6 COL. COX: Most of the ones in this that  
7 were captured and labeled as heat injury were the  
8 primary diagnosis. We were focusing on the  
9 primary diagnostic code. The TRAC2ER system does  
10 allow you to capture three ICD-9s. It's not as  
11 robust as, say, the in-garrison, inpatient where  
12 you can capture eight or nine -- I forget the  
13 number. But these were for primary.

14 Again, it wasn't common. It's not like  
15 there were hundreds of those people. That was the  
16 rate. So it's not a terribly common thing. It  
17 did achieve a certain degree of notoriety, though,  
18 when there were these cases that were being found  
19 dead in their cots. The original decision was  
20 that they were heat related because their body  
21 temperature was high. But the ambient temperature  
22 happened to be 120 at night. So if they had been

1       there for several hours, you wouldn't expect them  
2       to be very chilly. So those things had to be  
3       sorted through. Major Pearse had a great deal of  
4       involvement with that. So many of those that were  
5       initially labeled as heat-related were later  
6       changed to a different diagnosis.

7                 That brings up another issue. In these  
8       systems, there is no going back. You know, what's  
9       coming out of theater is the initial guess of what  
10      the condition may be or the rule-out diagnosis.  
11      There is no going back in and correcting that,  
12      should the final diagnosis be different after  
13      further evaluation.

14                DR. OSTROFF: Dr. Patrick, and I'll  
15      point out you are standing between lunch --

16                DR. PATRICK: I know. I'll try and keep  
17      this brief. But I wanted to second Greg's comment  
18      on this, this whole notion of really applying new  
19      technology to this. I think the population may be  
20      a little further along. Certainly the technology  
21      is. It's unimaginable to me that DARPA isn't  
22      already doing some work in this area. I would

1 frankly love to get briefed. I think that the  
2 group should get briefed.

3           Implantable chips are a technology  
4 that's now. It's not in the future. They are not  
5 only static reader technologies, they are  
6 uploadable technologies. In fact, as Greg says,  
7 this relates to a lot of things that we address  
8 here, the notion of having information that can  
9 follow these folks wherever they go and be  
10 accessible and usable for tracking. I can't  
11 imagine a population in which the risks and the  
12 benefits calculated appropriately wouldn't work  
13 out in favor for the application of these  
14 technologies, perhaps not for everyone, but for  
15 those that we put in harm's way. I think this is  
16 a very, very important issue for us to think  
17 about.

18           Again, this is not rocket science. This  
19 is already there. It's being used in animals and  
20 it's being used experimentally in individuals.  
21 It's not just the information chips, but it's the  
22 chips that relate to monitoring such things as

1 lactose and glucose and other kinds of things.

2 Frankly, I can't recall -- I've been on  
3 the Board for about 4 years -- a briefing that we  
4 have had from DARPA or others that are really  
5 beginning to look at the future of these  
6 technologies. But I think it would be useful, and  
7 I think it has enormous implications for the kind  
8 of things we address in this Board.

9 DR. OSTROFF: Just one comment,  
10 Commander Ludwig and then Ms. Embrey.

11 COMMANDER LUDWIG: I was just going to  
12 say, sir, please don't call it tracking. Call it  
13 safety and security, an implantable chip.  
14 Tracking has got bad connotations.

15 DR. OSTROFF: Ms. Embrey.

16 DR. EMBREY: The whole idea of using  
17 higher technology to address this issue is being  
18 addressed at our research sites. Sensors,  
19 biomonitoring, and nanotechnology are all part of  
20 what we are trying to do in our research programs.

21 But, yes, I think that unfortunately,  
22 you will find that most of the people sitting in

1 this room are just as frustrated as you about the  
2 lack of the accountability of personnel in the  
3 system. The medical people have been trying to  
4 drive correction in this arena. But the personnel  
5 community has for whatever reason had a difficult  
6 time addressing this as a high priority. So it is  
7 a medical problem as an outcome, but the personnel  
8 community owns the problem and they don't seem to  
9 be wanting to move forward. So if there's a  
10 recommendation from this community about the  
11 importance of this and the requirement that we  
12 aggressively pursue these technologies, that's one  
13 thing. But I don't think that this Board can  
14 influence personnel decisions per se, other than  
15 to recognize the impact of that lack of priority  
16 on our ability to do what we have to do.

17 DR. OSTROFF: Thanks for those comments.  
18 I will just make a brief comment that back in  
19 February I was at a meeting at the White House  
20 where a lot of this spectacular technology was  
21 presented. Some of it truly is breathtaking in  
22 terms of what types of information can be

1       communicated.

2                   Colonel Cox, I love your presentations  
3       and I really admire the precision with which you  
4       present information. All of us recognize that  
5       there are strengths and weaknesses or strengths  
6       and limitations in all of the data that we all  
7       deal with. Having been at CDC for 20 years, we  
8       all know that the reportable disease data has  
9       exceptional limitations in terms of the quantity  
10      and quality of the information that's presented.  
11     The frustration I have is that you spent about 45  
12     percent of the presentation talking about the  
13     limitations and very little of it talking about  
14     the actual information. I think the Board likes  
15     opportunities to kind of chew on the actual  
16     information itself, because even though we know  
17     it's reportable disease data, that it's  
18     exceptionally difficult to really understand  
19     what's there, we do use it and it does prove  
20     useful in terms of getting rough estimates of what  
21     the trends are.

22                   So hopefully in all of this effort to

1 collect all of this information and parse it all  
2 together, while you are working so hard to try to  
3 improve it, you recognize that some of it actually  
4 is useful and usable, because there things that  
5 you can take from what data that you have and  
6 hopefully translate it into doing something.

7 COL. COX: We'll keep doing that.  
8 Again, we are updating this system. It's being  
9 automated. If nothing else, we are going to be  
10 putting some just gross counts of injuries,  
11 non-battle injuries and disease cases, on that  
12 public website where they list the wounded in  
13 action and killed in action stats, at least to  
14 show the world that we are collecting this data  
15 and that that will give them some idea of what's  
16 going on in a very gross sense. It's like the  
17 weather vane. It's pretty good within 20 degrees  
18 of showing what direction the wind is blowing.  
19 But if you want the quantity, it's not there. So  
20 we'll keep working towards the quantity side.

21 DR. OSTROFF: Thanks very much. I think  
22 with that we'll break for lunch.

1 (Whereupon, at 12:30 p.m., a  
2 luncheon recess was taken.)  
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1 for the opportunity to speak here. I will go  
2 through some slides over here, and hopefully we'll  
3 be able to make up a little bit of time, because I  
4 only have three topics that I need to cover and  
5 some of this has been covered before. I hope it  
6 will be informational to you.

7 The three topics I'd like to talk about  
8 a little bit this afternoon are an overview of the  
9 occupational and environmental health surveillance  
10 program; the status of the anthrax vaccination  
11 program, some of which we have already talked  
12 about yesterday through the excellent presentation  
13 of Colonel Grabenstein, so I won't repeat much of  
14 what he already said -- I will try to add some  
15 additional points of information that might be  
16 useful; then I wanted to talk about an issue that  
17 came up this past year, raised from one of our  
18 combatant commands, from CENTCOM, regarding Iraqi  
19 sand.

20 Just as an overview, and I'm sure this  
21 is a refresher for most of you, this is a  
22 schematic of a summary of the occupational and

1 environmental health surveillance and hazard  
2 control model. We've talked a lot this morning  
3 and yesterday as well about deployment health  
4 surveillance. The point I'd like to mention here  
5 is that health surveillance is one portion of the  
6 entire process. We have goals to identify,  
7 evaluate, and collect environmental hazards,  
8 predeployment, during the mobilization up to  
9 deployment, throughout the deployment, and  
10 postdeployment. Many of the same people tasked  
11 with doing the environmental health surveillance  
12 piece are responsible for a lot of these other  
13 pieces as well. So there's a very significant  
14 workload that's attached to this process in  
15 theater.

16 Just as a review, some of the pertinent  
17 policy letters governing occupational environment  
18 health surveillance, DOD directive 6490.2 was  
19 recently updated and signed this past October.  
20 The DOD instruction governing medical surveillance  
21 for deployments is currently under review. I'd  
22 like to take some opportunity to discuss this

1 further. There's also a series of policy letters  
2 and memorandums that have supplemented these  
3 documents that hopefully will be incorporated into  
4 the final occupational and environmental health  
5 surveillance policy that results in the revised  
6 Department of Defense instruction.

7 Talking specifically a little bit about  
8 the proposed Department of Defense instruction  
9 6490.3, this document has been under review for  
10 several years. The current version in force is  
11 dated 1997. The proposed revision has many  
12 significant changes. It redefines deployment from  
13 the existing definition that's in the DOD  
14 instruction. It incorporates many policy letters  
15 that have already been established and puts the  
16 requirements in the instruction for deployments,  
17 including TDYs. It requires the combatant  
18 commands to provide daily six-digit grid  
19 coordinates of all personnel. This goes to what  
20 was discussed in the discussion prior to lunch.  
21 It includes government civilians and contractors.  
22 And it urges Reserve component personnel to stay

1 on active duty to resolve medical requirements.  
2 It certainly doesn't mandate, but it urges. These  
3 are draft proposals at this point.

4 The proposed instruction is basically a  
5 very significant expansion at all levels of the  
6 requirements for the medical and the personnel  
7 systems. The Services and the combatant commands  
8 have great concerns about this document. The  
9 perception is that the technology currently  
10 doesn't exist to accomplish the required tasks.  
11 I'm putting myself at risk a little bit here,  
12 based on the tone of the previous conversation. I  
13 know that there's great interest to try to  
14 increase the requirements and be more specific.  
15 There is just some concern from the combatant  
16 command in the theater commander level that these  
17 are unimplementable right now. There's also  
18 significant concern about adding potential  
19 applicability to non-hazardous events, such as  
20 routine training in garrison. Do we need to do  
21 pre- and postdeployment surveillance for a 3-day  
22 training exercise in the back forty of the base?

1 Perhaps, perhaps not. The basic fundamental  
2 concern that the Services and the combatant  
3 commands have on this instruction is that it's  
4 potentially directing limited resources to  
5 documenting activities that present very low  
6 hazard potential.

7 Our key point to this is that the latest  
8 GAO, Government Accountability Office, audit of  
9 the Department's deployment health surveillance  
10 program was conduct in September and October of  
11 this past year. We are starting to get better  
12 grades than we have gotten in the past from the  
13 GAO. The GAO has said that our compliance rate is  
14 improving with our current policies that are in  
15 place. But still, the overall compliance rate  
16 they assessed was at approximately 43 percent  
17 across all the Services, which is not where it  
18 certainly needs to be. That's compliance with the  
19 existing deployment health surveillance policies  
20 and instructions that are out there. The concern  
21 is that if we add these great increased  
22 requirements, we will certainly not be able to

1 meet them at the practical level.

2 I certainly want to make clear that  
3 there's many things that the Joint Staff and the  
4 combatant commands like about this proposed  
5 document. There's many good things in here. It  
6 incorporates numerous policy letters issued since  
7 1997 that we need to have codified. It definitely  
8 clarifies rules and responsibilities to a greater  
9 degree than ever before, and it incorporates a lot  
10 of lessons learned from numerous operations in the  
11 past 7 years. Tracking the conversation from  
12 yesterday, we are very grateful that the AFEB  
13 working groups are looking at these issues related  
14 to deployment health surveillance, and we're  
15 anxious for as much as feedback as we can get on  
16 this, so that we can balance what's practical and  
17 what's feasible on the field with what's best  
18 practices and what we should be doing.

19 Just briefly, I'd like to go through  
20 some additional topics on the anthrax vaccination  
21 program, most of which you have seen yesterday, so  
22 I won't repeat them, certainly. But in summary,

1 if the Department of Defense receives the  
2 authority from the district court judge to  
3 implement emergency use authority, there is a plan  
4 in place that we have developed with MILVAX and  
5 with OSD health affairs to immunize categories of  
6 personnel that are at the highest risk and most in  
7 need of the vaccination first. There are no plans  
8 right now to restart vaccinations for  
9 non-deploying, non-high risk personnel who for  
10 some reason had interrupted their series of shots,  
11 however.

