

UNITED STATES OF AMERICA {PRIVATE }

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ARMED FORCES EPIDEMIOLOGICAL BOARD

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MEETING

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TUESDAY,

FEBRUARY 19, 2002

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SAN DIEGO, CALIFORNIA

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The Board met at the Island Club, North Island Naval Air Station, San Diego, California, at 7:24 a.m., Dr. Stephen Ostroff, presiding.

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

(7:21 a.m.)

DR. OSTROFF: Let me call the meeting to order.

Let me begin by introducing Ms. Ellen Embrey, who was recently appointed the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness in Dr. Winkenwerder's office. As the designated federal official, she has the honor of calling the meeting to order.

MS. EMBREY: Thank you, Dr. Ostroff. The formal beginning of the meeting as the designated federal official for the Armed Forces Epidemiological Board, federal advisory committee, Secretary of Defense, which serves as a continuing scientific advisory body to the Secretary of Defense for Health and the surgeons general of the military departments, I hereby call the winter 2002 meeting to order.

I am pleased to see such a large turnout today for this meeting. I think that this reflects both the importance of the AFEB, Department of Defense and interesting topics that are on the meeting agenda.

Captain Luz, please accept my appreciation for your willingness to host and provide the outstanding support for this today and tomorrow.

DR. OSTROFF: Thank you very much. On behalf of the board, let me welcome everybody. We certainly look forward to working with you and with Dr. Winkenwerder. Certainly I can

1 speak for all of the board members in my tenure as the board  
2 president.

3 In comparison to many of our recent meetings, we  
4 have a very robust agenda, to say the least. There are a large  
5 number of issues that we have before us.

6 Let me just begin by thanking Captain Luz and the  
7 Naval Health Research Center staff for hosting the meeting of the  
8 AFEB. I realize how difficult it is to put on a meeting of this  
9 size, and we certainly appreciate it.

10 Let me just take a minute or two and just say the  
11 last time that we met in September, we knew that a lot was going  
12 to happen even at that time. That was the week after September  
13 11th. I think all of us were very pleased and proud to be able  
14 to at least contribute in some small way. I think, speaking at  
15 least for myself and, I'm sure, for all of the board members, we  
16 certainly are very proud of what's been achieved during that  
17 interim time period.

18 In addition to what's been going on with our  
19 forces overseas, another thing that we're very pleased about is  
20 that Dr. Winkenwerder was nominated to be the Assistant Secretary  
21 of Defense for Health Affairs. He was nominated on September  
22 21st, I think, just after the last board meeting and was  
23 confirmed by the senate on October the 16th. His CV and bio are  
24 in the briefing books. He's responsible for overall supervision  
25 of the health and medical affairs of the Department of Defense

1 and serves as the principal staff assistant and advisor to the  
2 Secretary of Defense for all DOD health policies, programs and  
3 activities and, subject to the direction of the Secretary of  
4 Defense, exercises oversight of all DOD health resources.

5 One of those resources is the AFEB. We're  
6 extremely pleased that he took the time out of his very busy  
7 schedule to be here with us for part of today and for part of  
8 tomorrow as well. I had the pleasure of meeting him back in  
9 December.

10 DR. WINKENWERDER: Thank you, Dr. Ostroff. It's  
11 really nice to be here. I appreciate the strong participation  
12 and involvement of so many people, including a lot of bright,  
13 thoughtful and very well-trained individuals who -- all of you  
14 have a very, very important role in helping to advise the  
15 Department of Defense, including surgeons general and my office.

16 So I want to thank you, first of all, for being here and doing  
17 what you do.

18 I understand that you do this work without pay.  
19 So you're really doing yeoman's work. We really appreciate that.

20 I personally appreciate what you're doing.

21 I'm going to just make a couple of prepared  
22 remarks and then I'll close with a couple other comments.

23 The AFEB considers -- and I'm saying this for some  
24 of you who -- and I've already run into a couple of you -- who  
25 are here for the first time, to outline the mission

1 here -- considers medical issues as they relate to operations,  
2 policy, research and development and include, but are not  
3 necessarily limited to, preventive medicine, occupational  
4 environmental health and health promotion programs. AFEB  
5 prepares and makes recommendations based on science,  
6 technological and epidemiologic principles. All of you are  
7 nationally recognized with competence in your field.

8 The board, for those of you who are wondering  
9 about the history, was conceived in the beginning of World War  
10 II, established formally by the Secretary of War, before there  
11 was a DOD, in January, 1941. It was rechartered later when there  
12 became a Department of Defense and has operated since that time.

13 Since 1955, the board has produced over 400  
14 recommendations with numerous individual reports. There's a  
15 tremendous history here. I think with that history goes a  
16 recognition not only within DOD but outside the rest of the  
17 federal government and even beyond that to the general public  
18 that this is a very important group that can be counted on to  
19 give unvarnished, unbiased, scientific advice. That's what we  
20 need. We need that. We need it today, I think, as much as we  
21 have ever needed it.

22 There are many, many important issues that have  
23 been worked on and are certainly the very important ones today  
24 that we'll consider. I look forward to working with you. I'm  
25 here not on a perfunctory mission, but I'm here because I

1 consider the work of this group very important. I want to send  
2 that signal. We've got a lot of important issues that we need to  
3 make recommendations to the secretary on, frankly.

4 So your perspective and your thought behind it,  
5 that's all helpful to me personally, but I think particularly to  
6 the leadership of the department.

7 So thanks again for being here. I look forward to  
8 participating for a couple of hours this morning and learning  
9 about your work. I may jump in from time to time.

10 I won't bother you with my background, but I was  
11 originally trained as an internist and also spent a couple years  
12 working to become an epidemiologist and health services  
13 researcher. Fate didn't take me in that direction in terms of a  
14 long-term career, but I enjoy this kind of work and appreciate  
15 what's involved with it.

16 So thanks so much. I turn it back over to you. I  
17 think we've got some presentations to make.

18 DR. OSTROFF: Right. Thanks very much. The other  
19 thing you didn't mention about your background is that you worked  
20 for a number of years at that other fine Atlanta institution down  
21 the street from the CDC.

22 DR. WINKENWERDER: Yes, exactly.

23 DR. OSTROFF: What we're going to do  
24 now -- unfortunately I think, as probably many of you are aware,  
25 there was some sort of accident on the bridge coming over the

1 causeway. Captain Luz isn't here yet, but we're going to go  
2 ahead and do the presentation anyway. I think Commander Ryan is  
3 going to accept the plaque.

4 LT. COL. RIDDLE: So, Captain (sic) Ryan, if you  
5 would please accept this plaque on behalf of the Armed Forces Epi  
6 Board. It's to the command and staff of the Naval Health  
7 Research Center in appreciation for hosting the winter 2002  
8 meeting of the Armed Forces Epidemiological Board.

9 (Applause.)

10 LT. COL. RIDDLE: If we could have Shawn and  
11 Suzanne to join us too.

12 From Dr. Winkenwerder we have certificates for  
13 Shawn, for Suzanne.

14 Commander Ryan, Ms. Suzanne Clark and Mr. Shawn  
15 Watson, please accept these certificates of appreciation for your  
16 outstanding professional knowledge and willingness to assist and  
17 cooperate on all issues supporting the Armed Forces  
18 Epidemiological Board winter 2002 meeting.

19 Ms. Leslie Henry and Ms. Jennifer Strickler are  
20 not with us this morning. They'll be here later, but they've  
21 also helped us tremendously in setting this meeting up. I'm  
22 fairly new to the board. Believe me, it takes a lot of  
23 logistical efforts to pull one of these together and make it  
24 happen. We couldn't do that without the support of the hosting  
25 organization. We really appreciate that.



1 (Applause.)

2 CMDR. RYAN: Well, I'm not quite sure what  
3 happened to Captain Luz, but I'm --

4 REAR ADM. HART: Let me go ahead and welcome  
5 everybody on behalf of Captain Luz.

6 I have a certain intimate relationship with NHRC  
7 since I'm the reporting senior for our two research commands. I  
8 have spoken with Captain Luz periodically in the past about the  
9 importance of the AFEB -- maybe I better have someone speak for  
10 me now. He and I share the same high regard.

11 There's a number of treasures that we have in the  
12 Department of Defense. One of those treasures is our association  
13 with the AFEB. Anything that NHRC can do to further the good  
14 work of this body, we're more than welcome -- more than eager to  
15 do so.

16 So I don't know where Travis is. He's probably on  
17 the bridge somewhere. I hope he's behind the accident instead of  
18 in it. On behalf of Captain Luz and the NHRC, we welcome the  
19 AFEB.

20 CMDR. RYAN: Thank you, sir. Is this on, Colonel?

21 DR. OSTROFF: Yeah, we're going to go ahead. We  
22 have a couple of administrative remarks.

23 There are two new board members that are in  
24 attendance. I'd like to welcome them. We also have five of the  
25 six nominees, in addition to Dr. Haywood, over there, who

1 probably is the longest serving member of the board. It's good  
2 to see him come back. The two new board members are Dr. Cline  
3 and -- I have to find out where everybody is sitting -- Dr.  
4 Cattani, who also serve as a consultant.

5 What I'd like to do -- because, to many of you,  
6 not all the board members are familiar -- is to just go around  
7 the table and have everyone introduce themselves so you know who  
8 they are.

9 Why don't we start on this side?

10 CMDR. LUDWIG: I'm Commander Sharon Ludwig. I'm  
11 the Coast Guard preventive medicine officer.

12 DR. WHITEHEAD: I'm Jeff Whitehead. I'm with  
13 Force Health Protection, Canadian Department of National Defense.

14 MAJ. BALOUGH: Brian Balough, joint staff,  
15 preventive medicine officer.

16 COL. GUNZENHAUSER: Jeff Gunzenhauser with the  
17 Army Surgeon General's Office.

18 LT. COL. WOODWARD: Lieutenant Colonel Kelly  
19 Woodward, Air Force Medical Operations Preventive Medicine.

20 DR. NESS: Roberta Ness.

21 DR. MALMUD: Leon Malmud.

22 DR. BERG: Bill Berg, Captain, Virginia Health  
23 Department.

24 DR. PATRICK: Kevin Patrick.

25 DR. POLAND: Greg Poland from the Mayo Clinic,

1 previously served on the board for six years.

2 DR. RUNYAN: Carol Runyan, University of North  
3 Carolina School of Public Health and Injury Prevention.

4 DR. SHANAHAN: Dennis Shanahan. I'm a private  
5 consultant.

6 DR. SHOPE: I'm Bob Shope with the University of  
7 Texas Medical Branch at Galveston.

8 COL. CROPPER: Leo Cropper of the Air Force  
9 Research Laboratory.

10 MS. EMBREY: Ellen Embrey with the Department of  
11 Defense.

12 LT. COL. RIDDLE: Lieutenant Colonel Riddle, the  
13 Executive Secretary for the AFEB.

14 DR. OSTROFF: Steve Ostroff from the Centers for  
15 Disease Control and Prevention.

16 DR. WINKENWERDER: Bill Winkenwerder again from  
17 the Department of Defense.

18 REAR ADM. HART: I'm Steve Hart, the Navy Surgeon  
19 General's representative and director of Navy Medicine Research  
20 and Development.

21 DR. CAMPBELL: I'm Doug Campbell. I'm a  
22 consultant in North Carolina in occupational and environmental  
23 medicine.

24 DR. CATTANI: Jacqui Cattani, director of the  
25 Center for Biological Defense in South Florida and professor of

1 public health at the College for Public Health.

2 DR. CLINE: Barnett Cline, professor emeritus,  
3 Department of Tropical Medicine, Tulane.

4 DR. FORSTER: I'm Jean Forster.

5 DR. GRAY: My name is Greg Gray with the  
6 University of Iowa.

7 DR. HERBOLD: John Herbold.

8 DR. LEMASTERS: Grace Lemasters, Department of  
9 Environmental Health, University of Cincinnati's College of  
10 Medicine.

11 DR. HAYWOOD: Julian Haywood, University of  
12 Southern California School of Medicine.

13 DR. GARDNER: I'm Pierce Gardner. I'm a professor  
14 of medicine at the State University of New York at Stony Brook  
15 and also work as a consultant at the Fogarty International  
16 Center.

17 COL. STAUNTON: Michael Staunton.

18 CAPT. YUND: I'm Jeff Yund, the preventive  
19 medicine doc in the Navy and the Navy's liaison officer to the  
20 AFEB.

21 LT. CMDR. CONNER: Byron Conner. I'm actually  
22 sitting in for Captain Schor. Either that or he grew a little  
23 bit.

24 DR. OSTROFF: We're sorry that Captain Schor had  
25 an illness in the family and was unable to attend.

1                   Let me turn the microphone over to Colonel Riddle  
2 for a few administrative remarks.

3                   LT. COL. RIDDLE: Good morning and welcome. We  
4 couldn't plan for the accident this morning.

5                   I have a couple of administrative remarks before  
6 we begin. I would like to thank Admiral Hart, the NHRC staff  
7 here for hosting this.

8                   I also want to thank Ms. Jean Ford and Ms. Karen  
9 Bralley and Lisa Mims for all of their efforts in the background.

10                  If you haven't signed in, please make sure you  
11 sign in at the registration desk. As a federal advisory  
12 committee, we are required by law to make a record of all at the  
13 meeting.

14                  This afternoon when we finish up, the board and  
15 the preventive medicine officers will be going to MCRD for a  
16 tour. So we'll just carpool from here at 11:30. We have lunch  
17 reservations over at -- restaurant and then the tour starts at  
18 1:30.

19                  We do have a roster out there. If you don't plan  
20 on attending, let us know, because we have several folks that  
21 wanted to go, but they did limit us to about 30 people for the  
22 tour and then a presentation over there.

23                  The next AFEB meeting is the 21st and 22nd of May.  
24 We have three formal meetings a year. That is February, May and  
25 September, the third Tuesday and Wednesday. This meeting will be

1 at the United States Army Medical Research Institute for  
2 Infectious Diseases at Fort Detrick in Frederick, Maryland. It  
3 looks like we already have a fairly robust agenda for that  
4 meeting. We'll work the security clearances for all of our folks  
5 getting in, because at that meeting we review the chairman's  
6 threat list and make recommendations on immunizations and  
7 biologics in accordance with the ranked biological warfare.

8 We'll have refreshments both this  
9 afternoon -- this morning and afternoon and tomorrow. Lunch  
10 today is available at the 19th Hole Restaurant and the Beach  
11 House Cafe for those folks who are staying here. Tomorrow there  
12 will be a buffet here and also at the 19th Hole and Beach House  
13 Cafe.

14 The restrooms are just right outside the door. If  
15 you do have any information that needs to get to you while you're  
16 here at the meeting, we do have a fax here in the building. The  
17 number is 619-545-0522. Then there's a phone right outside the  
18 door here. That number is 619-545-0360. Lisa will be out there  
19 to handle it.

20 For any transportation issue, please see myself or  
21 Lisa or Karen.

22 Tonight we have the dinner of the board. There  
23 are maps up on the table. It's open to all of the board members  
24 and attendees. We'll try to leave from the Navy Lodge lobby at  
25 about 8:45 -- or 6:45 this evening. That's in Old Town.

1           We also -- to aid with the transcription, if you  
2 could please identify yourselves and speak into the microphones.

3           I think our audio guy is tied up in the traffic also. Karen is  
4 taking a crash course this morning filling in. So we'll get  
5 through it.

6           Also, please remember this is a federal advisory  
7 committee. It is open to the public. There may be members of  
8 the public and press present here.

9           DR. OSTROFF:       Let's move on now to our  
10 presentation since Captain Luz is not here yet. I think  
11 Commander Ryan is going to give the overview. She's the director  
12 of the Department of Defense Center for Deployment Health  
13 Research at the Naval Health Research Center.

14           She's going to give the overview and then also  
15 talk about some of the work being done at NHRC. Thank you.

16           CMDR. RYAN:       Thank you, sir. Actually, I hear  
17 that Captain Luz is on his way up. So I may -- should I wait,  
18 Colonel, or --

19           LT. COL. RIDDLE:    If you want to -- you want  
20 to -- or we could transition --

21           CMDR. RYAN:       Do you want me to go to the next --

22           LT. COL. RIDDLE:    Yeah, let's go ahead and give  
23 your brief and we'll let Captain Luz --

24           CMDR. RYAN:       Dr. Winkenwerder, Ms. Embrey, Admiral  
25 Hart, Dr. Ostroff and members of the board and distinguished

1 guests, welcome to Naval Health Research Center. I'm delighted  
2 to represent my group, the Department of Defense Center for  
3 Deployment Health Research, which is one of the directorates at  
4 the Naval Health Research Center.

5 We have within our center sort of two research  
6 arms, if you will. One is deployment epidemiology. We think  
7 we're one of the largest, if not the largest, group of  
8 epidemiologic researchers in the Department of Defense. We also  
9 have a research interest in emerging infectious disease. We have  
10 an impressive infectious disease laboratory where our focus is  
11 mostly respiratory infections.

12 Tomorrow you'll hear a little bit more -- I'm  
13 sorry, not tomorrow, but later today -- a little bit more about  
14 the infectious disease part from my colleague, Dr. Russell, who  
15 will speak about the pneumococcal vaccine trial.

16 We currently have 68 research staff. Three of us  
17 are active-duty medical officers in the Navy. We currently have  
18 one or two Air Force billets about to come to fruition at our  
19 research center, which we're delighted about since it is a DOD  
20 center. The rest are Henry M. Jackson contract staff, really a  
21 wonderful staff that I'm privileged to work with.

22 The origins of our team actually grew out of the  
23 legacy of the Gulf War, that is, the brunt of our research and  
24 the concerns about what made Gulf War veterans have problems  
25 after deployment.



1           The original Gulf War studies in our team are a  
2 credit to Captain Gray, Dr. Gray, who is now a distinguished  
3 member of the board. He developed these seven studies which were  
4 well embraced by the Department of Defense and led to some  
5 wonderful research products.

6           The studies of symptoms, hospitalizations and  
7 reproductive health effects, which were the main concerns of the  
8 Gulf War veterans -- and these are some of the highlights of  
9 products that grew out of that research.

10           We actually still have some active projects  
11 looking at Gulf War exposed veterans and the epidemiology about  
12 the Gulf War exposures. Most of the research has, of course,  
13 developed past the Gulf War to more current deployment concerns.

14  
15           Again, the focus of our group is always to publish  
16 in the peer review literature, which is the standard we hold  
17 ourselves to.

18           Because of that success, the Department of Defense  
19 stood up three centers for deployment health back in 1998, '99.  
20 One was the Deployment Health Research Center, which was  
21 designated here at NHRC. Then there's a clinical center, our  
22 sister center, at Walter Reed, and a medical surveillance center  
23 at CHPPM, at the Army's Center for Health Promotion and  
24 Preventive Medicine. So all three make up the centers for  
25 deployment health.

1           These are some of the projects that we evolved  
2 into after the Gulf War. You can see there's still a few points  
3 here -- registry studies relate to Gulf War illness. Health  
4 experience of Saudi Arabian National Guard is an interesting  
5 study that we're doing with our colleagues in Saudi Arabia and  
6 their post-Gulf War experience.

7           We're comparing the experience of those deployed  
8 to Southwest Asia, which is the Gulf War area after the war, and  
9 Bosnia to the Gulf War veterans. We have some interesting  
10 epidemiologic work looking at the health experience of those who  
11 have received Anthrax vaccine.

12           We're looking at ciprofloxacin used in the last 12  
13 months, which is an interesting epidemiologic analysis after the  
14 bioterrorist threats in 2001. We're looking at risk factors for  
15 dysfunctional careers and dysfunctional family life that may be  
16 predicted in recruits by some current screening tools. We've got  
17 a little bit of work in tobacco cessation in recruits because we  
18 have this interest in basic trainees.

19           We've looked at epidemiology of other common  
20 things of concern, like STDs and asthma, H. pylori infections.  
21 Then we have some large survey studies. These are two small  
22 survey studies, actually, immunization knowledge, attitudes and  
23 beliefs and a study of complementary and alternative medicine.

24           We have a clinical trial center. It's actually  
25 down the hill from us, physically removed, but at one of the

1 clinics that's a branch clinic of the large medical center here,  
2 the Naval Medical Center San Diego -- at this branch clinic,  
3 we've stood up a center where we've staffed it with folks who see  
4 patients for some clinical trials.

5 We stood this up originally to do two VA/DOD  
6 cooperative studies in Gulf War veterans, which have recently  
7 wrapped up. Those were studies of antibiotic treatment and  
8 multi-symptom treatment of those with chronic multi-symptom  
9 illnesses.

10 Now we're doing two sort of interesting studies  
11 with patients and the effect of combination treatment with  
12 D-permethrin and pyridostigmine bromide on symptoms and  
13 neurocognitive function and an assessment of the potential  
14 relationship between obesity and adenovirus infection, sort of a  
15 marrying of our interested infectious disease and other  
16 epidemiology.

17 These are our three large projects in our center.

18 So all of what I've just shown you are actually smaller projects  
19 in relationship to these through Recruit Assessment Program, the  
20 birth and infant health registry and the millennium cohort study.

21  
22 This morning I'll be giving you a few more slides  
23 particularly on the birth and infant health registry and  
24 millennium cohort study, as I know they're of interested to the  
25 board, and the Recruit Assessment Program is, of course,

1 something we'll discuss all morning tomorrow.

2 Just a few quick slides on the overview of the  
3 laboratory. Again, Dr. Russell will perhaps give you a better  
4 feeling of the laboratory work that we're doing. We have some  
5 unique capabilities for diagnosing respiratory pathogens of  
6 importance to our deployed members and to all of our active-duty  
7 members.

8 We have a wonderful relationship with centers  
9 around the country and a few that are outside of the United  
10 States in respiratory disease surveillance and respiratory  
11 disease research projects.

12 So we're doing surveillance for viral pathogens,  
13 which of importance includes adenovirus, influenza, some  
14 surveillance for Group A strep, for strep pneumonia. There's a  
15 pneumococcal vaccine trial, again, Dr. Russell will speak of,  
16 some pertussis work at a few of the basic training centers. It's  
17 surveillance for respiratory syncytial virus, which is actually a  
18 collaboration with our colleagues in the United Kingdom.

19 Again, the standard we hold ourselves to is to  
20 publish in the peer review literature. These are some of our  
21 recent products. We're also proud that the laboratory is CAP  
22 certified, College of American Pathology certified, since 1999  
23 and that we're under consideration as a WHO collaborating center.

24 That's my team up on the hill there in Point Loma.  
25 It's really a beautiful place to work and some wonderful people

1 to work with. I'm privileged to represent them today to give you  
2 this brief overview. I'd be happy to answer any  
3 questions.

4 DR. OSTROFF: I think we have a minute or two.  
5 Are there any questions?

6 (No audible response.)

7 DR. OSTROFF: It's early. Captain Luz is here.

8  
9 We switched the order so that you can do the  
10 overview. Welcome. Thank you for hosting the meeting.

11 CAPT. LUZ: Good morning, and we're certainly  
12 honored to be hosting this group and this meeting this next few  
13 days.

14 My apologies. I had no idea that Point Loma was  
15 an hour and ten minutes away. Actually on the bridge there was a  
16 four-car accident and somebody actually pushed me during that  
17 particular period, trying to get me here early. So I appreciated  
18 that as well.

19 Again, welcome. I think a few of you are coming  
20 over to see us while you're here in town. Again, we're happy to  
21 host you and welcome you, again, to our facility over at Point  
22 Loma.

23 You have a more complete version of this slide in  
24 your packets, but I just wanted to take the opportunity to  
25 address the other capabilities that we have outside of Point

1 Loma. It's, again, in support of Force Health Protection and the  
2 pillars therein.

3 Starting up in your upper left-hand corner, again,  
4 the Naval Health Research Center San Diego is just part of, you  
5 know, the laboratories that are in support of operational medical  
6 research. You can see the DOD centers that Commander Ryan talked  
7 about with her group.

8 We also have birth defects and the agent for AIDS  
9 and the epidemiological issues that we're confronting right now  
10 in Africa. Commander Schafer was actually a part of the SG's  
11 lineup this morning, giving that brief. It's been a wonderfully  
12 successful effort that's been continued with funding through DOD  
13 as well.

14 In the lower left-hand corner we have our  
15 electromagnetic radiation facility. That's at Brooks Air Force  
16 Base down in San Antonio. Again, addressing such issues as  
17 lasers for air crew -- we hope to get involved in the electric  
18 boat that's coming out as well within the Navy. That's a very  
19 capable group down there.

20 Continuing over to the Naval Aerospace Medical  
21 Research Laboratory in Pensacola, Florida, they're doing anything  
22 from trying to determine the best candidates for the aviation  
23 curriculums and programs down there to sound attenuation issues  
24 and others.

25 Moving up a little bit north of that, we have

1 Wright-Patt Air Force Base, toxicology detachment there as well.

2 Then in the upper right-hand corner, all the way  
3 up, is the Naval Submarine Medical Research Laboratory in Groton,  
4 Connecticut.

5 We gave you a little more complete version of that  
6 in your packet. I won't talk about that any longer, just to show  
7 you the versatility of the capabilities we have within the Naval  
8 Health Research Center.

9 Again, we just wanted to put out on our web page,  
10 we have a wealth of information out there for you. Please dial  
11 in, take a look.

12 I wanted to thank Commander Ryan and Commander  
13 Russell for all that they've done in helping put this together.  
14 Again, welcome to San Diego. It's a great time of year to be out  
15 here, as opposed to on the East Coast, for some of you. I hope  
16 you get an opportunity to enjoy some of that while you're here as  
17 well. So thank you.

18 DR. OSTROFF: Thank you very much. For all of us  
19 it's a pleasure to be here.

20 I think what we're doing now is we're moving on to  
21 the preventive medicine update.

22 Oh, I'm sorry, return appearance by Commander Ryan  
23 first.

24 CMDR. RYAN: Again, in the interest of the board,  
25 I know they wanted to hear a little bit more about two of our

1 efforts here, the birth and infant health registry.

2           These are our collaborators. Toni Hooper from  
3 USIS is -- actually is in the audience. We're privileged to have  
4 her with us today. Then our local research staff and several  
5 consultants work on this project, Larry Edmonds from CDC, Dr.  
6 Jones from local UCSD and Dr. King from the Naval Medical Center.

7           The origins of the birth and infant health  
8 registry go back to the senate committee on veterans affairs  
9 recommending specifically the establishment of a birth defects  
10 registry for military service members. This was back in 1998.  
11 Again, there's some interest post-Gulf War for some of these  
12 efforts. Some of the wonderful epidemiologic work actually grew  
13 from the experience of the Gulf War.

14           Justification for birth registries or birth defect  
15 registries -- just quickly, birth defects are, of course,  
16 extremely common, may be represented in 15% of all conceptions.  
17 They're very costly. A quarter to a third of pediatric  
18 hospitalizations are related to birth defects. They're the  
19 leading cause of infant mortality. Of course, they're  
20 extraordinarily concerning.

21           Thirty-five states have birth registries or birth  
22 defect registries or birth defect monitoring programs. Each of  
23 those 35 states does the surveillance in a little bit different  
24 way, but all of them have the same concern.

25           It's interesting -- not everybody realizes that



1 not all 50 states do this. It's not an extremely easy thing to  
2 do surveillance for and to do it well.  
3 They're very concerning things.

4 Occupational environmental exposures concern both  
5 parents and policy makers and, of course, Department of Defense.

6 This picture from Life magazine brought it home again. It's  
7 sort of a Gulf War interest, but this is a Marine with his son,  
8 who has some severe congenital anomalies.

9 So what do we do in our birth defect surveillance  
10 work? The population under surveillance includes all Department  
11 of Defense beneficiaries, which is really a very large umbrella,  
12 so anybody who receives health care under the umbrella of DOD.  
13 We capture outcomes from both inpatient and outpatient encounters  
14 in both military and civilian facilities. The capability to do  
15 this only became realized in about '98, '99, which is one of the  
16 reasons why we really didn't have a birth defect registry or  
17 surveillance program before that time. We're able to capture all  
18 that data to create the denominator, which is all live births in  
19 any given period of time, and then the numerator, if you will,  
20 the outcome of interest are ICD-9-coded birth defects from all of  
21 those health care encounters.

22 We use the ICD-9 code list -- it's nationally  
23 recognized and created by the Centers for Disease Control and  
24 Prevention. Again, it's just ICD-9 coding, but it does allow  
25 comprehensive capture of the outcomes of interest. What we show,

1 then, is the prevalence of birth defects diagnosed in the first  
2 year of life for all infants born under the DOD umbrella.

3 These are acronyms that show the databases that  
4 are put together to do this. STR, SATR and HCSR are actually  
5 databases that include all of the inpatient and outpatient  
6 encounters both in civilian and military facilities. Again, all  
7 of that gets put together into the registry.

8 About 40% of babies are born at civilian  
9 facilities -- I'm sorry, are born at military facilities and 60%  
10 are born at civilian facilities, which is why it's  
11 extraordinarily important to capture the civilian health care  
12 encounters under the tri-care system, if you will.

13 There's complex algorithms that we have developed  
14 to account for duplication and miscoding. We're privileged that  
15 we have unique identifiers for all of our beneficiaries and all  
16 of the infants born to our beneficiaries, but still there's a lot  
17 of algorithms that are necessary to look at this data, to look at  
18 them well.

19 How strong are the data on outcomes? Well, we do  
20 active case validation at this large medical center that's down  
21 the road from us, the Naval Medical Center San Diego. They have  
22 about 3,700 births per year at that DOD facility. Again, this is  
23 a military facility. We look at every one of those births and  
24 see if the ICD-9 coding is correct, so to speak. We find that  
25 it's an extremely strong correlation between the actual infant

1 records and the ICD-9 coding.

2 This just shows you a little bit of this data.  
3 Ninety-three percent have completely matched records. Most of  
4 the mismatches are slight miscodings. A classic example are some  
5 of the heart defects I've shown you down here -- patent ductus  
6 arteriosus is one of those diagnoses that's most challenging for  
7 all birth defect surveillance programs because the ICD-9 coding  
8 doesn't do justice to the kind of things that are most concerning  
9 to birth defects researchers, and we find the same thing that the  
10 civilians state registries find which is that's the most common  
11 source of challenge in the data.

12 REAR ADM. HART: What happened in '98 or '99? Was  
13 it policy or technology that gave us this capability?

14 CMDR. RYAN: To my understanding, technology but  
15 probably policy as well which drove that technology. It's the  
16 access to HCSR data -- Health Care Service Record data -- which  
17 is all the Tricare data -- was not available before about '98 or  
18 so.

19 LT. COL. RIDDLE: In addition, sir, I actually  
20 worked this policy. We funded from the P-6 research side of  
21 it -- the feasibility of doing it, based upon the feasibility  
22 study.

23 CMDR. RYAN: What we see in our surveillance  
24 system is about 90,000 births per year to military families.  
25 Nineteen percent of those babies are born to active-duty mothers,

1 and the rest are born to other beneficiaries, either dependent  
2 wives or other beneficiaries.

3 The basic demographics we see is relatively young  
4 population with mean maternal age of 26 years and a racial  
5 distribution that looks a little bit like the rest of the  
6 Department of Defense and not unlike the rest of the United  
7 States.

8 Sponsors are spread out much like the rest of the  
9 Department of Defense with mostly Army and the smallest  
10 proportion coming from the Marine Corps.

11 It's interesting that we can see DOD-sponsored  
12 births in all 50 states, whether there are military facilities  
13 there or not, and that's because, again, the civilian facilities  
14 are captured, and then we see births, of course, in foreign  
15 countries. There's more than 2,000 births per year in Germany  
16 and Japan, and then those are the largest states where we  
17 actually get data from this well.

18 What's cool about the birth defect registry and  
19 the Department of Defense is that we can link these data to  
20 things like occupational code, past duty station, past  
21 deployment, some occupational exposures of interest that are not  
22 necessarily easy for our nonmilitary counterparts to do, so we  
23 can actually say quite a bit about maternal and paternal  
24 exposures in the birth defect cases, and these are the attributes  
25 that make our system very attractive to CDC and the states who

1 are doing birth defect surveillance.

2 This is a graph just to give you an example of  
3 something -- it's a little bit before the birth defect registry,  
4 but this is birth rate in the military facilities among active  
5 duty, and what it shows is a little baby boom after the Gulf War.

6 In fact, right after '91, there's a little baby boom, and then  
7 the rate goes down.

8 This also illustrates that, if we could fill in  
9 the data, we would assume that the HCSR data or the Tricare data,  
10 the civilian facility data, actually makes up for a lot of that  
11 gap, if you will, in birth rate. There are more births at  
12 civilian facilities now than in the past decades.

13 So what do we see overall? We actually contribute  
14 to the annual national birth defects prevention program that 35  
15 states contribute to, so in a way we're another state, if you  
16 will, and we see a prevalence of birth defects overall in about  
17 three to four percent of live births which is very consistent  
18 with civilian data.

19 The most commonly diagnosed defects are, again,  
20 some of the heart defects and hyperspadias epispadius which is  
21 also very consistent with our civilian counterparts.

22 It's important to talk about the limitations when  
23 we talk about the surveillance system, and it's the same  
24 limitations that others who are doing the same kind of registries  
25 or surveillance systems have to deal with.

1           Our surveillance is limited to live births, so we  
2           can't capture birth defects on early pregnancy losses, abortions  
3           or stillbirths. In those instances, the denominator would be  
4           pregnancy instead of births which is extremely hard to capture,  
5           and again this is an important limitation, but in terms of  
6           comparing data overall or comparing it to our peers, it's not a  
7           fatal limitation because that's really what all of the  
8           surveillance systems are able to capture.

9           And it may be the tip of the iceberg when we think  
10          about teratogens, but it's an important component to be able to  
11          fully capture the data on live births.

12          We can't capture anything diagnosed after one year  
13          of age, and this is important because certainly the diagnosis of  
14          developmental disabilities, autism and so on are becoming  
15          increasingly important and not diagnosed before one year of age.

16          The ICD-9 codes can't describe everything we'd  
17          like them to. They don't describe well constellations of  
18          defects. They don't describe well severity of defects, and  
19          really it takes a lot of chart review and case validation if you  
20          really want to look closely at those defects.

21          So we're limited to some extent when we look at  
22          these electronic data.

23          And, again, the active case validation at Naval  
24          Medical Center may not represent the entire Department of Defense  
25          or our civilian facilities that we're interested in. So that's

1 an important limitation as well.

2 The value, though, of the system is that the  
3 system does completely capture the data we intended it to  
4 capture, and our ability to link again to environmental and  
5 occupational exposures is really an exciting attribute.

6 We do think that the system complements our  
7 civilian counterparts doing this kind of public health research  
8 and surveillance, and we've been very well received by those  
9 folks who are doing this kind of surveillance.

10 That's the sublink on the website to the birth  
11 defects or birth and infant health registry page which is easily  
12 found on the NHRC website.

13 I'd be happy to answer any questions.

14 DR. OSTROFF: Thank you. Dr. Berg?

15 DR. BERG: Bill Berg. Megan, as you've alluded  
16 to, the validation of the birth defect coding is critical, and  
17 you pointed out that just because it's accurate in San Diego does  
18 not mean it's accurate elsewhere.

19 Is it possible that the accuracy in San Diego has  
20 increased -- the scrutiny that you conducted it to -- which might  
21 speak a little bit to the accuracy reporting elsewhere? In other  
22 words, how long have you been coding -- scrutinizing the coding,  
23 and has it gotten better over that time?

24 CMDR. RYAN: We have that concern, about whether  
25 or not we have influenced the coding in San Diego. We don't

1 believe that we have. We call it the prime directive, if you  
2 will, the noninterference directive.

3 So we do our work as invisibly as possible at  
4 Naval Medical Center-San Diego, and the one full-time extractor  
5 we have there is literally in the basement of the hospital,  
6 looking at records -- he's not able to interact with the coders  
7 or the people who put in those ICD-9 codes into the STR system.

8 So we don't believe that we have influenced it.

9 The other thing that makes us feel good about that  
10 is in the feasibility study that Colonel Riddle alluded to -- the  
11 kind of agreement that was found there which was in the very  
12 genesis of the birth defect surveillance system is the same that  
13 we're finding now.

14 So Naval Medical Center may be doing a great job;  
15 we don't think we're influencing the great job they're doing, and  
16 we know that it may not represent the rest of DOD or the civilian  
17 facilities.

18 DR. BERG: What happens if your extractor finds a  
19 significantly different coding than the -- it stays in the  
20 record.

21 CMDR. RYAN: That's correct. Yes, ma'am?

22 DR. LEMASTERS: Grace Lemasters. I want to  
23 comment on a very intensive effort I know this setting must take  
24 to accomplish. I was just wondering -- it appears that you're  
25 gearing up for some analysis, and I was wondering what are your



1 first occupational analysis exposure groups. Have you made any  
2 decisions along that line?