12 The third topic I'd like to talk about  
13 briefly is an issue that came up last year with  
14 regards to Iraqi sand. This issue came out of  
15 CENTCOM. There was a study published by the Naval  
16 Institute for Dental and Biomedical Research this  
17 past summer entitled "The Unique Properties of  
18 Iraqi Sand and Their Military Significance." This  
19 study was originally intended to try to answer  
20 some questions about the effect that sand was  
21 having on dental instruments. But it very quickly  
22 went into the toxicology realm and they modified

1 the study accordingly. This study's preliminary  
2 interpretation of the data is that Iraqi and  
3 Kuwait sand, for geological reasons, is unique and  
4 has unusually small respirable particles with  
5 large numbers of crevices that can harbor metals  
6 or microorganisms. This is very preliminary  
7 information at this point, and it's certainly not  
8 backed up by other studies. But I wanted to bring  
9 it to the Board's attention that there is  
10 additional research going on in this area.

11 So far, what we know is that this  
12 research is not consistent with the existing  
13 regional sand knowledge obtained since 1991. The  
14 Naval study accomplished this past year was  
15 basically a series of bulk samples, and it was  
16 only selected from three sites. It was not  
17 breathing zone samples and was not accomplished in  
18 accordance with a statistically representational  
19 sample methodology. The sampling data bases we  
20 have so far on Arabian Peninsula sand composition  
21 since 1991 come largely from an environmental  
22 health site assessments and data that resides at

1 USACHPPM. It includes both breathing zone and  
2 respirable particulate samples.

3 Right now the Navy is working in a  
4 collaborative effort with USACHPPM, Naval  
5 Environmental Health Center, and AFIOH to  
6 collaborate this information and coordinate this  
7 information with existing studies to compare and  
8 contrast the data. According to a preliminary  
9 literature review conducted, there's some data  
10 gaps that exist on sand toxicity. There's a lack  
11 of regional epidemiology on the subject. The  
12 epidemiology that we do have is not consistent  
13 with the hypothesis. There are some data gaps on  
14 the types of soil characterization that was done  
15 and some research gaps on the toxicology of small  
16 sand particulates.

17 What the end result was was that the  
18 Service surgeon generals recommended a  
19 reassessment of the hazard potential once an  
20 additional review and study is complete between  
21 the Navy in coordination with USACHPPM and AFIOH.

22 I don't believe this is a pressing or

1 immediate concern at this point. I wanted to  
2 bring it to the Board's attention that there's  
3 ongoing research in this area. I'll be happy to  
4 answer any questions you may have.

5 DR. OSTROFF: I have to confess I'm  
6 quite interested in the sand issue, because I've  
7 now moved the Hawaii and plan to spend a fair  
8 amount of time on the beach. I'll also point out  
9 that you've got me there, because I thought when  
10 you were putting up "Iraqi sand" that it was a  
11 code name for a training exercise like Operation  
12 Cobra Gold or something like that. But you are  
13 really talking about sand.

14 I guess one question that immediately  
15 comes to mind is if there is a problem, it's not  
16 like you can move the war to some place else. You  
17 are sort of stuck with the sand that's there. So  
18 the question is what the potential implications of  
19 that are. But those are just sort of some of my  
20 preliminary thoughts. I imagine that there must  
21 be some other folks around the table that have  
22 more expertise on this issue than I do.

1 Dr. Gray?

2 DR. GRAY: This is Greg Gray. I don't  
3 have necessarily more expertise, but I do remember  
4 two articles published in Military Medicine  
5 alleging that this unusual sand etiologic syndrome  
6 was the cause of the multisymptom conditions among  
7 the Gulf War veterans.

8 I don't know that the DOD or VA ever  
9 attempted to counter that or attempted to do any  
10 studies to evaluate those largely, I think -- what  
11 do we call them? They are not studies; it is more  
12 a review of literature and conjecture. But it's  
13 interesting to hear this.

14 DR. OSTROFF: Dr. LeMasters. Go ahead.

15 MAJOR SMITH: No, sir. I just wanted to  
16 partially respond to your concern, sir. There is  
17 an extensive sampling database and an extensive  
18 analysis that's been conducted ever since 1991 of  
19 Arabian Peninsula sand. There are still some gaps  
20 in the three primary areas that I mentioned, but  
21 the database is pretty robust. There are  
22 apparently 28,000 valid samples that have been

1 taken over the years. Their various  
2 investigations to date have not drawn the link  
3 between what's commonly known as Gulf War Syndrome  
4 and this issue. That's been pretty carefully  
5 looked at by the department, the data in use at  
6 USACHPPM. This study apparently came out. It was  
7 sort of a surprising conclusion that came out of a  
8 study with a different intent. But we do know  
9 that there's some data gaps, and it has to be  
10 looked at in more detail.

11 DR. OSTROFF: Dr. LeMasters and then Dr.  
12 Brown.

13 DR. LEMASTERS: Could you tell us what  
14 exactly are the physical and chemical properties  
15 of the particles and what is the particle size?  
16 Is it like .01 or micrograms? Has there been any  
17 naturally-occurring asbestos fiber found in it?

18 MAJOR SMITH: The asbestos question, I  
19 don't know. I'd have to check into that, ma'am.

20 Regarding the supposed differences  
21 between this sand, because of the geological age  
22 of the Iraqi-Kuwait Desert, it's one of the oldest

1 deserts in the world. The hypothesis is that the  
2 percentage of respirable particulates, 5 microns  
3 or less, is higher because of the smaller size of  
4 the sand. We have gotten additional information  
5 from the U.S. Geological Service on this subject.  
6 Right now that data is being looked at by NEHC and  
7 AFIOH and USACHPPM. I don't know if we have a  
8 definitive answer at this time. We do know that  
9 it's an older desert, and we do know that there is  
10 some evidence that the sand particulates are  
11 generally smaller than in younger deserts. Whether  
12 that has any physiological or toxicological  
13 impacts, we don't know.

14 DR. BROWN: Mark Brown speaking. I  
15 remember that article that article that Craig was  
16 mentioning. There is a name for it, Alaskan  
17 (phonetic) disease or something like that, where  
18 somebody speculated that sand particles or  
19 biological materials on sand particles caused  
20 morbidity among Gulf War veterans. But if you  
21 think about it, I mean, there have been so many  
22 risk factors associated with so-called Gulf War

1       Syndrome or Gulf War illnesses in general, these  
2       things seem to rise and fall with the phases of  
3       the moon or something like that. I mean, you hear  
4       that chemical warfare agent exposure, trace levels  
5       of chemical warfare exposure stuff gets a lot of  
6       play sometimes, and uranium gets a lot of play  
7       some of the time, and anthrax vaccines or  
8       vaccinations in general get the play some of the  
9       time. Articles get published that seem to  
10      indicate that. Sand has sort of been off the  
11      radar for a while. But I'm not surprised that  
12      there seems to be something like a cyclical action  
13      as new risk factors kind of rise and fall over  
14      time.

15                   Probably the most important thing is  
16      that no single risk factor ever seems to actually  
17      ultimately pan out. Having said all that, gosh,  
18      maybe it is the sand.

19                   DR. OSTROFF: I would point out that  
20      there's 25 million Iraqis who live in Iraq and are  
21      exposed to the sand too.

22                   Dr. Patrick and then Dr. Halperin.

1 DR. PATRICK: I can defer if there's  
2 another sand question, because I want to go back  
3 to the first topic.

4 DR. HALPERIN: I'm sand.

5 DR. PATRICK: I thought that might be  
6 the case.

7 DR. HALPERIN: There's a little sense of  
8 unreality about what we are really talking about  
9 here. But you know, sand equates to sandblasting  
10 and to silicosis and to silicotuberculosis. So  
11 there is an air of reality to the question of  
12 whether sand can be harmful. Yes, it can, ground  
13 to the appropriate dimension. And whether it can  
14 be harmful from an infectious disease point of  
15 view, yes, miners develop silicon tuberculosis  
16 because of the combination.

17 But the real question would be, has  
18 there been any kind of an industrial hygiene risk  
19 assessment, getting back to Grace's question.  
20 What's the size of the sand? What's the air level  
21 of the sand? Is this at a level where we would be  
22 concerned from an occupational point of view, or

1 is it de minimis? Where are we from that point of  
2 view?

3 Then there's a whole other question of,  
4 okay, if we are not talking about silicosis and  
5 tuberculosis, are we talking about some new entity  
6 of war-related -- or whatever this other entity  
7 is, which is a whole other question. But I'm kind  
8 of lost as to what we are talking about vis-a-vis  
9 the risk of sand and the risk of sand related to  
10 microbes.

11 MAJOR SMITH: Sir, I'll attempt to  
12 answer that. There have been a lot of breathing  
13 zone air samples collected; several thousand among  
14 the 28,000 samples that have already been  
15 collected. I forget the exact number. The  
16 breathing zone samples to date don't indicate a  
17 hazard from an industrial hygiene risk assessment  
18 standpoint. Now, there are data gaps in the area  
19 and that's one of the things that we identified as  
20 being something that needs to be looked at  
21 further. Like there's a lot of sampling in Saudi  
22 Arabia, for example; there's not a lot of sampling

1 in Iraq because of the recency of the operations  
2 there. That's also filtering out what's  
3 respirable versus what's not respirable. Some of  
4 them are just bulk samples. Some of them are just  
5 total volumes. So there is a data gap there that  
6 is being looked at. So far, no environmental  
7 health site assessment that I'm aware of has drawn  
8 a clear link to this being a hazard, but it's  
9 something that needs to be more researched.

10           Regarding your question about  
11 epidemiology in the local area, that was something  
12 that's just missing. Right now there's no  
13 database with the level of detail in these  
14 countries to assess whether or not there's a low  
15 level of disease risk. We don't have the data  
16 that good in order to be able to look at it yet.  
17 Getting better epidemiology would be part of the  
18 additional research.

19           DR. OSTROFF: Dr. Oxman, if your comment  
20 is related to sand?

21           DR. OXMAN: I'm still on sand too. Mike  
22 Oxman. I would think that if you looked at

1 autopsy lungs from America and from Iraq, you  
2 might at least find out if there's retention of  
3 sand in the lung in Iraq.

4 MAJOR SMITH: That's something we should  
5 look into, sir. I don't know the answer right  
6 now.

7 DR. OSTROFF: Dr. McMillan.

8 DR. MCMILLAN: I think an important  
9 point for me, at least, in looking at this was  
10 that the dentists started looking at how this  
11 affected dental instruments, and so they were  
12 doing a pretty good job at that. Then they  
13 decided to look at how this affected human beings,  
14 and they really got out of their lane. They  
15 looked at the soil and found some heavy metals in  
16 it. So using some calculations of daily breathing  
17 rates and forgetting all about proportions and  
18 airborne particle matter and all those things that  
19 we normally use as occupational environmental  
20 surveys, they came up with an idea that this could  
21 cause heavy metal poisoning and was the cause of  
22 Gulf War illness. They overestimated by a factor

1 of 10,000 in their calculations, but that didn't  
2 seem to bother them. Then they also decided then  
3 to look for microbes, so they were actually able  
4 to culture out a whole list of microbes from the  
5 soil. I guess it never struck them that dirt has  
6 microbes in it.

7 Of interest at least to me was that  
8 Acinetobacter was not one of the ones that they  
9 grew out, and everything else was pretty much just  
10 non-human pathogen. We do know that the PM-10, as  
11 far as airborne dust, was elevated. It has pretty  
12 much been elevated everywhere we have been as far  
13 as the industrial hygiene sampling that I've seen.  
14 There's no doubt in my mind that it is a  
15 respiratory nuisance issue. Guys complain of the  
16 Iraqi crud. They get a kind of chronic rhinitis,  
17 a bronchitis that clears up -- sometimes it takes  
18 several months after they get back. What we can  
19 do about that is the question. As far as the  
20 question of silica, there was not an issue of  
21 silica. There was no asbestos, not any of the  
22 industrial hygiene issues that we have worried

1 about. That stuff has been looked at.