3 CMDR. RYAN: We have -- one first study is the  
4 linking of Anthrax vaccine to birth defects outcomes among  
5 active-duty women who received Anthrax vaccine, and some of the  
6 board members have already been involved in discussions of this  
7 work which is fairly interesting.

8 I may leave it to Dr. Ostroff to see if we want to  
9 digress into talking about that. It's been a fascinating  
10 analysis.

11 And then I spoke to you, ma'am, about a year and a  
12 half or so ago about jet fuel exposure, and it's still an  
13 interest or ours to use the jet fuel-exposed occupations as  
14 something of interest and analysis in looking at the birth defect  
15 outcomes.

16 So we have that ability, and it's really an issue  
17 of which things rise to the top in terms of DOD priorities and  
18 objectives, which things may get funded in competitive research  
19 grants that we may put out, as things that we want to look at.

20 The Anthrax vaccine issue was not one that was  
21 funded by a competitive grant. It was just of such high interest  
22 to DOD that we were asked to specifically make that a priority.

23 DR. RUNYAN: Carol Runyan. I'm curious to know if  
24 the registry is also capable of tracking other outcomes besides  
25 birth defects. I'm, of course, particularly interested in trauma

1 and perhaps issues of child abuse.

2 CMDR. RYAN: It's a fascinating question. We  
3 actually have one spin-off study, if you will -- it's not so much  
4 a spin-off but a complementary study on infantile neoplasms.

5 We think neoplasms, like birth defects -- there  
6 are sort of major ICD-9 codes that are relatively consistent and  
7 easy to capture. Now, there's not a lot of civilian counterparts  
8 for doing infantile neoplasm surveillance. There's certainly  
9 childhood cancer -- is of great interest.

10 We have a little more trouble with childhood  
11 cancer because of the denominator's so moving for children  
12 and -- under the DOD umbrella. Children come in, and children go  
13 out at all ages of childhood.

14 But infants -- that first year of life is  
15 relatively stable, so we're doing some basic surveillance in  
16 infantile neoplasms -- capable of getting anything that  
17 is -- right now in the first year of life is our limit in terms  
18 of the data we're collecting, but yeah, trauma, any other outcome  
19 of interest would be in there.

20 DR. RUNYAN: Do you know if the data are e-coded  
21 as well as having diagnostic?

22 CMDR. RYAN: E-coded -- I'm sorry?

23 DR. RUNYAN: E-code is external cause of injury.  
24 Right?

25 AUDIENCE MEMBER: They're not.

1 DR. RUNYAN: They're not.

2 (Side discussions in audience.)

3 CMDR. RYAN: So there are some V-codes for  
4 procedures and so on, but not that degree of granularity.

5 DR. NESS: Roberta Ness. We've actually discussed  
6 these issues -- the Anthrax and birth defects, and I wondered  
7 whether there had been any discussion at any point in the  
8 creation of this database with regard to the collection of  
9 biomarker data on even a subset of the infants born within the  
10 DOD.

11 CMDR. RYAN: Not so far. There's not any sort of  
12 set system to collect either blood or sera or something on  
13 infants or placenta samples.

14 It certainly could be written in as protocol in  
15 and of itself, but there's no archive or ability to do that right  
16 now.

17 We do have -- we do make use of a sera repository  
18 for active-duty members. Occasionally in studies when we have  
19 sera drawn annually for HIV testing -- gets kept in a sera  
20 repository, and that's been a wonderful asset in looking at  
21 things retrospectively like hepatitis-C and so on in the  
22 Department of Defense.

23 So for parental archives, there may be something  
24 there, but not for -- there's no archive of infantile  
25 biospecimens.

1 DR. NESS: Even if there are maternal data, there  
2 may be some opportunity to do some creative matching which may  
3 enhance the validity of some of the exposure numbers.

4 CMDR. RYAN: Absolutely.

5 DR. OSTROFF: Other comments? I have one  
6 question. Is there any thought being given to validate the type  
7 of validation here in San Diego and anywhere else -- even on a  
8 periodic, if not ongoing, basis?

9 CMDR. RYAN: Yes, and it's been an  
10 increasingly -- a topic of increasing interest to do the  
11 validation at other facilities. It takes some work to get into  
12 the facilities to do this work.

13 We have a letter from the admiral at the Naval  
14 Medical Center-San Diego that gave us sort of a five-year  
15 permission to look at records. It's certainly not easy to look  
16 at medical records, civilian or military.

17 So it would take some work to get in the door, and  
18 we're looking at that now, but whatever door we get into, we want  
19 to pick one that's important and fruitful, and it would seem like  
20 a civilian facility would be nice to really look at, but the  
21 civilian facilities are sort of onesies and twosies, if you will,  
22 compared to the military facilities for births. There's so many  
23 civilian facilities where births -- DOD births could happen.

24 So it's going to take some --

25 DR. OSTROFF: And there's also the issue of the

1 overseas births --

2 CMDR. RYAN: Exactly.

3 DR. OSTROFF: Of course, there's deployed  
4 personnel -- and there's always the issue about whether or not  
5 they have the risk factors --

6 CMDR. RYAN: Right, and the overseas births -- it  
7 actually can be complicated, too, because many high-risk births  
8 in members overseas are born in the United States.

9 When we look at birth defect prevalence in the  
10 overseas hospitals, it's much lower than in CONUS -- than in the  
11 United States because, of course, many high-risk pregnancies are  
12 sent back to the United States to give birth.

13 So the location of birth may not represent the  
14 location of pregnancy or conception or exposures of concern.

15 DR. OSTROFF: Or they may not be coding them  
16 right.

17 CMDR. RYAN: That's true.

18 DR. OSTROFF: Thanks.

19 CMDR. RYAN: Thank you, sir.

20 REAR ADM. HART: Megan, you mentioned the  
21 limitations of the birth registry. Do we just accept that as a  
22 fact of life, or do we need to address it? Do we need to lessen  
23 those limitations?

24 CMDR. RYAN: The primary limitation that all of us  
25 struggle with in birth defects research is this issue of only

1 knowing about live births, and epidemiologically we accept that.

2 To get the denominator to be pregnancies is an  
3 enormous amount of work, and you can do that in focused ways in  
4 cohort studies. It's an enormous amount of work. It's a very  
5 different epidemiologic surveillance system.

6 So the first one, you accept.

7 Diagnosing things after one year of age in the  
8 Department of Defense would be very difficult. As I was alluding  
9 to, children -- anytime we make the denominator bigger than about  
10 12 months of age, children come in; they go out; it can be very  
11 complicated. So we -- if you're worrying about some exposure to  
12 children, you know, that may happen after birth, it can be very  
13 difficult.

14 So in the Department of Defense it's going to be  
15 difficult for us to do good epidemiologic research on  
16 things -- in children in this kind of surveillance system after  
17 one year of age.

18 But then, again, we're still consistent with  
19 civilian registries when we say birth defects -- the congenital  
20 anomalies are diagnosed before one year of age.

21 And then the other things, we can work on by doing  
22 the validation work at other facilities, just what Dr. Ostroff  
23 said.

24 So the last two bullets, I think, we can work on,  
25 yes. Yes, ma'am?

1 DR. LEMASTERS: Commander Ryan, just one -- Grace  
2 Lemasters -- I was wondering -- at least on a subset if you might  
3 be able to do something with the first item if you got a fetal  
4 death certificate and stillbirth certificates -- maybe not across  
5 the plane but on the group that you would have a lot of control  
6 over.

7 It seems like with fetal death certificates and  
8 stillbirths I think, after 20 weeks of gestation, there's  
9 supposed to be a fetal death certificate. You might capture a  
10 lot of important information.

11 CMDR. RYAN: That's true, and in substudies we  
12 could do that, and the states try to do that. States have  
13 different abilities to capture death certificate date.

14 As you said, the fetal death certificates exist to  
15 varying degrees of coding and granularity in terms of diagnoses  
16 on those death certificates in different states, and so -- but  
17 you're right; there's room there for substudies.

18 DR. OSTROFF: We'll take one more question, and  
19 then --

20 DR. MALMUD: Are DOD hospitals as yet doing  
21 neonatal screens for deafness? If so, is that considered on a  
22 birth certificate?

23 CMDR. RYAN: Yes. Do we -- military facilities  
24 follow the same standards as civilians in terms of the auditory  
25 assessment of newborns, but no, it's not considered a congenital

1 anomaly or defect in the ICD-9 list.

2           There are many things, actually, that aren't in  
3 that list, and I didn't include that as a limitation because the  
4 list is what makes us consistent with the state and CDC  
5 surveillance programs, but things like congenital hearing  
6 loss -- if there's no physical anomaly of the year -- are not  
7 actually on that list.

8           So there are some things that are quite concerning  
9 that are not on the list, but the list is congenital  
10 malformations.

11           DR. OSTROFF: Keep going.

12           CMDR. RYAN: All right, thank you, sir.

13           The millennium cohort studies -- another large  
14 effort in our group -- really, the largest effort in our group,  
15 and I'm privileged that my co-investigators -- several of them  
16 are in the audience and -- Dr. Gray on the board today -- Dr.  
17 Amoroso, Dr. Hooper in the audience today.

18           The millennium cohort study evolved from issues of  
19 the Gulf War. After the Gulf War, there were multiple review  
20 panels, registry evaluations, over a hundred million dollars in  
21 research, risk management program by the Office of the Special  
22 Assistance for Gulf War Illness, and overall an expense of maybe  
23 a billion dollars from the government to these efforts of  
24 addressing Gulf War-related health concerns.

25           And the origins of the millennium cohort study



1 grew more specifically from the Strom Thurmond Act, the defense  
2 authorization bill of 1999, where specifically it was recognized  
3 that only a longitudinal study -- a prospective study -- would  
4 really be able to evaluate all of the issues of concern of our  
5 deployers.

6 And so in this authorization they said  
7 specifically we should do this longitudinal study.

8 Then there was an Institute of Medicine report  
9 that we also recognize as important in the origins of the  
10 millennium cohort, and specifically they said to capitalize a new  
11 and planned DOD surveillance and other data in the data systems  
12 growing by leaps and bounds in the decade after the Gulf War.

13 We could make use of these data and begin a  
14 prospective study and for the first time actually measure the  
15 impact of deployment.

16 Sort of a pictorial -- I think we've used this  
17 from the Office of the Special Assistance for Gulf War  
18 Illness -- in terms of describing what does a longitudinal health  
19 study mean? Well, it means sort of from cradle to grave, if you  
20 will, following our folks in the military, from the time they  
21 come in or just before they come in to even after discharge and  
22 all of the things that happen to them in between. If we could  
23 capture all of those data well, we could really say something  
24 about the impact of all of those exposures on people's lifetime  
25 in the military and afterwards.

1           The methodology of the millennium cohort is to  
2 enroll 100,000 members which is about three percent of the  
3 military personnel who were on duty in October 2000, hence the  
4 name "millennium", and to enroll them in a study that would be  
5 just over 20 years, every three years, to survey them, to have  
6 them fill out a survey which was their self-report of functional  
7 status and health status, and to link those data to important  
8 outcomes.

9           The schema that you see there is how we enroll so  
10 there is an introduction and then this is a modification of  
11 Dillman methods, of surveying folks so we mail out with an  
12 iteration of a series of mailings to try to enroll people in the  
13 survey.

14           And then in 2004 and 2007, we'll enroll more, so  
15 we'll begin with 100,000 just this past year -- the beginnings of  
16 the enrollment began in 2001, and 2004 and 2007 -- there's an  
17 effort to get an additional 20,000 members which will represent  
18 younger people or newer people in the military in those years  
19 because we'll be a little bit overrated into older folks from the  
20 military in the original cohort.

21           And this is a little bit complicated schema of how  
22 the enrollment was determined. So there's a little bit of extra  
23 weighting to make sure we have an adequate number of women and an  
24 adequate number of reservists and an adequate number of people  
25 who have a past deployment history to Southwest Asia or Bosnia or

1 Casbo (ph) in the original cohort.

2 So it's a stratified random sample of folks who  
3 were on active duty in 2000 in the original invitation to join  
4 the cohort.

5 So the survey instrument itself includes standard  
6 measures of functional status and health outcomes and health-  
7 related behaviors, and we can link those data to important things  
8 like demographics and deployment history to occupational  
9 exposures, to immunization data, outpatient care, inpatient care,  
10 reproductive health data -- again, alluding to the birth and  
11 infant health registry -- some disability data and mortality data  
12 after service through the VA system.

13 How do we get people to enroll? Well, we're  
14 working very hard on this, and in the initial stages of the  
15 survey a lot of the work has gone into enrollment, so we  
16 pretested the survey with focus groups. We made a very simple  
17 mark-sense questionnaire; we telephone-interviewed nonrespondents  
18 to see what made people not respond so we could reduce the  
19 nonresponse bias as much as possible.

20 We have a toll-free number that people call with  
21 questions, and we have incentives -- the T-shirt incentive has  
22 been especially well received; I have a few samples that I'm  
23 happy to give you, and we have a website that allows people not  
24 just to get information but to complete the questionnaire over  
25 the Internet which makes it easier for folks; it's not a short

1 questionnaire; it's as short as possible, but it's not extremely  
2 short, and so the website is actually the quickest way to  
3 complete the questionnaire for people who enroll in the study.

4           Where are we now? Well, we completed the pilot  
5 study in the spring of last year -- almost a year ago, and the  
6 full survey was launched -- or the full study, if you will, was  
7 launched in August of 2001, so we're less than six months or just  
8 about six months into the mailing cycle.

9           We have almost 50,000 respondents; we're almost  
10 halfway there. Seventeen thousand have responded over the  
11 Internet, which is exciting for us; it's actually very cost-  
12 saving for us as well for people to enroll over the Internet.

13           We've had only 2,700 who specifically declined.  
14 We have 29 people who were invited who were actually deceased.  
15 We track that closely so we don't mail to people who have passed  
16 away.

17           We actually had several people who were invited  
18 into the study and were victims of the September 11th attack on  
19 the Pentagon, and we took great pains to make sure that we did  
20 not send any mailings to those folks after the initial  
21 invitation.

22           September 11th was important in another way, and  
23 that's when we drew an expected enrollment curve, after September  
24 11th our enrollment was markedly less than we would have liked,  
25 and we think it was because of September 11th and the outcomes

1 after that -- people deployed, people moved, people had different  
2 priorities -- mail was markedly slow. We've had people who have  
3 just received surveys that we sent them months ago. So it really  
4 was quite an impact to have the September 11th tragedy happen  
5 this year.

6 The oversight of management of this study is  
7 really a -- very privileged to work with all of these folks and  
8 the expertise that we've been given.

9 Dr. Foster, DDR&E, funds the study, and we get  
10 external consultation in designing the protocol.

11 American Institute of Biological Science does  
12 external peer review on the original study and an annual peer  
13 review on how we're doing. We have a specific scientific  
14 steering and advisory committee made up of Actimissions (ph) as  
15 well as Veterans Service Organization representatives, and the  
16 research working group of the Military and Veterans Health  
17 Coordinating Board also provides an oversight.

18 And these are the list of the specific co-  
19 investigators that I'm privileged to work with.

20 That's the meeting of the Scientific Steering and  
21 Advisory Committee last year, and we'll be meeting again this  
22 spring.

23 And this -- a little bit of pictorial of how we're  
24 doing and what we're doing.

25 The millennium cohort logo -- I don't know if

1 you've noticed our logos, but I have quite a few creative people  
2 who work in my group, and we've never paid for artwork because we  
3 have so many creative folks in our group, and Bay Senuchi (ph)  
4 actually designed this for our team.

5 That big warehouse-looking place is a big  
6 warehouse that is actually packing piles of surveys, and all of  
7 the white things you see in the room are papers that belong to  
8 the millennium cohort mailing. It's just a massive mailing when  
9 you mail to over 100,000 people.

10 That's one mailroom that you see in the bottom  
11 corner there with some of my team with stacks of mail, and then  
12 that's a picture of some of my team modeling our T-shirts.

13 This is just a little bonus slide showing website  
14 enrollment after each invitation, if you will, after each mailing  
15 has gone out.

16 You can see our very last mailing over  
17 there -- we've had a nice spike after -- so the -- perhaps  
18 September 11th was affecting us, and we may have recovered to  
19 some extent; we've increased some incentive work and looked at  
20 other strategies to potentially increase our enrollment, but it  
21 may take us a little longer than planned to get to our hundred  
22 thousand enrollees, but we will get there.

23 And that's all I've got on millennium cohort.

24 DR. OSTROFF: Thank you so much. It's really a  
25 fantastic effort. Let me open it up.

1 DR. WINKENWERDER: I have just a question and a  
2 couple of comments -- just so I understand -- was the millennium  
3 study developed in response primarily to concerns around the Gulf  
4 War, or was it more broad-based?

5 CMDR. RYAN: The Gulf War was the motivation for  
6 this study, but the concern is that deployments and other  
7 exposures that the military has will -- we will be faced with the  
8 same questions that are so difficult to answer from the Gulf  
9 War -- that is, were these exposures things that caused people to  
10 be sick or to have chronic multi-symptom illnesses so that -- we  
11 won't be able to answer a lot of questions for Gulf War deployers  
12 but much more for future deployers.

13 DR. WINKENWERDER: But it is meant to answer  
14 some -- possibly some of the questions associated with the Gulf  
15 War.

16 CMDR. RYAN: Yes, it may, because the people  
17 invited into the survey -- many of them include Gulf War  
18 veterans.

19 DR. WINKENWERDER: Good. And just a couple of  
20 comments. First, just on the millennium study -- when I first  
21 came to know about this -- not that long ago -- a couple of  
22 months ago -- I was delighted to hear about it because it's a  
23 landmark kind of study -- very important, I think, to the  
24 department and will be for years.

25 The fact that people don't know much about this at

1 this time -- only time will show that this very important study  
2 that will produce information for at least the next couple of  
3 decades -- so I commend all those involved with it, who work on  
4 it, to make it the best possible study process.

5 And secondly, I just wanted you and others to know  
6 that I am interested in finding answers to Gulf War illness. We  
7 in the department continue to be asked about that and continue to  
8 ask to testify to Congress about this issue and have indicated  
9 that I want to pursue this agenda.

10 That said, I would like us to -- and I would  
11 support continued efforts that are focused on high areas of  
12 opportunity, so I think it's incumbent upon us to make sure that  
13 research is targeted on to issues where we think we might get  
14 answers.

15 And at some point in the future, I think it might  
16 be valuable to have statements that have not been in the past  
17 commented upon -- some of the sort of larger issues of the Gulf  
18 War illness.

19 I think we need in that independent voice -- the  
20 Institute of Medicine provided some of that, but we need that.

21 As I think some people know, there's a small army  
22 of others, researchers, some funded by private citizens that are  
23 determined that there are answers there that we're not finding,  
24 so I think it's incumbent upon us to search agenda and to make  
25 statements to the best of our knowledge from a scientific



1 standpoint.

2 And so whether there's association between service  
3 and illness or not. Thanks for all your work.

4 CMDR. RYAN: Thank you, sir. Yes, ma'am?

5 DR. LEMASTERS: Grace Lemasters. Commander, as an  
6 epidemiologist, I can fully appreciate having sent out 5,000  
7 letters -- what it must be like to do 100,000. It's mind-  
8 boggling, actually, but I was thinking about your incentives and  
9 what we found to help increase response rate, and some research  
10 has shown that just enclosing a small cash incentive in your  
11 letter, sort of hooks the person into being a part of it, and I  
12 just wondered if you'd tried a cash incentive to increase  
13 response rate.

14 From the literature, it's pretty clear that that  
15 really helps.

16 The other thought I was having was -- is there any  
17 way that you could use this millennium data to cross-validate  
18 some of the findings of births and a birth cohort -- do you list  
19 any births, for example -- are you asking about births among the  
20 women in --

21 CMDR. RYAN: Yes. Let me answer the births  
22 question first. There are questions in the survey that  
23 particularly address pregnancy, and so that would be a wonderful  
24 way to collect a denominator of pregnancies in a subset of the  
25 cohort or in the cohort, so absolutely there's every intention to

1 look at reproductive health outcomes as a part of this cohort.

2 Cash incentives -- hotly debated among our co-  
3 investigators and research teams. We do know that it would  
4 likely help us to put cash incentives in the surveys, and I'm  
5 sorry if I didn't recognize Dr. Amoroso before as a co-  
6 investigator in the audience, but he's been wonderful in terms of  
7 helping us to figure out best ways to enroll people in the  
8 survey.

9 The Institutional Review Boards and some policy  
10 makers in DOD have said you can't do that with active-duty  
11 people -- entice people with cash. We're not so sure that we  
12 can't, but because of the challenges in getting over those  
13 hurdles of folks who thought that it may not be appropriate to do  
14 that with active-duty folks -- it wasn't included in the first  
15 round of inviting people in the survey. It may be something that  
16 we do add as we need to entice people to enroll in the cohort,  
17 especially for a 20-year commitment.

18 DR. HERBOLD: John Herbold. I'm reminded of a  
19 report of a former board member in 1985 -- Dr. Paul Densin -- the  
20 report that he gave me, I have a copy of it -- 1941 UMED report  
21 on the need for vital statistics, long-term follow-up of folks in  
22 the military setting.

23 So my question to you, Megan, might be a little  
24 bit unfair, but this is a fantastic study, but it's termed as a  
25 study -- it has an end date, 2002 -- the studies that I've been

1 involved in -- military have started and stopped -- do you think  
2 there's any possibility that at some time this would become part  
3 of the practice of occupational medicine and occupational health  
4 and it would become institutionalized in the operational  
5 funding --

6 CMDR. RYAN: Maybe that's a hard question for me,  
7 so -- I still intend to -- when the study is completed -- you  
8 know, in terms of operationalizing, the recruit assessment that  
9 we'll talk about tomorrow is one of those issues that likely will  
10 operationalize the collection of this self-reported data that  
11 we're interested in longitudinally, but right now there's not a  
12 current protocol on the table or policy on the table to  
13 operationalize collecting this kind of periodic data on all our  
14 forces except perhaps for maybe the HEAR surveys -- that's the  
15 health promotion, health assessment surveys, but they don't go  
16 past service; they don't go past people getting out of the  
17 service, which is a feature of this cohort -- Framingham-style  
18 cohort study which doesn't recognize a limit when people get out  
19 of the service.

20 So to answer your question, I think there's a lot  
21 of folks with those concerns that we need to operationalize some  
22 thing -- some pieces of this as what we will always do with all  
23 of our folks. Yes.

24 DR. OSTROFF: We have time for one or two more --

25 DR. CLINE: Barney Cline. I'm tremendously

1 impressed with the scope and the promise of this study, and I  
2 have one specific question about serum repository because it  
3 seems to me that could be exceedingly valuable in the long run.

4           Could you tell us a little bit more about that,  
5 and is that going to be linked? I understand the HIV screening  
6 is the driving point for the serum repository, but how does that  
7 link in with this, and are there plans for longitudinal and  
8 prospective collection of serum and banking?

9           CMDR. RYAN: The serum repository resides in the  
10 Washington, D.C. area, just north of D.C., and it is sera that's  
11 collected as -- because of HIV screening, so the sera that we  
12 have drawn when we get HIV testing close to annually is saved in  
13 this repository, and we have access to it for protocol-driven  
14 studies, so right now there's not a protocol on the table where  
15 specifically we're going to take those sera and do something to  
16 link them to the millennium cohort data, but absolutely those are  
17 things that are discussed as future protocols.

18           The limit of the sera repository is that it ends  
19 when people get out of the service, so there's no biologic  
20 specimens after that.

21           And right now there's no part of the millennium  
22 cohort that would specifically ask the invited participants to  
23 give a biologic sample outside of the sera repository that they  
24 do for the HIV work, but it's possible.

25           If there was an important question down the road,

1 then a subset of the study could be invited to give a biologic  
2 specimen or have a physical exam.

3           Currently, there's no protocol on the table, but  
4 we do recognize that as a possibility as we go forward.

5           DR. OSTROFF: Last one.

6           DR. POLAND: Greg Poland. My question -- it was  
7 actually very similar to that and extended beyond sera but also  
8 DNA samples.

9           I would urge you -- if there's any way  
10 possible -- to begin building those bridges, thinking about ways  
11 that that would happen, that would make this, I think, the most  
12 powerful prospective database bar none -- anywhere in the world.

13           The second question I had is it looks like you're  
14 going to get at some health outcomes and health-related  
15 procedures, and I recognize you have to be a bit careful with it,  
16 but are you going to be collecting any MMPI-like data or  
17 instruments that might give us hints or indicators for post-  
18 appointment breast illness?

19           CMDR. RYAN: Yes, and actually a large component  
20 of the survey part is on psychological issues, especially PTSD-  
21 like issues because that's a concern for deployers. It's not a  
22 full MMPI, and there's -- you know, it's sort of the limit of  
23 time and space to do those instruments well, but there are  
24 actually quite a few psychological-related questions, and the  
25 SF36-V which is functional status and so on folks -- interesting

1 outcome that we have put in there because that's something in the  
2 military that's been used quite a bit to assess functional  
3 status.

4 DR. OSTROFF: Thanks very much. One last, I  
5 guess, comment or question for you. When you're talking about  
6 trying to link this longitudinal data to potential exposure such  
7 as immunizations, et cetera, et cetera, to some degree that's  
8 dependent on how valid those databases are, and I'm wondering,  
9 knowing that what we're learning is that some of these  
10 potentially significant -- whether or not we're going to be able  
11 to do that -- I don't know if you want to comment on that.

12 CMDR. RYAN: Well, I completely agree. Some of  
13 the databases, I think, are extremely strong -- like the  
14 hospitalization database -- the outpatient care database is  
15 becoming strong, but I wouldn't rely on those data back in about  
16 '96 or '97, but in the -- they're becoming stronger every year.

17 The immunization database is also growing in  
18 strength and validity. You know, it previously only had Anthrax  
19 vaccines as part of the database and in the future should have  
20 all vaccines. So there's degrees of confidence that we have in  
21 the different databases, and every one we make use of, we need to  
22 bring in those experts absolutely and understand the limitations  
23 of what's in those systems.

24 DR. WINKENWERDER: I just want to make one other  
25 comment to the suggestion about -- that you weren't quite

1 comfortable answering regarding the future of this kind of work  
2 and whether it ought to be an ongoing thing. I think the answer  
3 is yes, from my view, and I believe that we've crossed a  
4 threshold in the last few years -- it's hard to pinpoint exactly  
5 when that threshold was crossed to the point that the way we look  
6 at deployment and issues that arise with respect to people's  
7 health and our ability to collect the information and to assess  
8 what, in fact, might have happened and make associations and  
9 thereby improve the protection of those individuals in the  
10 future.

11 I think it's really turned a corner and it's  
12 improving because of improvement of the databases, various  
13 different pieces and components in the infrastructure that's now  
14 in place to study the issues.

15 And without that, I think we couldn't be doing  
16 these things, so it's a lot of different pieces pulled together.

17 My sense is that -- not to suggest that I'm about  
18 to do this -- but that, if we went forward to Congress and -- you  
19 know, with a thoughtful, coherent plan and said, "We really need  
20 to make this part of a longer-term scheme," that we'd probably  
21 get a lot of support for that.

22 My belief is that people realize now we have the  
23 capability to do this and do the work effectively and thereby it  
24 ought to be just part of the way we do business, so I'm  
25 optimistic -- if that's the track we're already on, it's just a

1 matter of formalizing it.

2 DR. OSTROFF: Let me commend you for all of your  
3 presentations and for the really -- I think speaking for all of  
4 the board -- tremendous work that you do. I think you're a  
5 credit to the Navy and Department of Defense -- I really thank  
6 you for both hosting it and for what you're doing.

7 I think now it's time to move on to the preventive  
8 medicine update so we don't get behind. Let's just get into it.

9 Colonel Diniega is not here at this meeting. He's  
10 in Atlanta at the ACIP, and so we have Major Balough is going  
11 to -- are we out of sequence?

12 (Side discussions.)

13 DR. OSTROFF: Okay. He's going to give the first  
14 presentation.

15 MAJOR BALOUGH: Good morning. I'm Major Brian  
16 Balough from the joint staff, and this is unusual. I've got to  
17 thank Colonel Riddle 'cause usually I'm the last preventive  
18 medicine representative to go, so instead of getting eight  
19 minutes to talk, I usually get about 30 seconds.

20 So I'm going to try not to shortchange my fellow  
21 officers who all outrank me, but anyways (sic), I've got six  
22 slides; I'm going to try to focus on three of them, talk about  
23 some current issues which is really what the joint staff focuses  
24 on.

25 This is a significant effort that the first bullet



1 talks about. We had a December '98 memo that talked about  
2 deployment health surveillance. We spent the last 14 months  
3 rewriting that.

4 I got to lead that -- now, that effort wasn't  
5 solely my accomplishment. A lot of the officers that are in the  
6 room -- Captain Yund, Colonel Gunzenhauser, Colonel Woodward,  
7 Commander Ludlow -- or Ludwig -- they spent a lot of time  
8 updating that memo.

9 And what we did is update all of the requirements.  
10 It includes the pre and post-deployment health surveillance  
11 forms that have to be filled out.

12 Probably the most significant aspect of that form  
13 was the environmental appendix which in the '98 memo had about  
14 one paragraph. In this memorandum, there is an appendix that's  
15 eight pages. So that was probably the biggest change.

16 We updated some other things -- it  
17 includes -- with HIV and TB.

18 We're working right now with Health Affairs on the  
19 I&D protocols for small pox and botulism. Those are in staffing  
20 right now. The suspense -- we've missed the suspense on when  
21 we're supposed to get those comments done, but we're anticipating  
22 the service is getting back to us the rest of their comments  
23 sometime this week, and early next week I'll hopefully finalize  
24 and get the information back up to Health Affairs.

25 What I want to focus on in the next two

1 slides -- this slide focuses on Operation Door on Freedom, the  
2 operations in Afghanistan, and the next slide focuses on  
3 Guantanamo Bay.

4 One of the nice things that happened as we were  
5 going through the rewrite of the December '98 memo and we were  
6 staffing it with the combatant commands, very timely because  
7 CENTCOM which is the sync that runs Operation Door on Freedom,  
8 took all of the requirements that were in the rewrite memo, even  
9 though it hadn't been signed yet, and they incorporated those  
10 into their operational planning. So that was great -- that was a  
11 very big initiative and undertaken from CENTCOM to do that.

12 They've got a very robust health protection plan.

13 Their appendix for preventive medicine is about 20 pages long,  
14 which I haven't seen before. That was a very good undertaking  
15 they did.

16 Something that is working very well is, as CENTCOM  
17 moves throughout the theater and they have identified new  
18 locations where they want to put forces, they will coordinate  
19 with AFMIC -- the Armed Forces Medical Intelligence Center -- to  
20 do -- to gather the intel assessment, what's there, based off  
21 industrial hazards -- what's there -- any of the intel that they  
22 can gather.

23 That information is all going to CHPPM, U.S. Army  
24 Center for Health Preventive Medicine -- and they've been doing  
25 industrial health hazard assessments, so they're taking that

1 information, raw intelligence, analyzing it; that's going back to  
2 AFMIC. AFMIC -- or not AFMIC -- CENTCOM is placing that on their  
3 websites.

4 So all of the commanders that are out in the field  
5 on the classified web system can access that information, both  
6 from AFMIC and both from CHPPM.

7 Then we've got the deployed preventive medicine  
8 unit which is going in and revalidating all of the information,  
9 updating it and incorporating that in.

10 So from that aspect, we're doing a very good job.

11 They've got the pre-deployment and post-deployment  
12 requirements. We've had -- last count -- last time I talked with  
13 Colonel Rubertone (ph), they had about 20,000 forms -- the pre-  
14 deployment forms filled out or received.

15 The problem they were getting is all of those  
16 forms were going to the Brentwood facility which kind of slowed  
17 down all the mail, but hopefully that issue's being reconciled.

18 And they're doing weekly DMBI surveillance.

19 The joint staff memo requires weekly DMBI  
20 surveillance; they're doing that. AFEIRA is the one who's  
21 analyzing all of that data for CENTCOM.

22 Now, typically, all of that data would have to go  
23 to the Army Medical Surveillance Activity and incorporate it into  
24 our large database; however, the problem we have with this  
25 current operation is that data is classified. AMSA can't handle

1 classified data.

2 They're going to solve that because about 60 days  
3 after the operation's done the data will be declassified, and all  
4 that information will be pulled in.

5 But if we need any information on current trends,  
6 we can go to AFEIRA, and they will do that.

7 And right now -- unless one of the other  
8 representatives have better information, there's been only one  
9 potential case of a paratyphoid case, and everything else is just  
10 what we would expect to see, so we're not seeing any unusual  
11 trends.

12 This is Guantanamo Bay, and Captain Yund is going  
13 to be talking about the fleet hospital we have down there, so I'm  
14 going to not focus on that.

15 But what SOUTHCOM is doing is they've incorporated  
16 the requirements for the joint staff memo also. A lot of focus  
17 has gone into protecting the flight crews and the guards that are  
18 taking the detainees from Afghanistan to Guantanamo and then,  
19 once they're at Guantanamo, and making sure that they've got  
20 proper protection to prevent mainly spread of TB.

21 They've got guidance that they put; they're given  
22 protective equipment, requiring TB screening tests, three to  
23 twelve months after they've completed their operation.

24 They are also doing the medical surveillance.  
25 Now, because this is a fixed facility, most of their

1 environmental surveillance is being focused on the entomology  
2 aspect. They've got -- the water aspect is already pretty well  
3 taken care of.

4 The next two slides -- these are just the DMBI  
5 slides that SOUTHCOM gave us -- I can't really go into detail.  
6 Probably the significance is this -- the ones for the detainee,  
7 and we see how -- they started out at about 40 percent, and  
8 they're down around 40 percent as they're getting improved health  
9 care.

10 And then the next one -- this is the rates for  
11 task force that's down there supporting the operation.

12 And I told you I'd keep it under eight minutes.  
13 Are there any questions?

14 DR. OSTROFF: Questions?

15 REAR ADM. HART: Short question. Is this data  
16 being reported consistent with or matched with the data for the  
17 millennium cohort study and other kinds of data we're collecting?

18 MAJOR BALOUGH: I can't tell you that, sir. I  
19 don't know.

20 REAR ADM. HART: Having been on the operational  
21 side, one of the frustrating things that leads to poor response  
22 rates is duplicate, triplicate, quadruplicate kind of reporting  
23 requirements of the data inputters, so I was just wondering.

24 MAJOR BALOUGH: The pre and the post-deployment  
25 forms -- they're two-page forms. They don't ask very many

1 questions, and basically on those forms, if you answer "yes" to  
2 certain questions, you have to go see a health care provider, and  
3 they're basically there to establish a baseline -- I think it's  
4 only about eight or ten questions that they ask, and it's just to  
5 determine whether you're fit to go on a deployment.

6 I don't really think -- I mean, I'm sure the  
7 millennium cohort study's got a lot more information than they  
8 ask in the pre and post-deployment forms.

9 LT. COL. RIDDLE: If I can, sir, probably one of  
10 the leaders on the pre and post-deployment form is really a  
11 go/no-go administered prior to and then on returning, but they  
12 probably play more into post-deployment health -- practice  
13 guideline, that if an individual does have a concern post-  
14 deployment, they would receive an evaluation on the clinical  
15 side -- but then the data capture and the data relation -- is  
16 anything that's captured (indiscernible (T-1, 6711)).

17 DR. BERG: Bill Berg. I would expect that there's  
18 a significant difference in the age of the eyeballs in the  
19 preventive medicine officers and the AFEB members. Would it be  
20 possible --

21 (Laughter.)

22 DR. BERG: -- to get some of these graphs a little  
23 bit larger?

24 LT. COL. RIDDLE: They'll all be on the AFEB  
25 website. Yes, sir, you'll actually be able to download the full

1 slide presentations.

2 (Side discussions.)

3 MAJOR BALOUGH: I'll be followed by Colonel  
4 Gunzenhauser.

5 COL. GUNZENHAUSER: Good morning. I apologize to  
6 Major Balough for any minutes I stole from him in previous  
7 meetings.

8 It's a pleasure to be here this morning to give  
9 you an update from the Army perspective. I've just got a couple  
10 of topics.

11 In public health practice, of course, there are  
12 three major functions: assurance, policy development and  
13 assessment, and usually we talk about policy development 'cause  
14 that's our main business at the Surgeon General's Office.

15 But I'm going to talk a little bit about ESSENCE,  
16 which is an assessment tool that we're using and also about some  
17 health information products, and how we're assuring that some of  
18 these things are being done.