2 As Major Smith mentioned, they are going  
3 back now saying, hey, if you want to look at this  
4 stuff we need to consider the proportion of it and  
5 actually what's airborne to be inspired.

6 Also, as Dr. Ostroff pointed out, you  
7 know, with Iraqis living there, we do have  
8 somewhat of a referent population. AFIP did look  
9 at some autopsy samples to look at whether or not  
10 there was any issue related to some of these  
11 particles becoming embedded in the lower airways,  
12 and if there was something related to that. And  
13 with the autopsies in which they specifically  
14 looked at that, they didn't really find anything  
15 of note. As part of the expanded survey, that's  
16 one of the things at least that has been  
17 recommended out of our office, is to look at --  
18 you know, if you want to look at local tissue  
19 levels of some of the components and some of the  
20 people and you can maybe develop some further  
21 analysis of time in country versus local tissue  
22 loads and stuff, that we may be able to come up

1 with something like that.

2 DR. OSTROFF: Well, I'll also point out  
3 that many on the Board may recall the outbreak of  
4 the eosinophilic pneumonia. That was very  
5 extensively investigated. And one of the issues  
6 that arose in that circumstances was whether the  
7 ambient environmental conditions could be a  
8 co-factor that was related since the etiology was  
9 never determined. So indeed, there are a number  
10 of issues.

11 I think, Dr. Patrick, you had a question  
12 or a comment about an non-sand subject.

13 DR. PATRICK: Yes, non-sand. This will  
14 take us back to the first issue on surveillance.  
15 Major Smith, you had mentioned that this connected  
16 a little bit to the conversation we were having  
17 prior to lunch on finding ways to really monitor  
18 more closely, because I think the big picture, as  
19 I look at the overall goal with the surveillance  
20 program, is to really understand what's happening  
21 to who, where, when, why, and how, and really at a  
22 more granular form, to risk a pun on the sand.

1           I wonder if this isn't an opportunity  
2           for us to nudge along this process of attempting  
3           to factor in more technological approaches to  
4           this. I read in one of the slides that you are  
5           required to provide daily six-digit coordinates of  
6           all personnel. There are plenty of things that  
7           really relate to this. But yet there's the  
8           question that the technology really isn't there.  
9           I really beg to differ.

10           What I guess I'm asking, and this is  
11           partly to you but also partly to the Board, do we  
12           have an opportunity here to nudge the tanker a bit  
13           to move to develop the appropriate systems? I  
14           mean, can we consider this a question to the Board  
15           that we can respond to that says that the Board  
16           sees great value in potentially accelerating the  
17           investigation of strategies for surveillance of  
18           personnel that not only meet overall personnel  
19           needs, but the needs to do the surveillance and  
20           occupational and environmental health and the  
21           other problems that the Board finds are important  
22           from a force readiness protection standpoint?

1 DR. OSTROFF: My comment on that is that  
2 based on the presentation that we heard this  
3 morning from Colonel Cox and the information that  
4 we just heard from Major Smith, I do think that if  
5 we see an issue that would benefit from some input  
6 from the Board as a result of the fact that it was  
7 presented here, I think we do have an opportunity  
8 to provide feedback and comment if we'd like to do  
9 that.

10 COL. COX: Sir, if I could add, we are  
11 certainly welcoming input from the AFEB on this  
12 issue. I don't want to give the wrong impression  
13 here. We are absolutely very supportive of  
14 improved surveillance efforts at the Joint Staff  
15 and the COCOMs. The concern is the disconnect  
16 between policy and the ability to carry it out.  
17 We have some serious structural issues, like many  
18 of the COCOMs don't even have full-time preventive  
19 medical people on their staff. Most do now, but  
20 not all of them. We would have to radically  
21 increase the number of deployable preventive  
22 medicine people to accurately capture these

1 information points.

2 DR. OSTROFF: I'm all for that.

3 COL. COX: Then that goes contrary to  
4 the SECDEF-stated position of only people in  
5 uniform are trigger pullers, so paraphrasing  
6 slightly. But we are increasing workload  
7 requirements on a very overwhelmed group of people  
8 in a very austere environment. I'm sure we all  
9 sensitive to that. But I think we need to strike  
10 a balance between what's achievable and what is  
11 desirable.

12 DR. OSTROFF: I mean, I think that if we  
13 do have a particular perspective that we ought to  
14 be able to enunciate it.

15 DR. MCMILLAN: What form would that  
16 take?

17 DR. OSTROFF: Well, in general, if it's  
18 not a direct response to a question that has been  
19 put before us in terms of a recommendation, then  
20 we can submit an official position in the form of  
21 a letter to Health Affairs.

22 Can I ask one last question? I'm sorry.

1 I see Dr. Parkinson down there at the end.

2 DR. PARKINSON: I have been listening to  
3 this, and there's a couple of moving parts. One  
4 is the GAO scorecard, which is kind of out there,  
5 and I'm not quite sure how that works. But I  
6 guess periodically GAO is going back to assessing  
7 the level of progress that DOD has made on  
8 commitments that they made to Congress,  
9 ostensibly. GAO is acting on whose behalf at this  
10 point? Is it Congress?

11 COL. COX: Yes, sir.

12 DR. PARKINSON: So Congress has a  
13 scorecard report; Congress wants to know how DOD  
14 is doing on the things that we said we'd do?

15 COL. COX: Yes, sir.

16 DR. PARKINSON: That's the first piece.  
17 The second piece is the issue of the tactics to  
18 actually put in the field the policies that make  
19 up that GAO scorecard. The GAO says you've got  
20 the policies, but now we don't see it happening.  
21 I'm just making a cartoon version of this. To get  
22 to Dr. Patrick's comment here a minute ago -- and

1 I'm going to use the analogy on surgical  
2 innovations -- what's really dramatically  
3 different about the survival rates of people in  
4 this version of Persian Gulf is the technologies  
5 and the strategy and the doctrine that changed  
6 that said we're going to put surgical backpacks on  
7 people and get them to the field and we are going  
8 to rapidly evacuate so that more people survive.  
9 It was a combination of strategy, tactics, and the  
10 equipment that they did to execute that. I would  
11 suggest that we need the exact same intensity with  
12 the exact same approach for deployment  
13 surveillance. To date, we are all working hard,  
14 but we don't have that intensity, and we probably  
15 don't have the technologies that rightly -- I'm  
16 glad JCS pushed back. I wish they'd push back  
17 harder. Because when JCS pushes on DOD, you get  
18 action. Because they are the war fighters.  
19 Everybody else out here is doing memos. The way  
20 they see the world is -- that's great. But, we've  
21 got to put people over there.

22 So I see this as a tremendous

1 opportunity to say, is the money that's being  
2 spend across this campus on some things that are  
3 probably much lower threat -- I mean, we spend the  
4 first half morning here looking at some diseases  
5 that I still don't quite know why we are spending  
6 tens of millions of dollars, and we don't have  
7 portable units with connectable electronic data  
8 feeds for people in theater right now. So there's  
9 a macro-allocation issue here. Perhaps what we  
10 need as a Board is a little more information on  
11 what is the tactical plan for miniaturized  
12 electronic state-of-the-art deployment  
13 surveillance now? Where is that plan? Perhaps we  
14 can go that way in a more informed way than saying  
15 we don't kind of like what we're hearing.

16           Because I think the JCS, they probably  
17 have a very legitimate thing. If you have to add  
18 five more people, it wasn't until the Services  
19 said you are not bringing a big tent with all  
20 those big hunky medical pieces of equipment over  
21 there. We've got to be there in 28 hours, you  
22 know.

1           There's an equivalent to that, I think,  
2           in this area, maybe. I'd like your reaction to  
3           that. But perhaps we can be of construct by  
4           saying where is the whole plan, just like we were  
5           going to reengineer surgical care in theater.

6           MAJOR SMITH: Probably the best way to  
7           get information on that -- with the leadership of  
8           the Board's permission, it may possibly be a topic  
9           for a future Board -- a summary of the medical  
10          IMIT programs that are in the pipeline right now,  
11          funded by the military health care system. There  
12          are many initiatives and programs and efforts out  
13          there right now. A team theater medical  
14          integration program is kind of like an umbrella of  
15          many other systems underneath it. We could get  
16          people to give briefings on the status of the  
17          medical informatics programs that are out there,  
18          unless the Board has had that previously and I'm  
19          just not aware of it.

20          DR. OSTROFF: In addition to having a  
21          briefing, like I said, I went to this session at  
22          the White House back in February and I was just

1       literally blown away by some of the technology  
2       that they had on display.  It really would be  
3       wonderful to see some of it, because I think many  
4       of the Board members would be every bit as amazed  
5       as I was in what type of information could be  
6       transmitted in real time on the battlefield  
7       setting.  Dr. Patrick, one last comment.

8                 DR. PATRICK:  I have to thank Mike for  
9       your perspective on history that the Air Force has  
10      really, really helped.  I didn't really understand  
11      how to place this, but you stated this exactly.  I  
12      think now is the time to have that type of  
13      briefing to the AFEB, to a group of folks who are  
14      focused on prevention and on population health,  
15      because I have been involved in many settings in  
16      which medical informaticians sort of go off in all  
17      kinds of strange directions building things which  
18      are wonderful for enumerator health care, but  
19      which are not very helpful at all if you are  
20      really addressing prevention in population health.  
21      So I think the timeliness of that kind of  
22      briefing -- so we can provide some input of, well,

1        gee, that's quite useful, but it would also be  
2        useful if it could do this -- right now for the  
3        kinds of issues that we've talked about, it would  
4        be very, very timely.

5                    DR. OSTROFF: Major Smith, thank you  
6        very much.

7                    Our next presenter is Commander Luke  
8        from the Navy. He will do the Navy update.

9                    COMMANDER LUKE: I just want to take a  
10       minute to go back to the sand issue. When this  
11       came up about 3 months ago, people were using  
12       terms like "sand" and "Iraqi sand," "Arabian  
13       peninsula sand." Then there were some issues and  
14       it was the "secret sand" and the "sand who shall  
15       remain unnamed," and so forth. Commander McMillan  
16       alluded to it, but the proper term on the Beltway  
17       is dirt, and if someone tells you that they've got  
18       dirt all over them or that they are rolling in  
19       dirt, it means they have had an onerous task  
20       dealing with sand. So don't get fooled. Use the  
21       proper terminology.

22                    I also want to take just a quick minute

1 to address kind of a privilege issue from the MEPS  
2 processing centers and doing some prescreening.  
3 In the last recruiting day of April 1979, I happen  
4 to wander into the Los Angeles MEPS center. I  
5 walked into the Navy recruiting segment that they  
6 had, stood there until someone asked me what I  
7 wanted. I said, I'm here to sign up for the Navy  
8 Reserve. That had never happened before,  
9 apparently. Four very fat chiefs threw down their  
10 cigarettes and their coffee cups and descended  
11 upon me, starting pulling on me like a pack of  
12 wild animals because in those days getting people  
13 to sign up for the military was a rather difficult  
14 issue, and a fight broke out. And then something  
15 that resembled Jabba the Hut actually came out of  
16 another office. He turned out to be a senior  
17 chief who assigned me as a gift, manna from  
18 heaven, a prize to one of the chiefs, who let out  
19 a yelp and scooped me along and took me through  
20 the process. More to the point, there was a  
21 period of time when I was brought in to see the  
22 senior chief. He told me what was going to

1       happen. I was going to get on this line. I  
2       wasn't going to leave the line. I was going to  
3       keep my mouth shut. I was going to do what I was  
4       told. But at some point in time I was going to be  
5       given a series of written questions and a quack  
6       was going to ask me some questions. I was told  
7       that I was to say no to the no questions and yes  
8       to the yes questions. So that's basically the way  
9       it was. When I asked him what do you mean by  
10      that, he said, "Well, if they ask you if you are  
11      pink or a pinko, you will know what to say." And  
12      other questions. So that's how it worked in 1979.