19 I think that the AFEB received a brief on ESSENCE  
20 about a year ago or sometime in the past -- Major Pavlin (ph)  
21 talked about this, and so this has evolved somewhat. I'm going  
22 to give a little bit of a background.

23 ESSENCE -- you can read what the acronym stands  
24 for there -- is a global emerging infection system sponsored  
25 prototype system that was developed a few years ago, based in the

1 national capital region, to look for the development of outbreaks  
2 of communicable disease, and basically it relies upon encountered  
3 data generated through the Ambulatory Data System that's been  
4 referred to earlier.

5           These are sent, consolidated eventually on a  
6 single server at Denver under TMA, and on a daily basis -- or at  
7 least -- before they used to consolidate in the national capital  
8 region -- I'll talk a little bit more about some of the changes  
9 now.

10           What occurs -- there's a filter put on it; you  
11 just draw out the ICD-9 diagnoses that may be related to  
12 communicable diseases, and these are grouped into seven syndromes  
13 such as fever, respiratory, germ infection and so on and so  
14 forth.

15           And the system looks at historical data to  
16 determine whether or not at a particular location currently  
17 there's a higher-than-expected number of cases.

18           Since the system draws upon a pretty comprehensive  
19 amount of data through the Ambulatory Data System, there is an  
20 ability to actually drill down, then, locally and look at some  
21 pretty specific information about particular clusters, and this  
22 is all available through a secure Internet access on Johns  
23 Hopkins live physics lab website.

24           This is a slide that -- I think we might have  
25 missed a slide there -- or maybe they got out of order -- okay,



1 it's not in there. What I wanted to mention was on September  
2 11th or shortly thereafter it was felt that this system which was  
3 implemented solely in the national capital region should be  
4 implemented throughout all of DOD so that we could detect if  
5 there was some type of BW event that occurred or some type of  
6 outbreak that was of concern.

7 So at the request of the Army Surgeon General, it  
8 was expanded to capture data from all MTF's worldwide, all  
9 medical treatment facilities. These include 121 Army facilities,  
10 110 Navy, 80 Air Force, and two Coast Guard facilities -- over  
11 300 medical treatment facilities, and on a daily basis this data  
12 is received and analyzed, looking at seven different syndromes  
13 occurring over the past seven days.

14 So you have literally thousands of possible  
15 combinations of locations and syndromes over that last week.

16 This is an example of the printout. You might  
17 wonder, geez, how can anybody possibly look at it? This first  
18 cut on how to analyze this data is pretty simplistic.

19 What occurs is that for each syndrome at each  
20 location it looks automatically at the historical average and the  
21 expected number of cases for that syndrome that has occurred  
22 there, determines the two-times-standard-deviation upper limit  
23 for that cluster, that location -- for example, the first up  
24 there, Annapolis Fever -- historical mean is .3 cases per day,  
25 and if you add two standard deviations, you'd expect up to 1.4.

1           And you can see on this particular day, 25  
2           January, there were seven events that fell into that, giving a  
3           ratio of 5.1.

4           And so what this output does is it puts all these  
5           location, syndrome clusters in order by the size of the ratio.

6           So you can quickly identify places that have a  
7           higher-than-expected number of cases in a particular syndrome at  
8           a particular location.

9           If you click on the blue hyperchecks link that's  
10          on the right -- what it does is it automatically generates a  
11          graph that looks like this, so you can quickly ascertain what  
12          that number means.

13          Here, for example, this was an outbreak of  
14          gastrointestinal illness at Fort Monmouth that occurred in  
15          January, and you can see on one particular day there was a very  
16          large spike.

17          When we went looking for information about this,  
18          we had found out that the local folks already had identified a  
19          gastrointestinal outbreak and were in the midst of investigating  
20          it.

21          We've had a number of small clusters of interest  
22          that we've identified. Most of them, local folks, have already  
23          known about -- in some cases, they didn't, so we've had some  
24          conversations about how to look at it.

25          One very interesting rather large cluster that

1 occurred simultaneously is we had a lot of gastrointestinal  
2 illness virtually simultaneously occurring at a number of  
3 training installations.

4 The local reports -- it sounded like this was a  
5 Norwalk-like type of outbreak. There had been anecdotal reports  
6 historically from training installations of the post-holiday  
7 gastrointestinal outbreaks, never clearly documented, but once  
8 this system was implemented, we saw multiple places had this  
9 occur.

10 Actually, we got a lot of help from the folks out  
11 here at the Navy, Marine Corps Recruiting Depot and from the  
12 Environmental Preventive Medicine unit here and confirmed through  
13 cultures that the syndrome was caused by a Norwalk-like virus.

14 So these are just some examples. One of the  
15 aspects that we're concerned about with ESSENCE is the timeliness  
16 of the data, and we've developed a metric whereby we look at each  
17 of the services and categorize for each medical treatment  
18 facility whether the data we're receiving from them is green,  
19 amber or red. This is an evolving process; we've identified some  
20 bottlenecks, and we're still working on improving this, and  
21 that's what this slide shows; we've briefed this occasionally to  
22 our Surgeon General, and we've made a lot of improvements.  
23 Actually, we've improved since here.

24 This is a summary -- ESSENCE is one of a number of  
25 tools that can rely on the Ambulatory Data System data, but it's

1 very powerful. It really is.

2 But there's a lot of experience that's going to be  
3 required to define how we use this -- for the various syndromes,  
4 you know, the same tool may not be exactly perfect, so for the  
5 kinds of things we're looking for, we're going to have to  
6 determine best how to use it.

7 Also, what I found is that all of a sudden we have  
8 access to data that the local folks don't, so this is really  
9 testing us in terms of developing our response capabilities, and  
10 probably we need to develop some corollary tools at the local  
11 level.

12 There are some other plans to augment ESSENCE with  
13 other types of data such as hotline call-in data, pharmaceutical  
14 usage, ICU cases and other things like that so that we can keep  
15 track of other important events.

16 Those conclude my comments on ESSENCE. I just  
17 wanted to talk just for a quick minute here about health  
18 information operations.

19 What we're talking about here is developing  
20 information products for deploying soldiers. I have a couple of  
21 booklets here, and if you just want to pass those around, Dr.  
22 Ludwig, and just show -- you can take a look at these, but we've  
23 developed a number of booklets -- for example, we have a rather  
24 large booklet on -- for health care providers deployed to the  
25 CENTCOM area.

1           We have a Staying Healthy guide for many  
2 locations, specific products about certain environmental  
3 exposures. We have NBC information.

4           And, of course, I think many of you are familiar  
5 with the blue, red and brown books that are put out by USAMRID  
6 (ph) and others on Cambayo (ph) Nuclear.

7           What our focus here -- is not just developing the  
8 products but getting them to the folks who need them. This is an  
9 assurance function -- and getting feedback on how useful they  
10 are.

11           So we have developed a metric that we track in our  
12 ops center at the Army Surgeon General's Office, looking at who  
13 the folks are that are actually deploying, getting a number,  
14 indicating that it's red unless we develop the product and ship  
15 it, and that'll make it amber, and it actually turns green when  
16 we have confirmation that the information products have been  
17 delivered to the providers, leaders or soldiers for whom they're  
18 intended.

19           This is run out of the U.S. Army Center for Health  
20 Promotion Preventive Medicine in Aberdeen, Maryland, and right  
21 now they're in the process of doing some comprehensive assessment  
22 of how good the products really are and trying to figure out the  
23 best way to deploy this information for future operations.

24           That concludes my comments. I'll be glad to take  
25 any questions.

1 DR. OSTROFF: Thank you, Colonel.

2 DR. POLAND: Greg Poland. One question on the  
3 historical means. Are those date or season-based, or is that a  
4 mean across a year?

5 COL. GUNZENHAUSER: When we started this system in  
6 October, we did not have access to historical information, so the  
7 best we could do was go back to July, and we took the last six  
8 dates.

9 We are in the process of submitting a request to  
10 get all of the historical data that's in the Ambulatory Data  
11 System so we can look at -- back -- several years back and make  
12 better estimates.

13 DR. SHOPE: Bob Shope. Is there anything  
14 comparable to ESSENCE in the collection of laboratory requests or  
15 laboratory data?

16 COL. GUNZENHAUSER: That is something that is  
17 being looked at, but right now in this system we don't have  
18 access to that.

19 The laboratory data could be consolidated, but  
20 it's not accessible centrally -- all the kinds of lab tests that  
21 we would like to look at, so I think that's -- I'm pretty sure  
22 that's a product that's being looked at not only by  
23 ESSENCE -- the staff that's working on it, but some of the other  
24 folks that are developing other products as well. Currently, no.

25 DR. OSTROFF: Dr. Patrick, Dr. Ness.

1 DR. PATRICK: Kevin Patrick. Two  
2 questions -- one, actually, on this ESSENCE system. Very  
3 impressive. It's really exciting for surveillance.

4 My question is: Are you doing any exploration or  
5 partnering with local, nonmilitary health departments in  
6 communities to aggregate data in a graphic area within the  
7 ESSENCE project?

8 COL. GUNZENHAUSER: There was quite a bit of work  
9 in the national capital region when this was originally stood up,  
10 and there's still some talk in the national capital region to do  
11 that.

12 I think that the reality is -- at least for this  
13 outpatient data -- we're of a very unique system in having access  
14 to this kind of information across a wide geographic area.

15 Some other places have expressed interest. I know  
16 some other MTF's have talked about working with their local  
17 partners, civilian partners. I know in New York City, for  
18 example, there's a number of surveillance tools which they use  
19 there, and we have tried to make some efforts to compare what  
20 we're seeing with them.

21 For example, with this gastrointestinal  
22 information, we asked the folks up at New York City whether they  
23 saw a comparable outbreak there, and they did not at the time.

24 But currently it's not integrated -- certainly not  
25 electronically.

1 DR. PATRICK: It would just seem -- Mr.  
2 Chair -- that this would be a wonderful opportunity to do some  
3 partnering -- and define pilot projects in a few local areas --  
4 this is an exciting area, very important area of public health.

5 The second question relates to the health  
6 information -- is there a -- I notice that these are largely  
7 print-based materials. Is there any exploration that -- CHPPM --  
8 is that what that's called?

9 COL. GUNZENHAUSER: Correct.

10 DR. PATRICK: That they're doing with computer-  
11 based learning media as well for these areas?

12 COL. GUNZENHAUSER: I know that's something  
13 they're very actively thinking about now is how to use the  
14 Internet to get products to folks and how to use the right  
15 educational venue so that learning actually occurs.

16 DR. PATRICK: But a lot of data to support  
17 that -- again, this generation of folks that are coming along --  
18 really learn quite well these kinds of things in a non-print-  
19 based approach.

20 AUDIENCE MEMBER: If I may, a lot of those  
21 products are available at the CHPPM website.

22 COL. GUNZENHAUSER: Correct.

23 COL. GIBSON: Colonel Gibson from Health Affairs.  
24 I wanted to echo the issue on the Washington, D.C. area. There  
25 is an ongoing effort there that's being led by the American



1 Public Health Association to build an early-detection model in  
2 the Washington, D.C. area, and we're at the table with those  
3 folks.

4 DR. NESS: Roberta Ness. I just wanted to point  
5 out -- you may very well be aware of this, but there's a very  
6 unique system being built also -- it's a collaboration between  
7 the University of Pittsburgh and Carnegie Mellon University which  
8 uses not only laboratory-based information but, in fact, text-  
9 based information from physical diagnosis and utilizes fairly  
10 sophisticated computer algorithms with respect to text mining.

11 And if you're not aware of that system, I'd urge  
12 you to -- I can certainly put you in contact with the folks that  
13 are working on that, but it's very unique and, in fact, so unique  
14 that just a couple of weeks ago we were lucky enough to have  
15 President Bush come down and highlight the activities that were  
16 going on in that area.

17 COL. GUNZENHAUSER: Thank you.

18 AUDIENCE MEMBER: Does the ESSENCE system -- how  
19 does that compare to the EWAR system which Captain Corwin has  
20 developed and implemented in Southeast Asia? It is a similar  
21 system, or is it a different system?

22 COL. GUNZENHAUSER: I'm somewhat familiar with  
23 that system. I think that's somewhat different. The main focus  
24 here is that we're using all encounters, and we're using existing  
25 ICD-9-coded data and pulling that electronic -- I think EWAR's is

1 more MT -- clinic-based and coding in certain syndromes. It's a  
2 little bit different implementation, but the intent is the same -  
3 - to look at certain syndromes and identify them early, but  
4 they're really different infrastructures in how they're created.

5 I'm sorry -- there may have been one other  
6 question that you'd like to have answered.

7 DR. CATTANI: Jacqui Cattani. Obviously,  
8 surveillance right now is "the" hot issue affecting particular  
9 biological terrorist events, and there are lots of different  
10 systems out there. Some of them are developing so quickly that  
11 the right hand doesn't know what the left hand is doing.

12 My question is: If your system -- well, one of  
13 the limitations of ICD-9 codes is the timeliness with which you  
14 can identify an event, and the more real time a surveillance  
15 system can be, the more effective it is.

16 I was wondering if you would like to comment on  
17 that. Several other -- McDill, for example, is implementing an  
18 Internet-based system that they can enter data directly on the  
19 web in -- from emergency rooms and nurse call stations and  
20 hopefully from clinics, and we'll be able to identify events  
21 within a -- less than a 24-hour period, basically, and they are  
22 linking with -- I might just add -- in the Tampa Bay area there  
23 are nine hospitals on an emergency room surveillance system,  
24 looking at syndromes, that will link with this McDill system  
25 which is slightly more flexible.

1           And I wondered how you see this system based on  
2 ICD-9 codes in the context of real time surveillance. It seems  
3 like this is a very comprehensive system that over time you can  
4 look almost retrospectively that these things have occurred, but  
5 as you yourself pointed out, the local area identified many of  
6 these outbreaks before the system, so how do you see this system  
7 fitting in with these more real time surveillance systems coming  
8 out?

9           COL. GUNZENHAUSER: I think it's a good question.  
10 I'm not sure we have a good feel for exactly how near real time  
11 we can make this system.

12           Our green category up there for timeliness was  
13 over 50 percent of the data received from an MTF had been  
14 generated within the previous three days.

15           At an individual treatment facility, some systems  
16 use paper forms; the provider probably fills that out at the end  
17 of the day. Sometimes these are fed in batch mode maybe a day or  
18 two later.

19           Some systems are all computer-based where the  
20 provider actually enters the diagnostic code that day and it is  
21 electronically available.

22           Even once the data's entered, it's still a stream  
23 of nodes until it's consolidated on the Denver server, so there  
24 is a delay, and we've looked at all of those, and we certainly do  
25 see that, when the SAS routines are run overnight, we do see data

1 from the day before, and we're looking at that to see how near  
2 real time it can be.

3 Agreed in certain situations where you don't have  
4 a system -- maybe like this one where you can't get the data  
5 immediately -- you may need to set up some other system where  
6 maybe folks -- I guess there's a tradeoff in some of the other  
7 systems having staff available, particularly in a crunch  
8 situation, to enter the data.

9 I understand in New York City they deploy a small  
10 team of EIS officers up there at the emergency rooms in order to  
11 ensure that data got entered so they could use another tool to  
12 monitor that. So there is a tradeoff, and that's why I agree  
13 it's probably important that we have several different systems  
14 that we can apply that fit the needs of a situation.

15 DR. OSTROFF: Thanks. I think we're going to have  
16 to move on, but let me just comment that I think one of  
17 the -- don't overlook the fact that one of the most impressive  
18 things, at least to me being an old-fashioned epidemiologist,  
19 that most of the time you saw something on the system, they  
20 already knew about it. That means that people are watching --

21 COL. GUNZENHAUSER: Yes.

22 DR. OSTROFF: -- where they need to be watching.

23 Let's move on to Colonel Woodward, a new  
24 representative taking over for Colonel Bradshaw and tough shoes  
25 to fill, but welcome.

1 LT. COL. WOODWARD: Thank you.

2 Good morning; it's a pleasure to be here  
3 representing Air Force preventive medicine.

4 This morning, I'm going to touch on two areas very  
5 briefly. First, I'm going to use an example of how we've derived  
6 benefits from our immunization registry system, and then second  
7 talk about -- just mention a couple of hot issues in Air Force  
8 preventive medicine today.

9 I'm going to use an example of a recent recall of  
10 hepatitis -- certain lots of hepatitis-A vaccine by the  
11 manufacturer -- put us -- gave us a problem to deal with in the  
12 Air Force, and that was how do we identify, in responding to this  
13 vaccine recall, how do we identify the magnitude of the problem  
14 in the Air Force and then come up with a remediation plan to  
15 assure that people are protected against the hepatitis-A virus?

16 Our approach was to use our Population Health  
17 Support Office to mine the Air Force Complete Immunization  
18 Tracking Application which is our immunization registry system to  
19 find out just how big this problem is, was, and identify the  
20 individuals impacted.

21 And what we found was that our Population Health  
22 Support Office -- the analysts there were able to go into the  
23 database and within six hours of asking them to look at the data,  
24 they had actually scoped out the problem for us and the results  
25 that I'll show you on the next slide.

1           What we found in our immunization tracking system  
2 is that we had about 113,000 Air Force people -- people in our  
3 system had received a hepatitis-A vaccine from the manufacturer.

4       Of those people who -- from this particular manufacturer, of  
5 those who had received the vaccine, about 10,000 of those had  
6 received vaccine from the affected lots.

7           We then further refined -- they further refined  
8 this to identify people who were still -- people who we could  
9 actually tell where they lived and where they were located and  
10 identified by name and got down to about 9,000 adults and  
11 children who had received affected lots of the hepatitis-A  
12 vaccine.

13           We thought that this -- we think that this  
14 database proved to be fairly robust because we only had about 150  
15 people in the database who did not have a recognizable lot  
16 number, so people had been incredibly -- our technicians and  
17 people out at our clinics have been very fastidious in putting in  
18 all of the relevant vaccine-related information in the system,  
19 and we think this is a very powerful thing.

20           Also, the Population Health Support Division was  
21 then in a couple more hours able to actually identify -- generate  
22 for every clinic in the Air Force a list of individuals who were  
23 affected by -- who had received vaccines from the affected lots.

24           What we then did was we then developed guidance to  
25 send out to the field to tell them how to respond both

1           logistically and clinically to the vaccine recall, and then  
2           through a secure website provide it to every MTF -- the list of  
3           by-name individuals and what their present location was,  
4           according to the database, and everybody was able to access that  
5           and download that and then actively reach out and touch people  
6           who we knew had been affected by this recall and, of course, also  
7           have a pass system around as people came in who might not have  
8           been identified by this recall, though we think that number is  
9           quite small.