13                    So the next slide, I'm Lieutenant  
14      Commander Luke. I'm the assistant director of  
15      Population Health and Fleet Support of the Bureau  
16      of Medicine and Surgery. This will be the second  
17      time that I have had an opportunity to present to  
18      the Board, and I'm very happy to be here. I would  
19      like to take an opportunity to actually tell you  
20      what we are doing in the Navy. It's kind of hard  
21      as far as Navy medicine is concerned. It's  
22      something like an elephant that I haven't seen in

1 its entirety. I'm going to be telling you, at  
2 least from our perspective, with Captain Kilbane  
3 and I, and whether it's going to be -- you know,  
4 what side of the elephant I'll be describing I'll  
5 leave up to you. But I want to talk to you about  
6 one issue, and that was the tsunami response, that  
7 Navy Medicine played a rather large role in that,  
8 and there were very many moving parts around the  
9 world that had some very significant and timely  
10 impact upon this disaster.

11           Probably the first Navy medical unit  
12 that got involved in this was at the Naval Medical  
13 Research Center in Djakarta, Indonesia, whose OIC  
14 is Captain Trevor Jones. He has had several tours  
15 in Indonesia and has a very close and personal  
16 relationship with the Indonesian Ministry of  
17 Health. He received a very urgent phone call from  
18 the Minister of Health who informed him that a  
19 terrible disaster had struck his country and he  
20 needed emergency medical supplies and personnel as  
21 quickly as the research unit could provide them.

22           Navy captains are typically trained to

1 make decisions. Captain Jones scraped up some  
2 emergency funds that were available to his unit,  
3 all available medical supplies, and quickly got  
4 those on an aircraft and into the hands of the  
5 Minister of Health, and did a tremendous amount of  
6 good, not only for the relations between our  
7 government and the Indonesian government, but  
8 also, I think, actually got these medical supplies  
9 to people who needed them.

10 I bring the story up because when  
11 Captain Jones had informed the bean counters about  
12 what he had done -- this had not been budgeted  
13 for, this hadn't been planned for, nobody had  
14 approved this -- he ran into quite a bit of  
15 static. Ultimately, he was completely vindicated  
16 as reacting to an emergency in need and not to  
17 some planned budgetary program. He should be  
18 commended for that.

19 In addition, in Pearl Harbor, Hawaii,  
20 there was a Commander Fred Landro -- who I'm sure  
21 that some of you know -- was at his office when he  
22 had been informed of this terrible earthquake and

1 tsunami and the extent of it. He immediately  
2 began a preplanning phase in his own head. Within  
3 a very short period of time, perhaps 90 minutes or  
4 so, he had come up with a sketch and an idea about  
5 what the EPMU could do if they should be tasked to  
6 go out and provide assistance. So we wrote this  
7 up, sent it up to his commanding officer, who got  
8 a phone call to go up to see the admiral of the  
9 Pacific fleet. The first words out of his mouth  
10 were something to the effect of, you know, "What  
11 the hell are you doing?" He said, "I've got this  
12 plan, sir," And from that plan developed a rather  
13 integrated, important Navy epidemiological  
14 presence in that ocean, and that preplanning was  
15 something that I think Commander Landro should be  
16 commended for, and just noted that there are  
17 people on watch who are thinking about these  
18 things and are prepared to act and answer  
19 questions.

20 As most of you know, there are four  
21 major fleets around the world. The Seventh Fleet  
22 is out in the area of Indonesia and Malaka Straits

1 and Taiwan and so forth. It happens that the  
2 aircraft carrier Theodore Roosevelt was somewhere  
3 in the vicinity of Singapore with a task force of  
4 amphibious ships that had an expeditionary unit of  
5 approximately 3,000 Marines, several thousand  
6 sailors. These task forces are essentially task  
7 organized so that they have really everything they  
8 need to survive for an extended period of time,  
9 either on the ocean or if they have a mission as  
10 designated by the President or the Congress to go  
11 ashore, they have essentially a 30-day supply of  
12 everything that they are going to need for a  
13 combat operation on a hostile shore, which means  
14 they have a mountain of gear and medicines and  
15 food and supplies that are within the holds of  
16 those ships. But in addition to those, they have  
17 cooking facilities. They have hospitals. They  
18 have sick bays. They have water purification  
19 facilities. They have electrical power plants,  
20 ventilation systems. It really is quite  
21 extensive.

22 So based upon the PAC fleet commander's

1 estimate of the situation, he sent them off at  
2 high speed to help the Indonesian people. This  
3 was done. I haven't quite figured out the  
4 mechanism by which this Admiral did this. But I  
5 will say it caught everybody by something of a  
6 surprise, and everybody was attempting in the  
7 Department of Defense to catch up with this  
8 admiral who basically made the decision that help  
9 was needed and he was sending it. So that was  
10 very interesting.

11 In addition, the United States Navy has  
12 two rather large hospital ships, one on the east  
13 coast and one on the west coast. The USNS  
14 Comfort's home port is here in Baltimore. The  
15 USNS Mercy is in the San Diego area. The decision  
16 was made that the Mercy would travel out to the  
17 island of Sumatra and adjoining areas to provide  
18 medical support to the people that had been  
19 injured in the tsunami.

20 The interesting aspect of this is a  
21 rather different mechanism by which this hospital  
22 ship would be manned. It was determined that it

1 would be partially crewed by U.S. Navy medical  
2 personnel, but would also bring aboard NGOs, or  
3 nongovernment organization medical personnel and  
4 aid personnel, for really the first time of a  
5 mixed company. So this was not strictly a  
6 military affair. This is being promoted as being  
7 a model for future disaster efforts, that it's  
8 going to be an NGO-military mix. We are working  
9 out at the DOD level and Navy level specific  
10 mechanisms and agreements to make that happen.

11 I want to take the opportunity here just  
12 to give you an example of an aircraft carrier.  
13 That's the Theodore Roosevelt. At the time that  
14 that picture was shot, it was probably by gross  
15 tonnage the largest ship afloat anywhere in the  
16 world. That's that USNS Mercy which made it out  
17 off the coast of Sumatra. What is not seen is a  
18 variety of amphibious ships, LHAs, LPHs and so  
19 forth, that have the thousands of Marines and  
20 literally dozens of helicopters which are flying  
21 hundreds and hundreds of relief missions onto the  
22 coast of this devastated area, bringing food,

1 supplies, and water to individuals who could truly  
2 use them. This is just, I think, a great  
3 photograph. I have put freedom of movement on  
4 this slide, because I would like to emphasize that  
5 the Navy is different than our sister Services.  
6 Not only do we have surface combatants, we have  
7 subsurface combatants, we have our own Air Force,  
8 and we have our own army. I mean, we've got it  
9 all. When we want to go somewhere, we go. I  
10 think that that needs to be seen.

11 I also want to talk about medicine in  
12 the sense of dealing with situations like this.  
13 You can see this young corpsman here is fighting  
14 an environmental battle, and this is not an  
15 area -- those gates and so forth are fine.  
16 Obviously, the tsunami hasn't hit this. He is  
17 actually probably saving more lives, he and five  
18 or six other guys that are traveling all day and  
19 night spraying for mosquitoes, vectors of dengue  
20 and malaria, Ross River virus. He is probably in  
21 this circumstance going to end up saving more  
22 lives than that hospital ship. That's just the

1 fact of the matter. It's very interesting to me  
2 when I sit around in these conferences and in  
3 other questions, people are talking, are we using  
4 too much Mefloquine? Is it a bad medicine? We  
5 kind of sliver these things very finely, but I  
6 have yet to have anybody saying, why aren't we  
7 using more pesticide? Because fundamentally the  
8 battle against vector-borne diseases is killing  
9 the vector, not treating the patient. Kill the  
10 mosquito; don't treat the patient.

11 So this has a lot of application. The  
12 situation in Liberia where the 80 Marines  
13 developed falciparum malaria could have been  
14 solved had this man arrived there in that facility  
15 first. The Mefloquine would never have been an  
16 issue. A little pyrethroids or carbonate  
17 insecticide and you can go a long way.

18 So I would like to just remind the  
19 Board, the AFEB, that prevention actually starts  
20 at an area like this. At the point in time where  
21 you are actually prophylaxing the patient or  
22 treating the patient, we've probably missed

1 something very important further on down the road  
2 or earlier.

3 I'd like to mention that we all are very  
4 cognizant that we have had an influenza vaccine  
5 shortage. From the Navy perspective, we had some  
6 rather severe growing pains with the FluMist. We  
7 all had committed to giving it to recruits and  
8 those healthy sailors and Marines and benefits  
9 that we could reach, and we probably reached a  
10 near 100 percent total force vaccine this year,  
11 like we always do, but it was delayed. The  
12 MedImmune FluMist is a LAIV or a live attenuating  
13 influenza virus nasal spray, and it has some  
14 peculiarities in it, logistic requirements  
15 requiring dry ice shipment, special freezers.  
16 It's brand new. And it has a property which was  
17 not recognized by the FDA to be given  
18 concurrently, which required a rather massive  
19 shift in the immunization schedules at the Marine  
20 Corps recruit depots and the Navy. However, the  
21 commanders bought off on this because their public  
22 health people were telling them, and by history,

1 that epidemic diseases in recruit depots is so  
2 severe that they are willing to turn their  
3 schedule completely around to make sure that our  
4 troops, our Marines and sailors, actually get  
5 their vaccines. I mean, many times you run down  
6 commanders on decisions and so forth, but when it  
7 comes to epidemics, they are very responsible.

8 I would like to also say that we've  
9 gotten the information the FluMist, which is now a  
10 cryo-preserved product, has been reformulated and  
11 may only require refrigeration in the future. I  
12 also want to make it clear that there's only two  
13 licensed suppliers for supplying this year. We  
14 are hoping that GSK and Chiron are approved. If  
15 that does not occur, I think that we could see a  
16 significant shortage in vaccines next year, as  
17 Sanofi is only planning on delivering 58 million  
18 to the United States and MedImmune only has a  
19 capability of about 3 million. So we are hoping  
20 that that gets resolved quickly.

21 DR. OSTROFF: Commander, you have about  
22 5 more minutes.

1           COMMANDER LUKE: All right, sir.

2           DR. OSTROFF: We have a few more things  
3 to get through.

4           COMMANDER LUKE: On the PDAK electronic  
5 submission there's a massive desire by the  
6 executive, the legislative, the judicial branch  
7 and the senior military and civilian leaders,  
8 doctors, physicians, patients, interest groups, to  
9 have everything on a computer system which is  
10 truly portable and can transmit information around  
11 the world at a moment's notice.

12           I just want to mention that this is a  
13 particularly -- we want to do this. But we would  
14 like to really advocate for CACS-2 and the TMIP  
15 program, because integrating these type of  
16 electronic systems on our aircraft and our ship  
17 platforms is not essentially easy. We have a  
18 stopgap measure for a Microsoft Access data system  
19 that we've developed. But we are hoping in the  
20 future that we can adopt this capability.

21           I just wanted to mention that there were  
22 two rather significant incidents of recruit

1 tuberculosis, both at the recruit depot in Parris  
2 Island and at Great Lakes. The specifics are not  
3 as important as the fact that the commanders of  
4 those bases, who really are required to move these  
5 recruits out into their A schools and out in the  
6 operational fields, recognize the danger of  
7 drug-resistant tuberculosis and just normal  
8 tuberculosis. We are willing to really hold  
9 hundreds of recruits on station until we are  
10 allowed the medical personnel to test them and  
11 identify an appropriate course of prophylactic  
12 therapy for them. So the message is getting  
13 through to our line commanders and they will  
14 listen if they are properly instructed.

15 Then the Navy is attempting to integrate  
16 an annual health risk assessment, a one-stop  
17 program, attempting on an annual basis to bring  
18 people in on their birthday to make sure that  
19 their personal risk evaluation and counseling is  
20 done, they have appropriate screening exams based  
21 on evidence that their dental immunizations and  
22 special referrals are taken care of and that they

1 actually have a visit with their provider. This  
2 is a rather aggressive approach. We're making  
3 headway on that. In some areas that they have  
4 done this, we have found that it is highly  
5 efficient and it is enjoyed by both the patient,  
6 but also the line commander, because this used to  
7 take four or five visits during the year to become  
8 accomplished.

9 Now, we are also bringing in the  
10 clinical epidemiology, and the preventive medical  
11 subspecialty now is being handled by industrial  
12 hygienists, nurses and so forth. This is going to  
13 place an additional demand on the prep-medical  
14 specialty for the Navy. We're currently about 66  
15 percent of our authorized strength. But  
16 individuals like Paul Roxwell, who you probably  
17 know, is going to be pushing clinical epidemiology  
18 at the NTFs rather hard in the coming years. We  
19 are very excited about the opportunities that that  
20 might present.

21 The last thing I want to say is that we  
22 have been working on the issues of Guillain-Barre.

1 Paul Roxwell has basically gathered some data. We  
2 are not prepared to really say too much about it,  
3 except there seems to be a slight trend, slightly  
4 increasing trend in Guillain-Barre rates. This is  
5 the crude data. Various reasons have been  
6 presented and so forth, but one of the strongest  
7 is the loss of the adenovirus vaccine. It looks  
8 like something that needs to be explored, because  
9 the cases seem to be trending upward after that  
10 vaccine was pulled from use.

11 Thank you very much, ladies and  
12 gentlemen. I'd be happy to answer any questions  
13 that you have.

14 DR. OSTROFF: Thanks very much. Let me  
15 open it up to questions and comments. I certainly  
16 was aware of the TB situation in Parris Island.  
17 It was part of a much larger problem that we had  
18 identified in the U.S. within the last several  
19 months of a large cohort of Hmong refugees that  
20 were brought into the United States into various  
21 locations, and many of them turned out to have  
22 tuberculosis. It wasn't recognized at the time

1 that they were in the camp. A large number of  
2 them had multi-drug-resistant TB, and it has been  
3 an extensive problem. I think that that was the  
4 source of the introduction into Parris Island, if  
5 I'm not mistaken.

6 DR. OSTROFF: Thank you. Any other  
7 comments or questions? Thank you very much,  
8 Commander.

9 SPEAKER: Tom, I have one question on  
10 your GBS.

11 COMMANDER LUKE: These are cases per  
12 100,000 recruits. That data is coming out of a  
13 variety of sources. And no, we are not at all  
14 sure that it's only recruits on that. So that's  
15 basically data which is taken from a variety of  
16 sources. So if you are getting data from Great  
17 Lakes, you have a large recruit population, but  
18 you also have other non-recruits who are also  
19 being provided services by the hospital. So the  
20 problem is going back retrospectively, which is  
21 really just the stuff you pencil drill, and  
22 actually pulling records and so forth is going to

1 take some time. But no, sir, it's not just  
2 recruits.

3 SPEAKER: I'll bring up just one point,  
4 and that is the person-years issue associated with  
5 recruits. Good training is a very short period of  
6 time. If you get to the point in this issue where  
7 you are comparing recruit data to U.S. population  
8 rates of GBS, we need to take that into  
9 consideration.

10 COMMANDER LUKE: Yes, sir. They are  
11 working on it. I'm not saying I understand it  
12 all, but they are putting it together and we hope  
13 to have something which is reportable and  
14 interesting for the Board the next time we come  
15 around.

16 DR. OSTROFF: My one last comment would  
17 be that I certainly appreciate what you were  
18 saying about vector control, and vector control is  
19 certainly an integral part of what we refer to as  
20 integrated test management. But I wouldn't want  
21 to suggest that that would be a substitute for  
22 anti-malarial chemoprophylaxis, because it isn't.

1                   COMMANDER LUKE: Yes, sir. But if you  
2 talk about a lot of the old anti-malarial folks,  
3 particularly from the '50s and '60s, they will  
4 talk about Gorgas in Havana, dealing with Aedes  
5 aegypti and yellow fever, as well as very highly  
6 successful malaria, filarial and other diseases  
7 that were controlled by vector.

8                   So the only point I would make is that  
9 it has to be a combined approach, and you have got  
10 to attack the mosquito as much as you have to  
11 treat the patient as well as prophylax against the  
12 disease.

13                  DR. OSTROFF: Well, you are absolutely  
14 right. I also will point out that at one point  
15 they tried to eradicate malaria, and they realized  
16 that back in the '50s and '60s that it simply  
17 wasn't possible, and mosquito control was the way  
18 they were trying to do that.

19                  DR. OSTROFF: For our next presentation,  
20 I think Colonel Snedecor is going to introduce the  
21 presenter.

22                  COLONEL SNEDECOR: Lieutenant Colonel

1 Snedecor here. Giving the Air Force presentation  
2 will be Major Mel Fotinos. He's the chief of  
3 preventive medicine at the Air Force Academy.  
4 He's going to talk to us about a TB outbreak that  
5 they had there recently.

6 DR. OSTROFF: Welcome. Thank you for  
7 being here.

8 MAJOR FOTINOS: Dr. Ostroff and the  
9 Board, I appreciate the opportunity to come and  
10 talk to you about this. What I'm going to do is  
11 figure out how to use these buttons. But I've  
12 come to kind of tell a story. What I'm going to  
13 try to give to the Board is a story that I was  
14 kind of involved in. Right out of my preventive  
15 medicine residency, I arrived at the Air Force  
16 Academy having been a family physician in my past  
17 life. One of the comments that my residency  
18 director said, "Well, as you know, your outbreak  
19 investigation, you didn't really have any good  
20 opportunities, but don't worry, you will get that  
21 later on." As you will see, I did get into that.

22 My objectives for this talk this

1       afternoon is kind of just summarize the cadet TB  
2       outbreak investigation at the Air Force Academy.  
3       Then what I'm going to do is go into the middle  
4       portion of my story and kind of compare the TB  
5       program that we have compared to a standard Air  
6       Force TB clinic, and then some of the things that  
7       we developed in order to kind of address the  
8       numbers of individuals that we actually brought  
9       into the TB clinic and to give the Board some  
10      ideas that we came up with as far as how, maybe,  
11      we could address this at the AFMS level as well as  
12      the DOD level.

13                 So as I mentioned, I'm going to start  
14      off with the TB outbreak investigation and kind of  
15      go through the active TB case, how we went about  
16      identifying the at-risk individuals, then an  
17      overview of the skin test reaction rates, and then  
18      some of the mandates that came down as far as how  
19      we were to screen the rest of the cadet wing.

20                 Our initial index case was a 20-year-old  
21      male. He was a cadet third class who was a native  
22      of Peru, who in August of 2004 presented the

1 clinic with a 2-week history of productive cough,  
2 weight loss and fever. I should mention that at  
3 this point there was no program in place to screen  
4 for TB for new cadets. This was something that  
5 had been talked about, but at this point there was  
6 no prescreening program. Incidentally, this cadet  
7 had a pneumonia back in October of 2003, and he  
8 was actually hospitalized on the 16th to rule out  
9 active TB. A chest X-ray showed bilateral upper  
10 lobe disease and a cavitary lesion in the left  
11 apex. AFB, sputum, and cultures were sent off,  
12 and he had four plus microbacterium and was in our  
13 hospital for just a little while.

14 At this point, right before I came into  
15 it, the commanders in the cadet clinic got  
16 together with the state health department, and  
17 they came up with a plan as far as how are we  
18 going to identify our at-risk population.

19 The contact period was from July of 2003  
20 to the time when the cadet was actually admitted  
21 to the hospital. As I had mentioned, there was  
22 that episode of pneumonia in October 2003. Just

1 to make things easy, they said let's just pick  
2 this whole timeframe. Personal contacts were  
3 identified through Public Health, through  
4 interviews with the index case to include friends,  
5 roommates, and the sponsor family. Cadets  
6 actually have families who sponsor them, and they  
7 actually go to their house, stay with them, things  
8 of that nature. Close contacts were identified by  
9 the Registrar's Office. These included basic  
10 cadet training, people who were in the squadron,  
11 and global engagement, which is a summer thing  
12 where the cadets go through -- it's a 6-week  
13 program, and these were actually the global  
14 engagement tentmates, the people that he was  
15 actually in the tent with. Other contacts -- this  
16 was based on the Colorado State Health Department  
17 guidelines as far as how do you identify people  
18 who are potential risks for being in a classroom  
19 setting for a specific period of time. Then at  
20 this point, we also included screening of the  
21 international students that may not have fit into  
22 the other categories, just given the potential

1 high risk of the areas they may have come from.

2 First off, I would like to apologize for  
3 this slide. I realized when I made this up that  
4 there are some numbers that are kind of wacky  
5 under the international and subcategories. But  
6 the main intent of these rates is just to kind of  
7 show you, on the left-hand column we have it  
8 broken down as far as the personal contacts, close  
9 contacts, internationals, and the subcategories as  
10 far as no contact and class contact. So there was  
11 obviously international students who were just  
12 screened for being international students. How  
13 the TB tests were placed is they were under the  
14 direction of our allergist/immunologist, so they  
15 were all standardized placement. We had one  
16 physician that read all the positive results.  
17 Those are kind of the numbers. And these rates,  
18 obviously, we picked the denominator, so these are  
19 kind of effected by who we picked. You can see  
20 for the personal, it was .05, the close, .12, and  
21 the international students really kind of raised  
22 the bar. I should mention for those international

1 students who did not have close contact, their  
2 cutoff for their PPD was 10 millimeters, whereas  
3 everyone else was 5 millimeters. And that kind of  
4 really raised the numbers across the board.

5 At this point there's a lot of  
6 discussion saying, well, are you sure that you  
7 caught everybody that potentially could have been  
8 exposed? Our answer, myself as well as Public  
9 Health is, well, we don't know. It's possible.  
10 But there's a likelihood that there may have been  
11 some other chance contact. We just don't know.  
12 So the directive came down, you will screen all  
13 cadets. We kind of fed it back up and said, well,  
14 you do know that we're going to run into a whole  
15 lot of people that potentially may have been  
16 exposed somewhere else. They may have other false  
17 positive reactions. They said, just press  
18 forward.

19 We developed a risk stratification tool.  
20 With the first group, it was pretty much they were  
21 identified as close contacts, so they had a cutoff  
22 of 5 millimeters. But what we did is, we wanted

1 to identify cadets who may have been at higher  
2 risk than just the general population. Just to  
3 kind of review for individuals at lowest risk,  
4 their cutoff for the PPD test is 15 millimeters,  
5 whereas if individuals have certain increased  
6 risks such as health care workers, have worked in  
7 health care settings, homeless shelters, things of  
8 that nature, are residents or recent immigrants to  
9 the United States from areas of high endemic rates  
10 of TB, their cutoff is 10. And then the high risk  
11 group, those goes with close contacts or other  
12 immunocompromised conditions, are 5 millimeters.

13 So that was the screening tool that we  
14 did. Screening was scheduled initially for  
15 November of 2004. We were trying to do this in a  
16 somewhat organized fashion to coordinate with the  
17 influenza vaccine program and also to catch those  
18 individuals during our first screening who may  
19 have been exposed right in August but had not  
20 converted yet. Finally, after all was said and  
21 done, when we were going to have the injectible  
22 flu vaccine and actually went to FluMist, we

1 finally got everyone else screened in the  
2 November-December time frame.

3 At this point, what I'd actually like to  
4 do is just transition into actually the cadet TB  
5 program. I'd like to compare and contrast the  
6 typical Air Force TB program with what we kind  
7 of -- the obstacles that we faced in the cadet  
8 clinic, and then kind of how we adapted to those  
9 opportunities.

10 Typically in an Air Force TB visitor  
11 clinic, once individuals have been identified as  
12 having greater than 5 millimeters of induration,  
13 they are sent to Public Health for initial  
14 screening. At that point, their intake is done.  
15 They have a risk assessment that categorized their  
16 risk. And if they fall into a category where they  
17 are identified as having a positive PPD test,  
18 chest X-rays are obtained as well as initial labs  
19 to include HIV and liver function tests. At that  
20 point they have a follow-up appointment scheduled  
21 with their primary care provider who does the  
22 initial assessment: Reviews their history,

1 addresses everything, and then makes their  
2 recommendations as far as treatment. Once that is  
3 done in the typical place, there's monthly  
4 follow-up visits. Roughly, they are 10 or  
5 15-minute appointments. At that time the  
6 provider, the primary care provider will discuss  
7 medication compliance with the individual, side  
8 effects of the medication, as well as the AST  
9 monitoring as indicated.