10                         Just a little bit about our immunization tracking  
11           system -- AFCITA -- it's a system that started in about 1997 and  
12           is currently used in all of our active-duty facilities, 98  
13           percent of Air National Guard facilities and about 88 percent of  
14           reserve installations, and currently we have records on over  
15           600,000 active guard and reserve Air Force members and an  
16           increasing number of other beneficiaries. It's used not only for  
17           active duty but all immunizations provided to dependents and  
18           retirees in our military health system. It is our sole  
19           documentation system for immunizations in the Air Force.

20                         It also is -- dovetails into our readiness  
21           tracking system, so we use it to improve performance in terms of  
22           coverage of vaccinations amongst all of our populations but also  
23           to support our readiness monitoring so that we know that troops  
24           are ready to go and immunizations is a critical piece of that,  
25           and our immunization system feeds directly into our overall

1 readiness tracking system.

2 I think this case for us demonstrated a sort of  
3 second order benefit from immunization registries and responding  
4 to this recall.

5 Of course, our system has also been very helpful  
6 in having us improve vaccine coverage levels for active-duty  
7 people as well as for children and other beneficiaries.

8 For example, in terms of improving coverage, we  
9 now know that -- we can now demonstrate in our system that over  
10 90 percent of active-duty Air Force people have completed the  
11 hepatitis-A vaccination series, so we think it's also very  
12 helpful in the performance feedback mode.

13 I'll just mention two hot issues. First and  
14 foremost, prevention has long been the foundation of force  
15 protection. It is now -- we are now having an increasing  
16 proportion of work in our preventive medicine areas that is  
17 targeting countermeasures for biological, chemical and nuclear  
18 agent threats.

19 Also, the recruit assessment program is a growing  
20 initiative in the Air Force, and we'll talk extensively about  
21 that tomorrow, but I do just want to mention that the priorities  
22 for the Air Force are to have a system that not only supports the  
23 lifelong longitudinal assessment of the health of our members but  
24 also one that has relevancy and immediacy to impacting the health  
25 of our youngest troops.



1           So you'll hear tomorrow that that's our area of  
2 emphasis with the recruit assessment program.

3           And that's all I have prepared. Thank you.

4           DR. OSTROFF: Any quick questions?

5           DR. GRAY: This is Greg Gray. I'm wondering about  
6 your immunization registry validation strategies. How do you  
7 know your data are accurate?

8           LT. COL. WOODWARD: We are just now actually  
9 exploring that. It's been a system where we have been -- since  
10 it's been implemented in '97, we have gone back in and had people  
11 have to transcribe back immunization records as far back as they  
12 go as well as real time -- include information in there, and what  
13 we have found is there are some problems in validation, and we  
14 are now -- just now exploring that, and this is one example of  
15 what prompted us to say, "Well, we need to start exploring the  
16 validity of the data," because its original intent was to improve  
17 immunization coverage, and therefore it was really used as an  
18 individual-level and unit-level feedback mechanism to say, "Kelly  
19 Woodward had all of his immunizations; everybody in the unit had  
20 all of their immunizations." And so it was the feedback loop,  
21 quite honestly, to the people inputting the data in -- was to get  
22 Kelly Woodward right on his immunizations.

23           But you're asking the question we're now  
24 asking -- and that is, "How do we know it's all accurate?"

25           One of our -- we thought it was very powerful to

1 see that, out of 113,000 records of people who had hepatitis-A  
2 vaccine from one manufacturer, only 150 of them -- the lot number  
3 didn't seem to make sense. The rest of them either matched  
4 exactly the lot numbers of the manufacturer of the affected lots  
5 or was a very close match, which at least suggests some pretty  
6 rigorous attention to data entry.

7 DR. GRAY: It sounds like you folks are ahead of  
8 the other services, and I think what you find in your validation  
9 would probably be very useful to other services who attempt to do  
10 the same, and I want to encourage you to share that.

11 LT. COL. WOODWARD: Absolutely. Yes, sir.

12 DR. OSTROFF: Dr. Gardner?

13 DR. GARDNER: Just a comment of -- hepatitis-A  
14 vaccine in general -- the -- I wonder if you thought about -- I  
15 was on the Advisory Committee for Immunization Practices during  
16 the introduction, and the first approvals for hepatitis-A were  
17 for three-dose in kids, and then, based on serologic data, it  
18 went to two-dose, but there's a lot of epidemiologic  
19 evidence -- using it in epidemic situations -- that one dose is  
20 quite effective, and we consider people protected after the first  
21 dose while they're waiting for the second dose, and there's  
22 excellent immune memory with booster responses, even far down the  
23 line.

24 So I've always sort of felt -- and there's never -  
25 - and we don't have to worry about chronic infection in

1 hepatitis-A, so we're just trying to prevent the spread and the  
2 immediate illness.

3           So I've always been the gadfly saying, "Do we  
4 actually need more than a single dose to provide real  
5 protection?" The second gives you a higher antibody level, but  
6 you are going to get an anamnestic response after -- if you see  
7 the virus and probably get very good protection.

8           So I would have been willing to settle for a  
9 single good dose.

10           How many -- were most of these folks -- had  
11 received a full-strength dose and then got the -- another dose  
12 that was subpar and now there's recall, or -- and if that were  
13 the case, you might not have had to do anything.

14           LT. COL. WOODWARD: Yeah, and part of the response  
15 to this recall was recommended by the manufacturer that, if  
16 people had received -- had received two doses of hepatitis-A  
17 vaccine with one or both being from the affected lots -- was to  
18 actually do serologic testing before reimmunizing.

19           We were actually talking with the manufacturer  
20 about whether we'll have enough of our people choose serologic  
21 testing to be able to do some sort of analysis of the  
22 seropositivity rate, if you will.

23           DR. GARDNER: Thanks. That would add some light  
24 to the debate.

25           LT. COL. WOODWARD: Yeah.

1 DR. OSTROFF: Thank you. The preventive medicine  
2 update -- that is, I think we're going to modify the schedule a  
3 little bit. Dr. Winkenwerder has to leave fairly soon, and what  
4 we'll do is we'll move on to the adenovirus presentation and make  
5 sure we get that in before he has to leave.

6 We have Mr. Bill Howell who is deputy director for  
7 acquisition and advanced development who accepted our invitation  
8 to give us an update about an issue that's been of great concern  
9 to the board for a long time. Thank you for coming.

10 MR. HOWELL: Not a problem. Thank you. In fact,  
11 I've been able to leverage a couple other meetings, one of which  
12 is at 1:00 this afternoon in the north side of San Diego, so I  
13 appreciate moving me forward as well.

14 Okay. I don't want to talk too much about  
15 background. Most everybody here probably is familiar with  
16 adenovirus and how we got in the dilemma that we're in, but just  
17 to make sure we're on the same playing field, Wyeth was the  
18 original manufacturer of the tablets that we use, both for set 4  
19 and 7 adenovirus, two separate oral tablets which they use for  
20 the vaccine.

21 In time, as the FDA does, they go through and they  
22 look at your projection methodologies and such and in many cases  
23 will force you to do an upgrade to your facility to be able to  
24 maintain to whatever GMP standards that are there.

25 They came through -- this particular vaccine is a

1 fairly old vaccine -- they came through the manufacturer back in  
2 the '90s, said, "You have to upgrade." Wyeth was not making a  
3 profit to speak of on this particular vaccine, so they came to  
4 the service and said, "Okay, I need y'all to fund this upgrade,"  
5 and in fact then we got stuck with a bill that none of us had  
6 anticipated, and in the end the dollars -- I don't want to get  
7 into the political game -- the earlier administration did not  
8 support it, and so the actual vaccine -- Wyeth discontinued it  
9 and went away.

10 We used up the last of the vaccine in '99, and as  
11 we saw quickly thereafter, the outbreaks followed.

12 That got the attention of the administration, and  
13 since then we have some dollars. We had 14 million originally in  
14 '99; we've had another seven million offset to that.

15 We spent a great deal of time -- I have to tell  
16 you -- there was an effort about three years ago to get Wyeth to  
17 pass that particular technology on to Greer down in North  
18 Carolina, and we worked for about three quarters of a year trying  
19 to make that pass. It failed.

20 In so doing, Wyeth became very hesitant to get  
21 back in the game at all. They say, "We spent about a million  
22 dollars of our time and effort trying to pass over to Greer for  
23 DOD," and at that point in time they said, "We've done our best  
24 offer, and we're just out of the business. Goodbye." And so it  
25 took us awhile.

1           If we were going to actually go to the quickest  
2 and most efficacious way to get a vaccine, going out and getting  
3 a new manufacturer and starting from scratch wasn't the way to  
4 get there 'cause it would have cost a heck of a lot more in time  
5 and money.

6           So we went back and we basically, you know, cooled  
7 our heels and went over to Wyeth and sucked eggs and tried to  
8 plead to them to come back in, and in fact, after about three  
9 quarters of the year, working actually with the president of  
10 their vaccine division, we finally got them to come back and say,  
11 "Okay, we will work with whoever you contract to. So, once you  
12 have a contract and you're firm, you're going to somebody, we  
13 will come back, we will sit down with them, we'll give them our  
14 production methodologies, we'll give them all the formulary and  
15 the rest so that they can make it, but until that time period  
16 we're going to sit on the sidelines and watch."

17           At this point -- at the same time we were doing  
18 this, we also had Wrair doing some work to try and help out to  
19 reduce the risk for whoever the new manufacturer would be and  
20 trying to pre-do some workup that would assist them in their  
21 process of getting FDA approval, and you can see the list of  
22 things there; I'm not going to go through all of them  
23 individually.

24           The bottom line is what we tried to do is -- by  
25 getting this effort in Wrair, we wanted to try and show whoever

1 the prospective manufacturer was going to be that we were in the  
2 long haul with them, and in fact we were willing to take on some  
3 of the effort to try and reduce their risk in getting this  
4 vaccine used and approved.

5 As I noted before, we got another seven million  
6 dollars this last year. The reason we needed that is because the  
7 actual first proposals that came in when we finally got to the  
8 contracting stage were over the 14 million dollars. We had to  
9 get to about 18 million dollars to get somebody in.

10 And we did award back on September 1 to Barr  
11 Laboratories. Now, those who are not familiar, Barr is a generic  
12 drug manufacturer.

13 We had about three different bidders. All of them  
14 were combinations of different people.

15 Barr has a great deal of knowledge in the  
16 tableting process and the production process which, of course,  
17 that's what this is, and that was one of the problems we had with  
18 the Wyeth process to start off was the tableting methodology they  
19 had was almost a World War II vintage tableting system.

20 And that's why -- one of the reasons why Barr  
21 Laboratories and Best Value Contract was looked at as a valued  
22 partner in this.

23 Also, they have combined themselves with VaxGen.  
24 VaxGen actually has an offshoot -- is an offshoot of Wyeth and  
25 has hired some of the people who were involved in the actual

1 production of the product, so it has been somewhat insidious in  
2 the sense they moved over from one manufacturer to another, but  
3 that is certainly something that we can leverage, and we're all  
4 in favor of.

5 So our strategy, then, was obviously to pursue the  
6 quickest means of getting back into remanufacturing with any  
7 reasonable cost. That sounds like motherhood and apple pie.

8 But in so doing, we wanted to maintain our  
9 relationship with the FDA. We had talked with the FDA certainly  
10 up front as to what was the best methodology for us to get there  
11 and would they accept the old one with an -- old vaccine with an  
12 upgrade if we did bridging studies and things of that nature that  
13 would try and expedite it, and they've been pretty good, the FDA,  
14 so far.

15 We wanted to make sure the contract was with an  
16 established manufacturer.

17 When we first did an RFI two years ago out on the  
18 street -- and how we ended up with Greer three years before is  
19 nobody else wanted to touch it. It just didn't have a profit  
20 motive in it. There's just so little manufacturing involved in  
21 this and so little use of the product outside of the services, it  
22 was not worthwhile.

23 So we tried to get the contract in a manner that  
24 we could get to someone who was fairly established -- obviously,  
25 keep Wyeth in the process as best we could, and the other two I



1 already talked about.

2           So where are we at the moment right now? Barr is  
3 in the process of doing -- or in the process of getting whatever  
4 their agreement they need with Wyeth to be able to gain the  
5 information to be able to build their production plant.

6           Now, two pieces in that. One, many of you may  
7 know that the adenovirus is actually a very good carrier for  
8 other particular means.

9           So they don't want to give it away free. There  
10 is -- in the sense they will do it free -- rephrase -- but they  
11 do have proprietary rights -- Wyeth does -- and they have to make  
12 sure from a legal standpoint they've got those agreements in  
13 place before they can pass it. But they're doing that at no  
14 cost.

15           They're in the process right now -- American Home  
16 Products owns Wyeth now in the new conglomerate of vaccine  
17 manufacturers, so Wyeth has already forwarded that legal packet  
18 up to American Home Products, and so we're working now with  
19 American Home Products -- and hopefully get that packet out and  
20 get the disclosure -- the information there all done.

21           In the meantime, we're working -- Wrair is working  
22 also to continue that support for the next three, four years.

23           The important piece out of that is not only the  
24 expertise that Wrair has in the science behind it but also when  
25 we get into clinical trials -- many of you know that we'll be

1 doing the clinical trials, actually, with military people.

2 And so to have a military institute to help Barr  
3 get in and do their clinical trials, I think, is pretty  
4 essential.

5 Here sort of shows you the schedule as it was laid  
6 out as to how long it will take.

7 Barr does not have to build a whole new facility  
8 for this. It's just an offshoot that they're -- basically a  
9 little wing that they're going to build to be able to do this.

10 That was one of the things that stopped us with  
11 Greer. Greer wanted to build a whole manufacturing plant for it,  
12 so we would have taken on a lot of the infrastructure costs that  
13 we will not have to take on in this particular contract and why  
14 the cost is less.

15 But you can see all the way  
16 through -- unfortunately, we will have to do clinical trials  
17 because as a new manufacturing process -- we will have to get, of  
18 course, the facility through FDA. That just takes time. They  
19 have to build it, so we're looking at an 18 -- really, an 18-  
20 month-to-24-month window to get the manufacturing piece built and  
21 through the FDA to get GMP standards to be able to go into the  
22 clinical lots -- clinical trials that will follow thereafter.

23 But our plan today would have an O-7 adenovirus  
24 production that we could then start to put back into the  
25 troops -- into the trainees.

1           So you can see the bottom end -- the  
2 responsibility -- Barr is obviously the overall contractor that  
3 we're working at, and they will do the final tablet production.

4           VaxGen is actually going to make the virus  
5 itself -- excuse me, Bioreliance is actually going to grow the  
6 virus -- that's another affiliation they have -- pass to VaxGen  
7 who will then put it into a lifelyzed (ph) form who will pass it  
8 to Barr who will then actually put it into its final form.

9           So, unfortunately, it's sort of a convoluted way  
10 in which we've got to go about it, but sort of the only way that  
11 we saw -- and a reasonable one -- rational manner to get there.

12           I think that's it. Oh -- excuse me.

13           Funding -- this is the good news. If I would have  
14 sat here 18 months ago, I would have told you I didn't have any  
15 money, and then through time we got about 18 million dollars or  
16 20 million dollars to get it started, and this is the money that  
17 came down in PDM recently and the last bill that came across.

18           So we have a fully funded program, and if you look  
19 at the 10 million in FY07, better than half of that is actually  
20 making product -- actually into field.

21           DR. OSTROFF: Thank you very much.

22           MR. HOWELL: Sure.

23           DR. OSTROFF: I continue to be amazed at what a  
24 tragedy this entire story is.

25           I appreciate when you say you're making a diligent

1 effort to be able to obtain the vaccine at a reasonable  
2 production cost.

3 I guess my question to you was what might  
4 potentially be an unreasonable production cost to truncate this  
5 schedule somewhat? I mean, here's a situation where you  
6 basically had the perfect product. It worked great.

7 And now you're stuck with a situation where you're  
8 coming up with a new product that's going to take five years to  
9 produce.

10 Many of us have difficulty understanding why it  
11 takes so long.

12 MR. HOWELL: By and far, the largest piece of that  
13 is -- even though it may be the same product, it has some  
14 new -- it will have some nuances because of the way the FDA is  
15 rated, but largely it's -- the fact that we've gone to a new  
16 manufacturer and you've got a new production piece.

17 The old production line's gone -- actually, Wyeth  
18 took it and is making something else there, so we don't have a  
19 production plant that we can go back to.

20 So you've got at least a 24-month window bringing  
21 that particular piece up.

22 Then the time limit to do clinical trials -- even  
23 though it's the same product again -- the time period -- or very  
24 close to the same product -- the time period to get through three  
25 phases of clinical trials will unfortunately eat up a good two

1 and a half years.

2 And then you look at the time period in between  
3 with the FDA discussions and the rest, we get to five years  
4 pretty quick.

5 DR. WINKENWERDER: Let me just add my voice here.

6 This is one of the most disappointing facts and stories that  
7 I've learned upon coming into my position, and I was extremely  
8 disappointed to hear about this, really -- and I don't want to  
9 cast aspersions on anybody who had responsibility in the past,  
10 but to be blunt this is a major screw-up, and, you know, I am  
11 committed to trying to accelerate this.

12 So what I've heard is not acceptable, as far as  
13 I'm concerned.

14 MR. HOWELL: Sir, we can certainly go back and  
15 talk to Barr and see what means --

16 DR. WINKENWERDER: Well, we will, and I'll  
17 be -- and Ms. Embrey will be meeting with whoever we need to meet  
18 with to accelerate this because we've got to make it -- we've got  
19 to make things move more quickly than this -- and, you know, I  
20 understand how the FDA works, but the FDA on the other hand is  
21 going to make, you know, the process work with a small pox  
22 vaccine in, you know, one fourth of the time. So if it can be  
23 done there, it can be done here.

24 MR. HOWELL: Certainly -- I would agree with you.

25 As a minimum, we should anticipate that we'll get into a fast-

1 track sort of situation with them.

2 DR. WINKENWERDER: Right.

3 MR. HOWELL: And we would -- I'll be honest with  
4 you, sir. The thing that's been driving this timeline to a  
5 certain degree has always been dollars as well. I mean, we  
6 haven't even gotten to the table till we got to the dollars.

7 DR. WINKENWERDER: It's very simple to me. If you  
8 believe that this is something that we should do, then we should  
9 do it and do it well.