10 Then I throw this in, this last bullet  
11 here, this PCM team tracking. It had been in the  
12 past that the public health department would track  
13 these individuals. But a new AFI came out that  
14 said we are going to transition that to the  
15 primary care clinics. So it's the PCM's  
16 responsibility to do this. The PCMs were doing  
17 that anyway, just to track if they didn't hear  
18 back from Public Health as far as saying, hey,  
19 what happened to Airman Snuffy? You lost him for  
20 the last 2 months. But I can tell you that there  
21 was a lot of variance as far as how well people  
22 were being tracked.

1           Now, with our cadet TB population we had  
2 a large influx of latent TB patients. Appointment  
3 demand was much greater than the availability.  
4 There was a lot of concerns as far as compliance  
5 tracking, as far as medications, labs, and then  
6 also, how would we deal with the potential side  
7 effects with cadets as far as also getting them in  
8 for appointments? Now, I should mention also that  
9 this was a public relations nightmare. We  
10 realized quite readily and quite quickly, as  
11 people have read the news about things that go on  
12 at the Air Force Academy, that we needed a very  
13 concerted effort with integration with the state  
14 health department as well as kind of one voice for  
15 TB as far as how we were going to address these  
16 things. So these are some of the things that we  
17 specifically paid attention to.

18           Our index contact group, that first  
19 group that we tested that were at risk, we had 75.  
20 The way that this process worked is, we did a  
21 one-stop shopping. Individuals came in. They had  
22 their PPD placed. 48 hours later it was read.

1 They had screening by Public Health to determine  
2 if they had any other risk factors, chest X-ray,  
3 lab, and the provider evaluation. They were  
4 actually started on medications that day and sent  
5 out. Follow-up visits, initially we were able to  
6 have a walk-in clinic. So we'd have the 75  
7 patients walk in. One day a week I had two Public  
8 Health techs and myself. We would screen these,  
9 and we would actually disperse their I and H and  
10 B-6 directly. We were really happy and kind of  
11 proud of ourselves that we had done this. It was  
12 a nice quick process. There was no wait time. We  
13 actually knew when people were picking up the  
14 medication that they were actually compliant, or  
15 kind of so, we thought.

16 Then we got hit with the next big round  
17 of individuals who tested positive. There are 245  
18 in this group. I should mention that not all of  
19 those -- there's a lot of different factors for  
20 that. As people can imagine, a lot of the cadets  
21 that end up at the Academy have quite significant  
22 travel histories as far as missionary work. A lot

1 of them are dependents of active duty and have  
2 traveled all over the world. So there are a lot  
3 of factors. We've not gotten down into all the  
4 numbers as far as what all those risk factors  
5 were.

6 This process was a little different. We  
7 kind of expected anywhere from about 150 to 300  
8 based on our initial rates of how many people we  
9 would get with latent TB. When they had their  
10 test read, Public Health was there, and we used  
11 this screening risk stratification tool, which is  
12 the one that I mentioned previously to kind of  
13 categorize them, because this was our low-risk  
14 group, so the cutoff was 15 millimeters unless  
15 somebody identified another risk factor. Labs and  
16 chest X-ray were obtained the following week,  
17 because we did not have the capability to have all  
18 this done on the same day. The provider  
19 evaluation took 6 days. We had about 40 cadets  
20 per day that came in, and we did group  
21 appointments to talk to them about what the  
22 condition was they had, what the recommended

1 treatment was, and what to expect on the  
2 medication.

3 At this point we made a decision that we  
4 could not see all these cadets in a regular clinic  
5 visit. It just would not be possible. The  
6 walk-in clinics, we would have had to have done 3  
7 days of that. It was a major disruption to the  
8 clinic. So we sort of came up with a new idea, so  
9 to speak, or what we believed was a new idea, and  
10 we developed a TB treatment questionnaire. From  
11 our previous experience with the first group, we  
12 noticed that during the first month after starting  
13 treatment, we had about a 15 to 20 percent of that  
14 population who came in having very specific  
15 complaints, whether it be upset stomach or  
16 fatigue. The rest of them were all right. They  
17 had no real problems with the medication.

18 So we said, well, let's do a screening  
19 questionnaire. We'll send the screening question  
20 out via e-mail. People will respond to it, and we  
21 will only intervene on those individuals who  
22 actually need specific intervention.

1           This kind of started making us think in  
2           kind of a bigger picture as far as, well, this is  
3           kind of a novel idea. How would this apply or how  
4           does this fit in, not only to our clinic here at  
5           the cadet clinic, knowing full well that this is  
6           probably going to be a short term thing, we'll get  
7           most of these people off medication, but how does  
8           it apply to the Air Force in general, and how does  
9           it apply to the DOD even greater than that?

10           So at this point, the last part, and  
11           this is part of the story that's not completed  
12           yet. The part that I throw out to the Board here  
13           is, why is a TB registry important? Then just to  
14           focus a little bit on the obstacles of TB  
15           management, the objectives of a TB registry, and  
16           the components of this registry.

17           As everyone is very aware, there's an  
18           increased deployment tempo. We have a significant  
19           number of troops in areas across the globe, and  
20           these are in areas where there are high risk  
21           regions, okay? There is also an increased contact  
22           with the indigent population, and due to a

1 smarter, more fit force, we are actually using a  
2 lot of indigent resources to support our troops in  
3 those areas. So there's increased contact with  
4 those populations.

5 Also, as we know, there's much greater  
6 utilization of Reserve units. One of the things  
7 that we've seen in other presentations is that  
8 oftentimes when an individual is exposed, they are  
9 on active duty, we do what's right for them, but  
10 sometimes we lose things when they go back to  
11 their Reserve status. So these are some of the  
12 things that we thought were very important in  
13 developing or thinking about a disease registry  
14 for tuberculosis.

15 Now, this is a slide that was estimated  
16 TB rates developed by the World Health  
17 Organization. I just wanted to bring it out to  
18 kind of show you the relative rates of where  
19 things are.

20 On the far left there is the United  
21 States of America -- very low. You can see the  
22 cadet who is a native of Peru, about 182 per

1 100,000. You can kind of just see some of the  
2 areas where we have been as far as what are the  
3 incidences of TB. I bring this up because we have  
4 large substantial amounts of forces in these  
5 areas, and so we can kind of see where their  
6 exposures are.

7           Some of the things that I learned  
8 personally during this experience is that there's  
9 some definite obstacles that come up in treating  
10 patients. As a family physician, I used to deal  
11 with ones and two of individuals who came in for  
12 latent tuberculosis. But having had 320 now,  
13 there's some very clear things that I have been  
14 able to identify and what I've described as  
15 patient-centered obstacles. Those  
16 patient-centered obstacles are very specific.  
17 Cadets would come to me and say, okay, fine. Who  
18 was it that I got this from? Why didn't you  
19 screen this person? Why weren't you guys  
20 protecting me? Why were you letting this person  
21 run around for this long? What is the condition I  
22 have?

1           It was amazing. We sent out numerous  
2       publications, numerous outreach education  
3       materials to say this is what TB is; you are not  
4       contagious. I kept coming back with the same kind  
5       of questions as far as saying, can I spread this  
6       to somebody through kissing, this, that or the  
7       other. Where did I get this? This was very  
8       important. Some people had very good immunization  
9       records, and we were able to kind of plot  
10      potentially when you may have been exposed, but  
11      once again, that's not an exact science. Then,  
12      why do I need to get treated? So we spent an  
13      awful lot of time about that.

14           The other thing that I recognized and  
15      realized is that individuals did much better when  
16      they knew the side effects of the medication. The  
17      first group we learned a lot from. The second  
18      group, we spent a whole lot of time on saying,  
19      these are the side effects that you will  
20      experience. The cadet population is unique in  
21      their fatigue ratio, as many of the other  
22      academies. So they are always fatigued. About 20

1 percent of our population was excessively fatigued  
2 on the I and H. We just had to say stick in  
3 there, stick in there. By the end of the second  
4 month, it's down to about 10 percent. Only less  
5 than 5 percent have fatigue after about 3 months.  
6 So those were some of the patient-centered  
7 obstacles.

8 The system-based obstacles, treatment  
9 standardization. Once we started doing this I  
10 started hearing all these anecdotal stories from  
11 other people in the hospital saying how their  
12 provider had treated them when they had their  
13 positive TB test. So there was variance as far as  
14 that.

15 Appointment access and availability. As  
16 we know, if you identify somebody with latent TB  
17 and it takes them 3 or 4 weeks to get in with  
18 their primary care provider, they perceive that as  
19 well, this isn't that big of a deal, so why am I  
20 even concerned about it?

21 Tracking and monitoring. As I  
22 mentioned, the Air Force 48105 has actually

1 changed to where Public Health primarily used to  
2 be the tracking responsible. That's now back on  
3 the PCM. So PCMs across all the various bases,  
4 across all the various places, will be doing their  
5 own tracking for patient compliance, medication  
6 side effects.

7 Then also one of the things is  
8 portability. If somebody leaves the Air Force  
9 Academy and goes to Patrick Air Force Base or  
10 somewhere else, how do we ensure that they are  
11 actually monitored and tracked appropriately?

12 So we kind of came up with some  
13 objectives as far as what we thought a TB registry  
14 should be able to do. One of the things based on  
15 the patient objective is standardized screening  
16 and management -- the same message to the same  
17 person as far as this is what you have, this is  
18 the condition, here is the treatment management.  
19 It's not what the Air Force -- this is what the  
20 Centers for Disease Control recommends in your  
21 case.

22 Automatic tracking and notification.

1 Our idea and vision would be that the system would  
2 automatically send out e-mail reminders to  
3 individuals. You need to fill out this survey.  
4 If they didn't fill out the survey, they would get  
5 another reminder to go and tell them, you need to  
6 fill this out. The system would actually monitor  
7 their responses on these surveys and update the  
8 providers as to what was going on with the  
9 individual.

10 I throw in this next bullet: Reduce  
11 appointment utilization. One of the things that  
12 we noticed is right now this program works fairly  
13 well, so I'm not in clinic taking care of this. I  
14 get no credit for doing this. There's no sort of  
15 little bean counts that I can get that says hey,  
16 this is how many individuals I've seen this month,  
17 because in effect we are keeping them all out of  
18 the clinic.

19 As it shows there, the first month  
20 there's about a 20 percent clinic visits where  
21 people actually have side effects from the  
22 medications. The second and third month it drops

1 down to about 5 percent, and after that it's  
2 pretty much negligible. We just did a quick  
3 little calculation as far as every visit was about  
4 \$40. Going along these numbers, for about every  
5 100 patients, you would save about \$50,000.  
6 That's just in direct clinic costs. That's not  
7 indirect costs due to the individuals having to  
8 get out of work, waiting for appointments, this,  
9 that or the other.

10 The other benefits, we think, of a TB  
11 registry would be a data warehouse, that we would  
12 be able to get real-time information as far as  
13 what are the side effect rates for medications?  
14 What are the demographics that would maybe help us  
15 figure out who is more compliant or less compliant  
16 with their medication?

17 Then the other issue is portability. If  
18 somebody was able to log into this system and then  
19 have a history as far as when was the patient  
20 diagnosed, what was their lab tests, what was  
21 their treatment regimens, do they have any  
22 problems, that would go a long way to helping take

1 care of our patients.

2           So the last slide before we go into  
3 questions is what would the components of this TB  
4 registry be? These are just ideas that we came up  
5 with. This is not the absolute or the end-all.  
6 But it would be a web-based application that we  
7 would be able to log into from various locations  
8 or bases. It would have an integrated platform  
9 that would incorporate DEERS data, CHCS2. It  
10 would also have the ability to have desktop data  
11 entry and retrieval. So instead of having a paper  
12 trail when you did your screening processes, you  
13 would just put it into the system and it would  
14 track that. The e-mail notification alert system.  
15 E-mails would automatically be sent out. The  
16 system would track when people were compliant or  
17 not compliant. Then what would happen is that if  
18 people were not compliant or there was hot items  
19 to do, it would come up to a queue for the primary  
20 care manager, whoever was managing, to say you  
21 need to intervene on X, Y, or Z.