10 If we don't, then we shouldn't do it, and we  
11 shouldn't complain.

12 But I think the decision has been made that we do  
13 believe this is important, and we do believe that it prevents  
14 morbidity and mortality.

15 MR. HOWELL: Yes, sir.

16 DR. WINKENWERDER: And we need to do it, so we  
17 need to get it done.

18 DR. OSTROFF: Here -- and then Greg.

19 DR. PATRICK: Kevin Patrick. Among my other  
20 roles, I direct a student health center that services 32,000  
21 students -- college students. It's hard for me to imagine that  
22 there's not another market here --

23 DR. WINKENWERDER: Yes, sir.

24 DR. PATRICK: -- for this vaccine or drug, and I  
25 just wonder if there's an opportunity --

1 MR. HOWELL: That area has been approached. In  
2 fact, that was one of the things we tried to stretch with Wyeth,  
3 and it was also part of the demographics certainly that Greer was  
4 looking at -- is could they sell in another location.

5 Historically, no, there's been no market there.  
6 Does that mean that with a good marketing program you could bring  
7 a market there? It's certainly possible.

8 DR. PATRICK: Well, I think with a good marketing  
9 program, in fact, they could, and our recent experience with the  
10 pneumococcal vaccine, for example, amongst college students and  
11 directed to consumer marketing and approaching parents has  
12 generated a tremendous interest.

13 So I think, if there's an opportunity to pull in a  
14 marketing expert on this and work with the population of folks  
15 that serve these 15 million people who are college students, it  
16 might help accelerate this process.

17 MR. HOWELL: Very good. Yeah.

18 DR. OSTROFF: Dr. Gray being an expert on this  
19 particular issue -- and I know you're doing some studies, looking  
20 at viral illness and a new college population in Iowa -- maybe  
21 you want to comment.

22 DR. GRAY: Well, thanks. Yeah, in addition to the  
23 estimated 1,200 to 1,400 unnecessary medical encounters that  
24 we're seeing from this loss in the military, there's strong  
25 evidence now that this -- some of these strains have changed.

1           In fact, there is a paper in press, Emerging  
2 Infectious Diseases, that's due to come out either in March or  
3 April, led by Dean Erdman (ph) of the CDC and Dr. Ryan and I,  
4 showing that new genotypes of adenovirus-7 have been associated  
5 with 27 deaths in various U.S. civilian populations since 1996.  
6 I strongly endorse the concept that there would be other markets.

7       I think we need to try to figure out ways to partner the  
8 military interests with the civilian interests and special  
9 populations that might benefit from these vaccines.

10           DR. BERG: Bill Berg. I have two questions. In  
11 what appears to be a press release from Barr Laboratories,  
12 there's a statement among potential problems, outcome of legal  
13 proceedings including Eli Luway's (ph) appeal to the Supreme  
14 Court. What's that all about, and how does that impact the  
15 adenovirus --

16           MR. HOWELL: To be honest with you, we don't know  
17 ourselves what that means. I have not even heard that before.

18           DR. BERG: My second question is --

19           MR. HOWELL: Sorry.

20           DR. BERG: -- in your description you said that we  
21 have to go through all of these hoops regardless of the fact that  
22 it's an old vaccine, and then you also interweave that with "but  
23 we're making some changes in it". Could this be speeded up if we  
24 exactly duplicated the old process and then refined it later on?

25           MR. HOWELL: I think that's the whole problem is



1 we can't exactly duplicate the old process, because that's what  
2 the FDA said wouldn't come up to standard. There's a tavening  
3 (ph) piece and a growth piece within the virus that we have to  
4 change from the old process that was there.

5 So we do have to make some manufacturing changes,  
6 but the -- I have to tell you, I don't think that's a  
7 great -- it's going to take a little time, but from a technical  
8 risk, there's very, very little technical risk there. The  
9 problem is going to be is that we're going to have to do the  
10 trials, but we may not have to do them in the size and the number  
11 that you'd have to do an initial piece. We're looking at  
12 hopefully a bridging study, for example, in a phase 3 trial that  
13 would give us a smaller sampling that would allow us to look at  
14 the efficacy against the old one and therefore go forward.

15 So there's some means in which I think we can  
16 lower the normal standard time, but at least in talking with the  
17 FDA at this point, they're not willing to give up the normal  
18 standard pieces.

19 DR. BERG: Thank you.

20 MR. HOWELL: Yeah. Dr. Winkenwerder, before I  
21 leave, I think it would be of great usefulness if, in fact, you  
22 or Ms. Embrey wanted to get involved in the conversation directly  
23 with American Home Products -- would work to break that legal  
24 stranglehold we've got at the moment to get them forward.

25 DR. WINKENWERDER: Well, the -- we will and

1 with -- not only for the Barr side but also Wyeth is -- we've got  
2 another issue with -- you know, they're the owner of the DRYVAX  
3 vaccine.

4 MR. HOWELL: Right.

5 DR. WINKENWERDER: So we've got two wonderful  
6 topics to talk about. You know, I want action.

7 MR. HOWELL: Yes, sir.

8 DR. WINKENWERDER: I want results. That's what  
9 we're here about. I was just saying to Dr. Ostroff that the  
10 irony is that -- and all of our worry -- and there is real worry  
11 about using the small pox vaccine and the possible mortality  
12 associated with that. Just on the back of the envelope, the  
13 numbers that you might calculate for mortality associated with  
14 that or morbidity for the military population is no different, no  
15 worse, in fact, probably less than the mortality and morbidity  
16 that we're incurring because we don't have this vaccine right  
17 now. That's just -- you know, it's unacceptable. So we've got  
18 to make this thing move. We will be in touch. It's the top  
19 priority.

20 MR. HOWELL: Great.

21 DR. OSTROFF: Can I ask one quick question? Do  
22 you have any sense as to what the track record is of Barr in  
23 bringing products to market within the time frames that they say  
24 they're going to bring them to market?

25 MR. HOWELL: I think that's one of the reasons why

1 we selected them, because two other people were nowhere near as  
2 experienced. Again, they're a generic drug manufacturer. So  
3 they do the back -- they're not necessarily a discoverer, but  
4 they are able to bring things to market in a manner that they've  
5 been able to crack into the market for those generic drugs.

6 So I feel really pretty secure that they'll be  
7 able to get it. In fact, I think the five years -- between me  
8 and y'all, I think the five years might be a little bit extreme,  
9 because that was based upon prior to knowing could they get into  
10 a fast track mode with the FDA and what would the time periods be  
11 and the turnaround of the paperwork with the FDA and things of  
12 that nature.

13 So there is some potential to do some shrinkage in  
14 there, not -- it may be somewhat marginal, but I think that's a  
15 relatively decent timeline. Anything earlier than that -- we  
16 were originally talking three to four years before that. I think  
17 that was pretty optimistic, to say the least.

18 DR. BERG: Bill Berg. The -- Merck recently  
19 announced a shortage of MMR vaccine. How often is that -- to  
20 what extent is that given to recruits? It used to be standard  
21 issue, but cohorts who got a second dose may have reached the  
22 point where the military no longer needs to do it. So, in other  
23 words, is the shortage of MMR impacting the immunizations we give  
24 the recruits or is that a past issue?

25 MR. HOWELL: I'm not sure I'm the guy that should

1 be answering that.

2 DR. OSTROFF: I think what we're going to do  
3 is -- was there --

4 COL. STAUNTON: I just wanted to raise one other  
5 issue on the international front as to what the status is now of  
6 the adenovirus vaccine with two potential outcomes. One is  
7 (indiscernible) speeding up the process, which obviously is of  
8 extreme importance, and the other is actually the potential for  
9 partnering in arrangement, say, with the (indiscernible).

10 MR. HOWELL: Traditionally, unless there was  
11 some -- how do I say this diplomatically? Unless there was some  
12 technology or some mechanism that you were going to bring to the  
13 table that we didn't already have in hand, that would certainly  
14 increase our capability and then, therefore, shorten it. I would  
15 be all in favor of it.

16 In this particular piece I think we've got it all  
17 together. It's just going through the -- you know, going through  
18 all the numbers.

19 Does that mean we wouldn't share our information  
20 and our findings and the rest of it? Certainly we can do that.  
21 But I'm not quite sure at this point, without seeing what it is  
22 you could bring to the table, where's the differential we're  
23 looking at at the moment? Unless you already had an adenovirus  
24 that was there and a production plant already there, but  
25 we -- I'm unaware of -- if there is, I'm unaware of that.

1 COL. STAUNTON: You're quite right. As far as I'm  
2 aware, that's -- your information is correct. What I was  
3 particularly referring to, the fact that we're -- when we speak  
4 of such issues, it seems to me -- and I'm speaking personally  
5 here (indiscernible) it seems to me that the importance of the  
6 work, the importance of -- the importance of the work that you're  
7 following, the programs that you follow don't stop or stay within  
8 the United States. They actually have implications which are of  
9 extreme importance. I know very well that the information is  
10 very readily shared, and we're extremely grateful for that.

11 The aspect of actually pushing the envelope a bit  
12 further in terms of using the vaccines with other services, with  
13 other forces internationally, I think is worthy of exploration.

14 MR. HOWELL: Certainly. I have to tell you, sir,  
15 I'm not smart enough to know what, if any, incident rate there is  
16 overseas. Certainly if there is, any way you can crack a CE mark  
17 as well as doing the FDA, I'm sure they would be in favor  
18 thereof, but I'm not knowledgeable enough of that overseas usage  
19 or requirement.

20 COL. STAUNTON: Thank you.

21 CMDR. RYAN: We have a little bit of overseas data  
22 from the collaboration we did with the UK in the Royal Navy Basic  
23 Training Center. About one third of their respiratory specimens  
24 grow adenovirus. That compares to about 60% of the specimens we  
25 get from CONUS, but still, a large proportion of their recruit

1 febrile respiratory illness is adenovirus.

2 MR. HOWELL: Great. Bad, but great.

3 CMDR. RYAN: And they're -- it's -- type 4 is what  
4 we got in the low number.

5 DR. OSTROFF: Let's take one more. Captain Yund?

6 CAPT. YUND: Captain Yund. I have a partial  
7 answer for Dr. Berg's question. I'm the person at UMED who  
8 usually gets the frantic calls from Great Lakes when they're  
9 having trouble getting a hold of something. I recently got a  
10 call about Baryvax (ph) from Great Lakes. I haven't received any  
11 calls about MMR. So it may be next week when I get back, but so  
12 far I haven't heard anything about Great Lakes having trouble  
13 getting MMR.

14 DR. BERG: But Great Lakes is continuing to give  
15 it to all recruits?

16 CAPT. YUND: Yes, sir.

17 MR. STUERKE: My name is Stacy Stuerke. I'm with  
18 the Merck vaccine division. I just wanted to echo the comments  
19 in your question about MMR.

20 We are making military first priority for any new  
21 releases that we have. Last week I understood we got over  
22 500,000 doses released. The same with varicella. When we got  
23 that call I think it was a 600-dose order. We made military top  
24 priority. Otherwise it's always first in, first out as far as  
25 the orders, but military does have first crack at any new

1 releases.

2 We are still making the vaccine. It's coming.  
3 It's just not as fast as what the orders are right now. So we  
4 hope we'll get this solved in the short term, but at the same  
5 time the military will get first priority.

6 DR. OSTROFF: Thank you very much. I think what  
7 we're going to do is take a break.

8 Before we do, let me just thank you for coming to  
9 give us this presentation and, in particular, let me thank Dr.  
10 Winkenwerder for his support on this particular issue. It's one  
11 that we will continue to watch very closely and look forward to  
12 hopefully seeing a better timeline in the not too distant future.

13 MR. HOWELL: If I can conclude, I'm taking two  
14 taskers home with me. I will certainly get with Ms. Embrey about  
15 who at American Home Products -- on that end. We will also sit  
16 down with Barr and see if there's any way that they can speed up  
17 and what the costing differentials or whatever would be involved  
18 in that. We'll shoot that to you as well.

19 DR. OSTROFF: Thank you so much. Let's take a 15-  
20 minute break and then we'll come back and get the rest of the  
21 updates.

22 (A break was taken.)

23 DR. OSTROFF: Let's go ahead and try to get  
24 started, because we really do have to be out of here at about  
25 11:30 so that those of us who are heading up to the Marine

1 Recruit Center will make it there in time for the wonderful lunch  
2 that we have up there.

3 I guess the next one on the schedule is Captain  
4 Yund. It's really good to see you looking well. For those of  
5 you who don't know, he had some health challenges over the last  
6 couple of months. So it's good to see you here.

7 CAPT. YUND: Can people see this slide well  
8 enough? Do we need to close some of these?

9 (Side discussions.)

10 CAPT. YUND: Dr. Ostroff, I'll say that, when  
11 you're the recipient of some of these high-tech miracles of  
12 modern medicine, it changes your perspective a little bit.

13 Okay, I have two presentations in rapid succession  
14 here. First, the preventive medicine update and then another  
15 follow-up from a previous board meeting.

16 I'm, again, Captain Jeff Yund from the Bureau of  
17 Medicine and Surgery. I work for Admiral Hart and a number of  
18 other admirals.

19 Two main topics. I'm going to tell you a little  
20 bit about Guantanamo Bay, what's going on down there.  
21 Then -- there's a little bit of preventive medicine in the  
22 Guantanamo Bay segment. Then the preventive health assessment,  
23 which is pretty much purely preventive medicine.

24 After September 11th, Navy Medicine was involved  
25 in many places in New York, of course, also at the Pentagon.



1 Staff from Bethesda were very involved in all of the Anthrax  
2 response in D.C. and Capitol Hill.

3 Eventually it became clear that Guantanamo Bay was  
4 going to be receiving detainees. I want to tell you a little bit  
5 about what's happening at Guantanamo Bay.

6 There's a small naval hospital there serving a  
7 population of about 3,000 people. The CO, Captain Shimkus, is  
8 now the Joint Task Force 160 surgeon. As of January 31st, his  
9 population had popped up, increased by about 60%. This  
10 additional 60% was a somewhat different population from the other  
11 3,000 that he had in his population and has necessitated some  
12 changes in business.

13 One of the first things the CO did was start up a  
14 six-bed detainee advanced care unit in the hospital. This had  
15 the staff that you see there. Interestingly, all of the  
16 detainees travel with two MPs in addition to their shackles. The  
17 next change to business was an echelon one for sick call and some  
18 emergency medical care at Camp X-ray, very close to -- right  
19 where the detainees are being housed.

20 Also very early on, a preventive medicine team  
21 from EPMU2, including a preventive medicine doc and EHO and IHO  
22 and microbiologist and also four technicians showed up to help  
23 deal with a number of anticipated preventive medicine issues in  
24 dealing with detainee health.

25 A couple of other things, a joint aid station was

1 for health care to be provided to the joint task force personnel.

2 This was kept pretty strictly separate from the aid station, if  
3 you will, at Camp X-ray.

4 Also, a SPRINT team, special psychological rapid  
5 intervention team, was brought down to -- primarily to assist the  
6 staff at the hospital and also the JTF -- deal with the  
7 issues -- significant issues that were anticipated that might  
8 be -- might surround dealing with such a different patient  
9 population from what they were used to.

10 Fleet Hospital 20 was rapidly organized as a  
11 subunit of the full fleet hospital and brought down -- the size  
12 of a full fleet hospital is up to 500 beds, but in this case it  
13 was pared down a little bit to 20 to 36 ICU and other acute care  
14 beds, capability for two surgical suites. The staff you see  
15 here -- and a great CQ-rity.

16 (Laughter.)

17 CAPT. YUND: I'm going to have to talk to my  
18 secretary about that.

19 A lot of security issues that the hospital and  
20 also the fleet hospital are having to deal with.

21 One of the very early decisions that was made was  
22 that the quality and level of detainee care was going to be equal  
23 to the care that U.S. troops receive there or anywhere. One  
24 proviso is that it will all be done at Guantanamo Bay. So this  
25 level of care that we normally provide is considerably more

1 difficult when the patient is in shackles and there are two MPs  
2 around -- and they're very close around. They're not off at the  
3 periphery.

4 In addition, there was going to be a need for  
5 long-term rehabilitative care, which is not usually in the  
6 mission of a fleet hospital, but in this situation, it was an  
7 added mission.

8 The number of infectious disease and preventive  
9 medicine issues -- I'll just mention malaria. A number of the  
10 detainees arrived with malaria parasites in their blood. There  
11 are two issues. Certainly you want to treat the malaria that the  
12 individual detainee has, but another issue is that malaria has  
13 been absent from this part of Cuba for -- or maybe from all of  
14 Cuba for quite some time. So another big issue is doing what's  
15 necessary to prevent malaria from becoming endemic in this area  
16 again.

17 A number of medical legal issues surrounding care  
18 with -- of the detainees. Informed consent is absolutely  
19 practiced. There are translators. Informed consent is probably  
20 more strictly applied in this situation than for our own folks.  
21 There are some times when there are procedures that are required  
22 to save a life that, even if informed consent is not obtained,  
23 the procedure is carried out.

24 There is a great deal of medical photography going  
25 on in order to document the before and the during and the after.

1 Mortuary affairs is an important but hopefully  
2 small aspect of the activities of the hospital. A number of the  
3 detainees have died of the wounds that they arrived with. So  
4 there's attention being paid to doing the things with the body  
5 that would be appropriate for their culture.

6 These are just a few of the Navy boots on the  
7 ground down there.

8 Now, we're going to move on to the preventive  
9 health assessment. I just wanted to give you a brief glimpse of  
10 Guantanamo Bay. If there -- I suppose there might be some  
11 questions about that. If anybody has any questions about  
12 Guantanamo Bay, I might be able to answer them.

13 Sir?

14 DR. CAMPBELL: Doug Campbell. What kind of  
15 surveillance did you do for the health issues that detainees had  
16 when they arrived there?

17 CAPT. YUND: Well, one thing that's ongoing in the  
18 detainee camp is disease and non-battle injury surveillance, the  
19 same type of disease and non-battle injury surveillance that our  
20 troops have applied to them on a deployment. In addition, every  
21 detainee received a complete history and physical examination  
22 when they arrived.

23 So there was -- we learned quite a bit -- our  
24 people down there are learning quite a bit about their health and  
25 about what sort of conditions they have when they arrive.

1 DR. OSTROFF: One quick question. I know that TB  
2 has been a particular concern from the very beginning. Is there  
3 any suggestion that any of them have had active tuberculosis?