22           Then also the longitudinal tracking and

1 portability. If anyone has seen the Air Force  
2 forms for tuberculosis tracking, they are quite  
3 varied across bases. They follow the AFI, but  
4 they don't look alike from base to base. That  
5 leads to the standardized documentation of latent  
6 TB.

7 Then the last thing we thought is, well,  
8 if you build the system and you build it right,  
9 you can put other diseases in there. So it's kind  
10 of, how do you build a framework for it?

11 So in closing, that's kind of what  
12 happened at the Air Force Academy, the obstacles  
13 that we ran into, and some of the thoughts that we  
14 had that we wanted just to bring to the committee  
15 here.

16 DR. OSTROFF: Major Fotinos, thank you  
17 very much. Let me open it up for comments and  
18 questions.

19 This brings back a lot of memories for  
20 me, because I think my first recommendation that I  
21 actually wrote as a member of the Board had to do  
22 with TB screening. Subsequent to that, I have

1 also written the recommendations regarding what  
2 might have been very useful to you in this  
3 particular situation, which is the QuantiFERON  
4 assay, because we know from lots and lots of  
5 experience that doing tuberculin skin testing in a  
6 circumstance like this, even though you had an  
7 individual with active tuberculosis, but once you  
8 start markedly expanding your screening into very  
9 low risk populations, the predictive value and all  
10 of the characteristics, the sensitivity and the  
11 specificity of that test are not very good.

12 So my presumption is that you were  
13 markedly, and I use the term "markedly" not  
14 lightly, but markedly overtreating. I used to go  
15 and do 2 weeks of clinical time at various Air  
16 Force bases in Europe. The first place that I was  
17 sent by then at the time Colonel Taylor, now  
18 Surgeon General Taylor, was to Izmir, Turkey,  
19 because of a scenario that was almost precisely  
20 like this: An individual that was diagnosed with  
21 active tuberculosis and then they had a screening  
22 program that absolutely ran amok. And by the time

1 I got there they had TB Tuesday, which was the day  
2 when they ran the TB prophylaxis clinic. There  
3 were just literally hundreds of people that were  
4 on TB chemoprophylaxis who just didn't need to be  
5 on TB chemoprophylaxis. He had asked me to go  
6 there and try to bring some sanity to that  
7 situation.

8           So it strikes me that maybe we haven't  
9 potentially progressed all that far. I wasn't  
10 there, so I don't know all of the details and the  
11 circumstances and how you got into the situation  
12 you got into. But when I got there I had to do  
13 mass discussions with all of the personnel  
14 assigned there, because there was such public  
15 relations difficulties in trying to make them  
16 understand exactly what was going on that by that  
17 point, I mean, everything was literally out of the  
18 box.

19           So whether this was the right thing to  
20 do or the wrong thing to do is beyond my ability  
21 to comment. But it's clearly another reason why  
22 in the screening programs in the military services

1 at some point, we have to move to this other  
2 assay, because its performance characteristics are  
3 so utterly better than tuberculin skin testing  
4 that you would have decreased the number of people  
5 that needed to be on prophylaxis probably by  
6 two-thirds.

7           COMMANDER LUKE: That's an excellent  
8 point, sir. We actually brought that up with the  
9 second screening to the command and said, we are  
10 now in an uncharted area because this is going to  
11 be a very low risk. We tried to identify people  
12 who were at higher risk to the screening thing.  
13 That was our initial recommendation. They said,  
14 no, you will place and read on every single cadet.

15           For what we are trying to do for next  
16 year, because this will be implemented, TB  
17 screening will be, is we will do the screening  
18 tool. We are actually trying to actively pursue  
19 the QuantiFERON. However, there are some  
20 logistical hurdles that we need to overcome to  
21 actually do that.

22           It doesn't look promising that we'll be

1 able to do it this next year, but possibly the  
2 year after.

3 DR. OSTROFF: Well, all I can say is  
4 that I would strongly urge, if you are going to be  
5 doing this type of tuberculosis screening, that  
6 you move to that test, or else you are setting  
7 yourself up for prophylaxing lots of people who  
8 just don't need to be prophylaxed. I mean,  
9 there's absolutely no question about it.

10 Are there other questions or comments?

11 SPEAKER: I have a question. Were there  
12 any additional cases of active TB besides the  
13 index?

14 COMMANDER LUKE: No, sir. There were no  
15 other active cases of TB.

16 DR. OSTROFF: It's 3 o'clock on the  
17 nose. I really appreciate your being here. That  
18 was a great presentation, and all of the things  
19 that you are discussing in terms of the registry  
20 are absolutely correct. I'll also point out that  
21 for lots of other circumstances like childhood  
22 immunizations, et cetera, this is the way to go

1 with these types of electronic registries and  
2 reminders and all the other things that you are  
3 doing. So you are absolutely correct that if you  
4 are going to set it up, just don't set it up for  
5 tuberculosis prophylaxis. There's lots of other  
6 things like diabetes and high blood pressure, et  
7 cetera, that this is an absolutely ideal system  
8 for.

9 Why don't we take a 5-minute break and  
10 let's come back and have the last presentation,  
11 which will be a repeat performance by Colonel  
12 Ruscio.

13 (Break)

14 COLONEL RUSCIO: Thank you, Dr. Ostroff.  
15 I'm actually here giving this presentation on  
16 behalf of Air Force Space Command, who asked that  
17 I present this to the AFEB to close the loop on a  
18 25-year-old issue.

19 The recommendations that AFEB provided  
20 actually have passed that we close this loop with  
21 the commanding --

22 DR. OSTROFF: I guess this is your

1 silver anniversary presentation.

2 COLONEL RUSCIO: Yes, sir. In February  
3 2002, the Air Force Space Command, through the  
4 Surgeon General, asked the AFEB to help out with  
5 an issue and provide recommendations and  
6 directions on an approach that the Air Force Space  
7 Command and the Air Force was taking in addressing  
8 community's concerns related to a PAVE PAWS radar  
9 site.

10 We asked specifically that the AFEB take  
11 a look at our occupational health standards,  
12 specifically look at the proposed plan that we had  
13 to address the community's concern and evaluate  
14 from an epidemiological perspective some of the  
15 issues that were of concern with the community and  
16 help us work with them in addressing those issues.

17 So real quickly, PAVE PAWS, for those of  
18 you who don't know, it's a land-based radar  
19 system. It's a phased array warning system. We  
20 use it to detect and track sea-launched  
21 intercontinental ballistic missiles. It is also  
22 used extensively for the space program, helping

1 guide and keep junk, for example, from flying into  
2 the shuttle and being somewhat of a police officer  
3 for some of those space issues.

4           They are Air Force Base Command  
5 resources. One exists in Cape Cod, one in Beale,  
6 one in Clear, Alaska. I'm sorry I neglected that  
7 there are two overseas, one in the U.K. and one in  
8 Iceland. They are all similarly designed. These  
9 are phased array technology. What that basically  
10 means is that the system is steered  
11 electronically. So instead of having the  
12 parabolic radar turn, you can direct this radar  
13 through electronic signals.

14           It's an imposing building. It's 100  
15 feet high. If you climb up on top of the one in  
16 Cape Cod, you can actually see Provincetown, the  
17 tower. So that's all the way out on Cape Cod, for  
18 those of you not familiar with it. There are two  
19 array faces, and there are a couple thousand  
20 elements. Each element is an individual radar, an  
21 individual emitter. Those working together in  
22 unison with some sophisticated computer stuff that

1 I have no idea about can electronically steer this  
2 system.

3 Quickly, on the history, the first of  
4 its type was in 1978. It was activated in 1979,  
5 so there is a 25-year history to this and to the  
6 concern.

7 Basically what you will see is, the  
8 radar system, 99 percent of the energy is out in  
9 the main beam. The main beam does a tracking  
10 fence looking out thousands of miles for missiles  
11 potentially coming up, breaking that fence line.  
12 Then it intermittently projects out into space.  
13 It does this at the nanosecond and less level to  
14 complete its mission.

15 A schematic of Cape Cod, this is where  
16 the facility exists. It's on the upper cape. It  
17 has about a 240-degree angle of coverage. That  
18 line going up there goes about up through Boston  
19 and the eastern coast of the U.S. and then south.  
20 You see the coverage on the bottom line.

21 Well, 99 percent of the energy, the  
22 power, goes out in the main beam. There are side

1 lobes that fall off and energy in those side lobes  
2 do touch the ground. You can measure the energy  
3 at the ground level.

4 To give you an idea where we are at as  
5 far as electromagnetic spectrum, I'll let you go  
6 ahead and take a look at that. The 420 to 450  
7 megahertz range, the facility does operate within  
8 that range, not specifically 420 or 450. The  
9 Board is familiar with the ADS system recently,  
10 which is way down -- or higher, but much higher  
11 than the civilian military radar system, just to  
12 give you a perspective on where you are at.

13 In the cell phone, the communication  
14 base stations, I think for the most part they have  
15 moved out of the 820, the 890 range and are up in  
16 the 1800 to 2000 megahertz range. I think the  
17 other point to identify is that increasingly, the  
18 wireless communications, Verizons and whatnot, any  
19 company, but they are moving towards a phased ray  
20 system on their repeater stations. So it's  
21 becoming a more common technology being used.  
22 It's efficient.

1           So in 1978, the Cape Cod community  
2           objected to the radar on the basis of a threat to  
3           public health. So did Beale. This was while the  
4           facility was being constructed. They were  
5           successful in getting a court order to stop  
6           construction, both, again, Beale and the community  
7           at Cape Cod. Things were worked out at that time  
8           to where the system was able to continue to be  
9           constructed and operate. It began operations in  
10          1979.

11           The Air Force engaged the National  
12          Research Council. The council made some  
13          recommendations as far as PAVE PAWS. They are up  
14          there for you to read. They did recommend that  
15          the Air Force continue on with some specific  
16          research related to the PAVE PAWS frequency range.

17           The Air Force did do that over the 15 or  
18          20 years. They spent about 40 million in a  
19          variety of studies looking at different aspects of  
20          this frequency and electromagnetic spectrum on a  
21          variety of biological potential adverse health  
22          outcomes.

1           Those studies, all the studies,  
2           indicated there was not a mechanism for adverse  
3           biological effects at the power levels that were  
4           below the levels that would heat at the cellular  
5           level. So the conclusion was that the heating  
6           mechanism is where you have your adverse health  
7           outcome.

8           Just for a quick summary, human  
9           permissible exposure, the levels, this is how the  
10          IEEE and other organizations address exposures to  
11          electromagnetic frequency and energy for the PAVE  
12          PAWS frequency range. It changes throughout the  
13          electromagnetic spectrum. But at this range we  
14          are looking at .28 milliwatts per centimeter  
15          squared. The early studies after the facility is  
16          up and operational -- '78, '79, and there was  
17          another measurement made in '86 at the community  
18          level -- identified levels 5,000 to 20,000 times  
19          below the permissible exposure levels. These were  
20          measurements made out in the community.

21                 This is just a graphic of some simple,  
22                 average power densities. Average power densities

1 are usually measured as far as evaluating  
2 exposures. You can also do peak power ranges.  
3 But to look at exposures, the standard is  
4 accomplished.

5 The issue really didn't go away in 1978.  
6 If you have an opportunity to read "The Zapping of  
7 America" and some other publications that are out  
8 there, you will find this facility is referenced  
9 in those. Then in 1998, the issue came about  
10 again in somewhat full force, I would suggest.  
11 There are allegations that the radar had a unique  
12 exposure that presented a health concern below the  
13 IEEE or the permissible exposure standard; that  
14 there were health implications by the unique  
15 characterization of the wave that's projected, and  
16 that the Air Force had secret, classified evidence  
17 indicating that this be the case.

18 These are some captured signals at the  
19 nanosecond level. I'm not going to even attempt  
20 to explain them to you, because I don't know. But  
21 what I do know is that they are images of the  
22 beginning of the wave and the end of the wave.

1 The position was that these beginning and ending  
2 wave frequencies and the way they are generated  
3 presented particular health problems for an  
4 individual.

5 Real quickly, the Cape Cod community is  
6 a complex community, I imagine like most are. In  
7 one aspect, it's a very healthy community. It's a  
8 very robust community. They do have some issues  
9 that have been identified, elevated cancer  
10 incidences for certain cancers. These are in  
11 relation to the state. You will probably  
12 recognize those as also the five top cancers in  
13 the U.S. So there are some concerns among the  
14 community members and have been some concerns from  
15 the community members about this radar  
16 contributing to those elevated rates.

17 It quickly elevated in 1998 and through  
18 2003, actually to be a very public concern.  
19 Articles in the Boston Globe, the Wall Street  
20 Journal, the Cape Cod Times were pretty much on a  
21 weekly basis. I just captured a couple of them.  
22 So it was a very public concerned issue.

1           One of the things that we did, the Air  
2 Force and others, was to partner quickly with the  
3 PAVE PAWS public health steering group. The PAVE  
4 PAWS public health steering group is a group  
5 formed by the local public health officers on Cape  
6 Cod. There are 11 communities, 11 towns,  
7 Sandwich, Bourne, Falmouth and whatnot. In  
8 Massachusetts, they each have a public health  
9 officer. On the Cape, it is fortunate they have a  
10 very talented group of public health officers.  
11 You may be aware you have Woods Hole there. It's  
12 an area where individuals can retire. So there  
13 are very talented individuals that retired there  
14 and took up some public service. These  
15 individuals formed a PAVE PAWS public health  
16 steering group and then worked with a variety of  
17 organizations outside to help address the  
18 community's concerns. The Armed Forces EPI Board  
19 Subcommittee made presentations to the PAVE PAWS  
20 public health steering group and worked very  
21 closely and helped considerably.

22           I should have another circle in here,

1 actually an international circle. After this got  
2 momentum and started moving we had questions from  
3 the U.K., the U.K. military, the U.K. local  
4 community via the internet; also from the west  
5 coast and the other locations where there are  
6 these radar sites. A lesson learned is that while  
7 it's all local, it's also all international very  
8 quickly.

9 In 1999 the Massachusetts Department of  
10 Public Health provided an independent scientific  
11 panel indicating -- their conclusions are up  
12 there. We had a presentation yesterday on the  
13 perception of ethics. There was a perception of  
14 ethics on -- a member of this Board actually went  
15 to the State ethics board. I think the important  
16 point is that the community perception, regardless  
17 of whether that was fact, and it wasn't, the  
18 community's perception of ethic issues essentially  
19 rendered this effort not useful for the community  
20 to draw a conclusion from, in their eyes, in their  
21 perspective.

22 In 2002, we asked the AFEB the questions

1 that I mentioned at the beginning of the  
2 presentation. You concluded that there's no  
3 evidence to suggest a cause and effect  
4 relationship between the elevated standard rate  
5 ratios of disease and the PAVE PAWS radar.

6 You also asked to have feedback when the  
7 National Research Committee completed its effort,  
8 and the NRC took 2 years to complete an effort.  
9 Essentially their conclusion on the health aspect  
10 is that bottom bullet there.

11 A little bit more detailed on the  
12 National Academy's report. It's a 247-page  
13 report. I do have it on PDF file. I can get it  
14 to Colonel Gibson if the committee members would  
15 like to read it. Actually, I found it  
16 entertaining reading. They went through the  
17 complete aspect of the signals, the concern with  
18 the unique propagation of the wave and biological  
19 mechanisms related to that. From a public health  
20 perspective, the bullets are up there. I'll let  
21 you take a look at them.

22 The NRC also was clear to address the

1 community's concern with the precautionary  
2 principle and made presentations all during their  
3 effort in educating the community and providing  
4 information to the community. They were involved  
5 all the way through the process, very intimately.

6 A couple more recommendations from an  
7 epidemiological perspective: The Air Force had  
8 been asked, the Air Force Space Command and the  
9 Massachusetts Department of Public Health, to  
10 implement some very extensive epidemiological  
11 evaluations, considerations of everything from a  
12 Framingham heart type of longitudinal study to  
13 some extensive case control cohort, a variety of  
14 recommendations from the community.

15 A recommendation from the NRC similar to  
16 the AFEB's, among others, is making sure you  
17 looked at adverse health outcomes where you had  
18 the power to evaluate it, consider biological  
19 mechanisms, things that were familiar dealing with  
20 the Hills postulate, Cox postulate. We're not  
21 finished yet. It's almost wrapped up, actually.

22 The NRC report has gone to the PAVE PAWS

1 Public Health Steering Group, as have the AFEB  
2 recommendations. This information is all fed into  
3 the local public health departments, and they are  
4 going to coalesce that, combine it, and provide  
5 kind of a final report. They are going to  
6 communicate to their community the issues related  
7 to the risks from this radar. They are in the  
8 process of putting that package together for the  
9 community. They were very appreciative of the  
10 AFEB's involvement and helping out.

11 Sir, that's it unless you have some  
12 questions.

13 DR. OSTROFF: Thank you very much,  
14 Colonel Ruscio.

15 I think I am the only one currently in  
16 the room that was part of the group that came up  
17 to visit -- I think that was in early 2003, if I'm  
18 not mistaken -- and meet with the community board.  
19 Fortunately, it was a beautiful day in  
20 Massachusetts. We all have very fond memories of  
21 standing on the top of this facility looking out  
22 over Martha's Vineyard. I think we could even see

1 clear towards Nantucket, if I'm not mistaken.

2 My recollection, I mean, there were a  
3 number of things that fed into this for those who  
4 weren't there. One of them is the relative  
5 paucity of good data, incidence data in terms of  
6 cancer incidents prior to when this facility was  
7 actually constructed, because there were many  
8 reasons to think that the variety of environmental  
9 hazards that were present in the area well  
10 predated the existence of this particular  
11 facility.

12 I think the other thing, and there has  
13 been a recurrent theme through many of the  
14 presentations that we have had over the last day  
15 or two, that there was a single individual who, I  
16 think, went a long way towards building this level  
17 of concern in the community with this theory that  
18 there was some alternative mechanism that might be  
19 operative here in terms of wave theory and all  
20 kinds of things that I don't really quite  
21 understand.

22 My presumption is that this individual

1 has not totally left the picture, just because  
2 everyone may be concluding that there's little  
3 basis for any of the potential health impacts that  
4 have been advanced. So I'm wondering how one  
5 intends to deal with those particular problems.  
6 As I think was stated, you can do studies ad  
7 infinitum and continue to expend large amounts of  
8 money to do these various studies.

9 I do think that what was done here  
10 particularly with the steering committee was  
11 brilliant. I think it really did go a very long  
12 way to turning around what was a very difficult  
13 situation.

14 Do you think that there truly is an end  
15 in sight for the various reasons that I expressed?

16 COLONEL RUSCIO: The short answer is  
17 yes. As far as the individual, he continues with  
18 particular efforts to discredit a lot of the work  
19 that has been done. I still receive a  
20 considerable amount of feedback from the  
21 community, community members there, because I  
22 spent a lot of time there.

1           Sir, I think one measure is that  
2 initially in '99 and 2000 time frames, we would  
3 have public meetings where several hundred  
4 individuals would show up expressing concerns  
5 throughout the community. At the last meeting  
6 there were two individuals that showed up. The  
7 other measure is the editorial that you see in the  
8 paper and the feedback that you get from the  
9 community.

10           I believe that the audience that we are  
11 shooting for is the 85 percent, and they are  
12 convinced.

13           DR. OSTROFF: The tide has turned, being  
14 that this is on the Cape. But again the tide  
15 rolls in and out and it could always roll back in  
16 again.

17           One or two quick comments or questions,  
18 and then I think we are going to have to wrap up,  
19 because Dr. Poland is going to have to run to the  
20 airport.

21           DR. BROWN: I'll try and be brief. We  
22 were talking just before you began your very

1       excellent talk about your thoughts about how you  
2       have been able to turn this around through these  
3       different techniques. It struck me as a very  
4       amazing story.

5               My own experience is when you get a  
6       community up in arms, whether it's a national  
7       community like a certain group of veterans or a  
8       local community about an environmental health  
9       issue, it's very difficult sometimes to turn it  
10      around and overcome the mistrust of government  
11      agencies, whether it DOD or VA, my own agency or  
12      some other agency.

13             You mentioned using this Board to write  
14      a report on the science. You mentioned using the  
15      NRC. You talked about having community meetings  
16      and other efforts that you use to try and respond  
17      to these concerns.

18             What in your opinion was the most useful  
19      thing that you did? We'll assume that the AFEB  
20      report was the most useful. What was the second  
21      most useful thing? If you were going to give a  
22      recommendation to someone else who was facing an

1 issue like this, what do you think was critical to  
2 making this work out?

3 DR. OSTROFF: I'll interrupt by saying  
4 it was him being there for the community. That, I  
5 think, was brilliant.

6 COLONEL RUSCIO: I think from a systems  
7 level, I'd suggest that being honest, getting  
8 information out early, getting it out consistently  
9 and showing up at the meetings. I'll tell you the  
10 truth, there were some meetings there that I  
11 didn't want to show up at early on. They were  
12 very difficult. But I think persistence. Then  
13 bringing in the outside experts and working with  
14 the community.

15 DR. BROWN: And you showed up in uniform  
16 so you were identified?

17 COLONEL RUSCIO: I did.

18 DR. SAVITZ: I think everybody should be  
19 aware that to the extent that this is a diffused  
20 problem, a lot of the credit goes to you.

21 In fact, Bruce had been with us for many  
22 years. He gained the trust of the community. As

1 he said, you were very proactive, very  
2 straightforward and honest. I got an opportunity  
3 to watch him interact with the Steering Group and  
4 other members of the community, and clearly they  
5 had his trust.

6 So I think a lot of the credit should go  
7 to you, because it never was really valid  
8 scientific problem. It was more a political,  
9 personal type issue which the airports chose  
10 wisely in having you be their representative.

11 COLONEL RUSCIO: Well, thanks. I think  
12 it was a group effort and I appreciate that.

13 DR. OSTROFF: Last comment, Dr. Haywood.

14 DR. HAYWOOD: One of the substantive  
15 complaints that they had was the incidence of  
16 malignancies was significantly increased as a  
17 result of the increased exposure. So showing that  
18 there was no relative increase compared to  
19 comparable communities in the same area, I think  
20 that the major step forward discounted their  
21 claim.

22 COLONEL RUSCIO: Absolutely.

1 DR. OSTROFF: This is really an amazing  
2 story. Before I take the opportunity to turn the  
3 gavel over to Greg Poland, I would like to  
4 acknowledge everybody who worked so hard to put  
5 this meeting together, particularly one of the  
6 unsung heroes who very generously gave of her time  
7 on a voluntary basis. That happens to be Roger's  
8 wife. So I really would like to acknowledge all  
9 of the assistance that Sue made.

10 (Applause)

11 DR. OSTROFF: As my last official act,  
12 I'll make you an honorary friend of the AFEB. So  
13 I'm not going to say anything else. I'm just  
14 going to turn the gavel over to Dr. Poland to  
15 bring the meeting to a close.

16 DR. POLAND: I'm going to cut my  
17 comments mercifully short, because the cab's  
18 waiting for me. I'd just make a comment about the  
19 legacy that Steve leaves us. I've watched Steve  
20 closely over these years, and I've discovered his  
21 secret for success, which I'll attempt to emulate.  
22 It's a time-tested formula. It goes like this.

1 The top people do what's expected of them and then  
2 some. They are thoughtful and considerate of  
3 others and then some. They meet their obligations  
4 and responsibilities fairly and squarely and then  
5 some. They can be counted on and then some. They  
6 do what's right regardless of the cost and then  
7 some.

8 When it's late at night and work needs  
9 to be completed, they do it and then some. When  
10 that extra push is needed, they do it and then  
11 some. When they get asked to do more than their  
12 fair share of work, they do it and then some.

13 So thank you, Steve, for what you've  
14 done. I hope that however life rewards you, that  
15 you get the best and then some.

16 (Applause)

17 (Whereupon, at 3:40 p.m., the  
18 CONFERENCE was adjourned.)

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