4 CAPT. YUND: I have heard that up until a couple  
5 days ago there had been no active cases of tuberculosis.

6 DR. CATTANI: Jacqui Cattani. This may be a bit  
7 of a detailed question, but you mentioned malaria and the  
8 prevention of reintroduction of malaria into Cuba. Can you tell  
9 me what you're actually doing, or is that a level of detail too  
10 sort of far down?

11 CAPT. YUND: No, I don't think that's too far  
12 down. If we had somebody -- the main thing that you want to do  
13 is --

14 DR. OSTROFF: If I can ask you to talk into the  
15 microphone.

16 CAPT. YUND: Oh, sorry.

17 DR. OSTROFF: Otherwise we can't record.

18 CAPT. YUND: The main concern is while you're  
19 treating someone who's parasitemic is to guarantee that vector  
20 mosquitoes can't get to that person. So, in order to do that,  
21 there are -- I mean, you can use insect repellants, both  
22 permethrin and Deet. Other ways to go about that are  
23 adulticiding and larviciding for mosquitoes in the area to cut  
24 down the number of mosquitos.

25 DR. CATTANI: I guess the point was are you

1 treating them with primaquine as a gamenocidalcidal (ph) agent?  
2 That would be more effective in most cases than just trying to do  
3 vector control or limitation.

4 CAPT. YUND: Right. Yes, ma'am, I think they are  
5 receiving primaquine.

6 DR. BERG: Bill Berg. Jeff, what is being -- can  
7 you give us a bit more detail on the diagnosing and ruling out  
8 tuberculosis? I was the JTF surgeon there when the Cuban  
9 refugees were there. There were two challenges. One, we had to  
10 get a technician in Gentmo (ph) who knew how to do AFB smears and  
11 then, because there were no AFB culture capabilities there, they  
12 had to be sent up to the Naval Hospital Portsmouth. What is in  
13 place to address that, that a diagnosis is not missed in an area  
14 that normally does not have much to do with TB?

15 CAPT. YUND: What I'm going to tell you is a  
16 guess, but there's a microbiologist there with the EPMU team. So  
17 that brings additional capability as far as smears. I doubt that  
18 they're doing cultures on site there, but that may be -- they may  
19 be doing that. So I don't really have a definitive answer for  
20 you.

21 DR. OSTROFF: Other questions?

22 (No audible response.)

23 CAPT. YUND: Okay, we'll move on to the next  
24 series of slides.

25 I wanted to tell you about a new initiative in

1 Navy preventive medicine or preventive health assessment.

2 Forgive me for just reading these couple of lines here.

3 The purpose of the preventive health assessment is  
4 to consolidate medical occupational health and risk screening  
5 services, medical record review, preventive counseling and risk  
6 communication under the umbrella of an annual assessment for all  
7 active duty men and women.

8 This is in effect now, as of 5 December. It  
9 carries the signatures of both the Navy Surgeon General and also  
10 the Assistant Commandant of the Marine Corps. It is based  
11 primarily on the United States Preventive Services Task Force  
12 recommendations. I know that everybody in this room is probably  
13 pretty well familiar with that, but I'll show the next slide.

14 This is not an exhaustive list, I don't think, of  
15 the things that are covered by the preventive health assessment  
16 but just some of the big items. So what we have here is a system  
17 to sort of codify into a recurring system of actually documenting  
18 the preventive measures that are taken and the counseling that's  
19 given in a yearly fashion, what is needed for all of our active  
20 duty folks, regardless of their age -- age appropriate tools.

21 So it's new and we don't know exactly what the  
22 impact is going to be, but we'd like to think that it's going to  
23 be a significant contribution to the health of all of our active  
24 duty men and women.

25 DR. OSTROFF: Any questions?

1 DR. HERBOLD: John Herbold. For the preventive  
2 services screening, how are you going to aggregate and manage the  
3 data for population inferences?

4 CAPT. YUND: Well, initially this will be kept  
5 track of on paper. We do not have a -- we don't have a system  
6 that will capture all of this electronically yet. It's coming.  
7 People often -- as a matter of fact, twice today already people  
8 have snickered when I mentioned that this is a capability which  
9 will be included in CHCS-2 because CHCS-2 seems -- every time a  
10 month goes by, CHCS-2 seems two months farther off. There has  
11 not been a specific electronic system designed to keep track of  
12 this data. It would certainly be short-lived -- at least, we  
13 hope it would be short-lived. So, initially, it will be paper  
14 data.

15 DR. FORSTER: Jean Forster from the University of  
16 Minnesota. I didn't notice tobacco use or alcohol use on your  
17 list of screening questions. Maybe they're aggregated under some  
18 larger categories, but --

19 CAPT. YUND: They are specifically included.

20 DR. FORSTER: Okay.

21 CAPT. YUND: I didn't have them up there on the  
22 slide, but they are specifically included in the instruction  
23 which guides the preventive health assessment.

24 DR. OSTROFF: Let's take two more.

25 DR. PATRICK: Kevin Patrick. I'm particularly



1 excited about the notion that it includes not only screening but  
2 counseling -- preventive counseling and risk communication. I'm  
3 wondering how that is going to be evaluated, how the impact of  
4 that over successive years will be determined.

5 CAPT. YUND: I think that a full evaluation of how  
6 successful that's going to be is going to have to wait until we  
7 have an electronic system to capture all of this data. The  
8 study -- I think it's an important step that we move forward and  
9 take direct action to be doing all of these things for each of  
10 our active duty folks. It's an important additional step to be  
11 able to look at the data across the population and across time.  
12 That part of the nut has not been cracked yet.

13 DR. PATRICK: If I can just do a follow-up on  
14 that. This is for those -- I do work in risk communication,  
15 health behavior modification. This is potentially as exciting as  
16 the millennium study overall in terms of following -- if, in  
17 fact, this is now in place and will be a going-forward process.  
18 So there's a wonderful opportunity here to do sub-studies, to do  
19 evaluation tests to see what works, what doesn't. I think this  
20 is, again, an incredible infrastructure that's being built that  
21 would be a gold mine for researchers to look at.

22 DR. OSTROFF: Last question.

23 DR. NESS: Roberta Ness. This is actually a  
24 related question to Dr. Patrick's comments. I just wanted to ask  
25 you if you could try to explain to us briefly what is the process

1 by which you go from screening to prevention. How does this  
2 process work by which you gather the information and then move to  
3 counseling? What does that consist of? How does that process  
4 work?

5 CAPT. YUND: Well, there are a number of ways that  
6 this screening can be done. One of the ways is to have people  
7 come in for a specific visit that is intended to accomplish the  
8 preventive health assessment, a dedicated visit to go through all  
9 of the items that are applicable for that person of that sex, of  
10 that age and to accomplish both the screening that's required and  
11 the education, risk communication that's required under each of  
12 these rubrics in the instruction.

13 The instruction does not mandate that this must  
14 happen at a single visit. It allows the possibility that the sum  
15 total of these screening and educational events can happen during  
16 the course of the year as long as they all happen over the course  
17 of the year.

18 I hope that answers your question a little bit.

19 DR. NESS: So is there -- so, given the fact that  
20 we all know that behavior change can happen slowly, is there the  
21 opportunity to have -- is this a repetitive process?

22 CAPT. YUND: Oh, yes, ma'am, this is annual.

23 DR. NESS: But -- okay, but I'm saying you  
24 identify somebody who is a smoker, and is there a process by  
25 which there is the opportunity for repetitive visits or

1 if -- with regard to counseling, with regard to smoking  
2 cessation, et cetera?

3 CAPT. YUND: Yes, ma'am. If someone is identified  
4 as a smoker and they're willing to consider quitting, one of the  
5 things that might very well happen as a result of the preventive  
6 health assessment is for them to be referred to a tobacco  
7 cessation program within the clinic. That wouldn't all happen  
8 within the umbrella of the preventive health assessment, but  
9 certainly referrals could be made to other capabilities within  
10 the clinic to perform what additional services are needed.

11 DR. OSTROFF: Last quick question over here.

12 LT. COL. GOODRICH: Hi, Captain Yund. Lieutenant  
13 Colonel Goodrich. I'm working at TMA. I'm just wondering, sir,  
14 how you envision this working with some of the other projects  
15 that are underway such as the health evaluation assessment  
16 review. Is this sort of a complementary type of product or  
17 project, or is this meant to augment what we're going to be doing  
18 with the HEAR survey in the near future?

19 CAPT. YUND: I think that the HEAR and the  
20 preventive health assessment would be complementary and that,  
21 when the new, improved HEAR hits the street and we start using  
22 it, certainly the output of that questionnaire could simplify and  
23 streamline some of the screening and questioning that would  
24 happen along with the preventive health assessment. So I see  
25 them as definitely complementary.

1 LT. COL. GOODRICH: Thank you.

2 DR. OSTROFF: Okay, I think, Jeff, while you're up  
3 there, you were going to do your other presentation just for  
4 efficiency.

5 CAPT. YUND: I was.

6 DR. OSTROFF: Good.

7 CAPT. YUND: If that's okay.

8 DR. OSTROFF: Yeah. For the board members who  
9 don't know, there's a history here in that, when data was  
10 presented at previous meetings, there was some question about why  
11 the Navy data seemed to be lagging behind some of the other  
12 services. So we asked Jeff to give an update.

13 CAPT. YUND: And I have a partial update, but  
14 we'll move ahead with it.

15 At the last meeting, some data was presented  
16 indicating that the Navy in particular had some difficulty  
17 getting a high percentage of conditions on the reportable event  
18 list into the AMSA system, the defense medical surveillance  
19 system.

20 If we go on to the next slide, this, some of you  
21 may remember -- I remember it especially well because it was a  
22 painful experience to be sitting with the AFEB and see this data  
23 go up, but this is the data indicating -- now, this deals with  
24 inpatient data, because there's fairly complete, accurate  
25 collection of inpatient data. Over these different years, this

1 was reported to be the percentage of those reportable conditions  
2 that actually showed up at AMSA as a reportable condition.

3 If we can go to the next slide. We did a couple  
4 of things. First, we started a working group to look into this  
5 to, first of all, try to figure out exactly what the problem was  
6 and pinpoint specific trouble areas and recommend what we could  
7 do to change this.

8 More specifically, what we did recently is get a  
9 line listing from AMSA of all of the reported reportable  
10 conditions from inpatient data, and we matched the medical event  
11 reports against that list to see which ones had been reported and  
12 which ones hadn't.

13 If we go to the next slide. Okay, and then I went  
14 back and queried the NEHC database -- actually, Captain Bunker  
15 did the querying for me -- to see if there were additional cases  
16 that were in the NEHC database that somehow had gotten lost in  
17 the translation and not ended up in the AMSA database. We found  
18 precious few of those.

19 The next slide is the previous slide with the new  
20 numbers superimposed. So, for --

21 (Laughter.)

22 CAPT. YUND: So, for '98, '99 and 2000, the  
23 numbers that I calculated, based upon AMSA's data, were  
24 significantly higher but certainly not as high as we'd like to  
25 have them.

1           Now, the last data point, which was for a partial  
2 year, really didn't bump much from the previously reported  
3 information.

4           So next slide. First, I don't think there's much  
5 data being lost in between NECH and AMSA since, when we went  
6 backwards, we didn't identify additional cases.

7           There are a number of other possible problems. We  
8 have not finished the diagnostic -- the troubleshooting here yet,  
9 but certainly a likely candidate is true non-reporting, where the  
10 reporting of reportable conditions doesn't always happen, for one  
11 reason or another.

12           That reporting goes from the MTF or the  
13 operational unit to the Navy environmental and preventive  
14 medicine units. It's possible that there's some data lost within  
15 the EPMUs. The sailing with our Navy disease reporting system  
16 and access-based electronics system has not been smooth over the  
17 two -- well, three or four years that it's been in existence.

18           It's possible that more data -- that there's data  
19 lost as the data is transmitted from the EPMU to NEHC. It's  
20 possible, although very unlikely, that there's any data actually  
21 lost at NEHC.

22           So I just want to tell you where we're going from  
23 this, because obviously what I'm presenting now is only an  
24 initial look and a starting point only. The working group is  
25 going to continue. This working group is going to be part of a

1 new program, an ongoing and recurring self-assessment of Navy  
2 preventive medicine, of which disease reporting with NDRS is  
3 going to be a major focus.

4 Upcoming next month is the 42nd NEHC occupational  
5 health and preventive medicine workshop. Preventive medicine  
6 personnel from all of the EPMUs and also from MTFs are going to  
7 be spending some time in a sub-workshop planning this ongoing  
8 self-assessment and specifically brainstorming, looking at the  
9 disease reporting issue to, number one, do some further diagnosis  
10 about what isn't working and, number two, come up with some ideas  
11 about what's the best way to fix it.

12 I think that's the last slide.

13 DR. OSTROFF: Thanks for the presentation. It  
14 strikes me this is such a core, fundamental public health  
15 responsibility that it baffles me as to why you see data like  
16 this. I'm wondering, is there anybody that's doing it well or is  
17 this system-wide?

18 CAPT. YUND: Well, if we went back to that slide,  
19 which I don't think we need to do --

20 (Laughter.)

21 CAPT. YUND: The Army's numbers are considerably  
22 higher.

23 DR. OSTROFF: No, I mean in the Navy.

24 CAPT. YUND: Oh. Well, within the Navy, there --

25 DR. OSTROFF: I mean, maybe you'll have some model

1 to have the others aspire to.

2 CAPT. YUND: Yes, sir, and we do have some data  
3 about that. There are certain MTFs that do an excellent job of  
4 disease reporting. I can't break it down MTF by MTF here.

5 There are other -- probably not MTFs, but there  
6 are a number of reporting sites, operational units -- there are  
7 reporting sites that don't ever send a medical event report into  
8 the NDRS system.

9 DR. OSTROFF: Hopefully Guantanamo isn't one of  
10 them.

11 CAPT. YUND: No, sir, I'd be very surprised if  
12 that were the case.

13 DR. OSTROFF: Good. Are you going to be audacious  
14 enough to set a target for 2002?

15 CAPT. YUND: Oh, for the percentage compliance?

16 (Laughter.)

17 CAPT. YUND: Well, they say you should start small  
18 and build, right? So we've started small. It would certainly be  
19 great to get it well above the 50% range, but I'm not going to  
20 suggest that I think that we can fix it all at one time.

21 DR. OSTROFF: Any other comments? Bill, this was  
22 your issue.

23 DR. BERG: Yeah, this reminds me of one of the  
24 classic military quotations in military preventive medicine,  
25 General Slim in World War II in the Pacific, malaria



1 chemoprophylaxis was a big problem and Slim said, "I had to sack  
2 two or three of my generals. After that, the rest got the  
3 message and the problem went away." So maybe including that  
4 quotation appropriately in Navy medicine might help a little bit  
5 too.

6 I have an unrelated question. What has been  
7 the -- how much cooperation is there between the detainees and  
8 the medical system in Guantanamo? Are they being cooperative  
9 with getting the care and answering the questions?

10 CAPT. YUND: We recently heard from Captain  
11 Shimkus at the tri-care meeting. He had a number of anecdotes  
12 dealing with the detainees' interaction with the medical staff.  
13 They were all surprisingly positive anecdotes. He did not relate  
14 significant difficulties, major roadblocks that the detainees  
15 threw down in the medical staff's way. They have, on a number of  
16 occasions, expressed gratitude and appreciation for the care that  
17 they have received. One of the problems down there is  
18 that it's important for not only the medical staff but also the  
19 MPs not to trust that too much. I mean, these are people who,  
20 with a little bit less restraint, might just as well be trying to  
21 kill us.

22 One of the anecdotes that I found touching, if I  
23 can use the word, one of the detainees required an annucleation  
24 (ph) for a chronic eye injury that had been sort of festering for  
25 quite a few months and agreed that that was needed, had the

1 annucleation. After the annucleation, the detainee asked the  
2 surgeon if he would come share tea with the detainee. He  
3 appreciated the care -- I think it's clear to them that they  
4 are -- I mean, they're not living in the Guantanamo Hilton. It's  
5 a spartan existence, but I think it's clear to them that they are  
6 getting high-quality medical care under otherwise adverse  
7 circumstances.

8 DR. OSTROFF: I think just one more. Admiral?

9 REAR ADM. HART: A partial question -- answer,  
10 Bill, is the data inputters are already highly taxed. If we  
11 don't start making the information reporting system easy to use  
12 for the provider that puts the data in, we can just keep firing  
13 people till there's nobody left.

14 I think the answer is probably non-reporting. If  
15 the operator doesn't see the benefit, immediately clear the  
16 benefit, then you have to have an information system reporting  
17 process that's easy. If the operator has neither, then you've  
18 got an overtaxed data input source. I don't know the solution to  
19 that.

20 So we're going to get back to CHCS-2. CHCS-2,  
21 however, doesn't work for the operators. So one third of our  
22 population isn't going to be able to use the system anyway.

23 If I could just comment on an earlier thing on  
24 PHCA. In some ways, it ought to be named PHI, Preventive Health  
25 Intervention. There's two metrics that are going to be attached

1 to this thing, an individual medical readiness metric and an  
2 individual health metric. The DOD, TMA has assigned primary care  
3 managers to every single person in the DOD system. They will be  
4 held accountable for improving these metrics.

5 So we have various assessment systems. This is an  
6 assessment system that is actually going to be used for  
7 intervention. The providers will be held accountable for  
8 improving the preventive health. It's a major step forward.

9 DR. OSTROFF: Thank you. I think we're going to  
10 have to move on so we can keep on schedule.

11 Jeff, you look great and it's good to see you  
12 back.

13 CAPT. YUND: Thanks.

14 DR. OSTROFF: Captain Schor is not here and has a  
15 report in your briefing books. We certainly wish him well. I  
16 don't know if you have any comments to make or --

17 LT. CMDR. CONNER: He actually just asked me to  
18 relay that the Marine Corps does have a significant response  
19 right now to muscular skeletal injury and prevention. This is  
20 something that's getting three-and-four-star-level support.  
21 It's, as you can see from his report, actually something that has  
22 a two-pronged effort, not only in the medical and clinical side  
23 of things but also the policy on how they are approaching  
24 training.

25 DR. OSTROFF: Thank you. It's great to hear.

1 Let's move on to Commander Ludwig.

2 CMDR. LUDWIG: Good morning -- I think it's still  
3 morning.

4 Just one comment about disease reporting,  
5 remembering that in some ways this is a passive system. Even  
6 though in the military we mandate it, it still is a passive  
7 system. It just so happens that we have very good tracking of  
8 hospitalization data so that we can compare the data, the  
9 reporting to the hospitalization data. There aren't too many  
10 other systems that have that good of data. So I dare say any  
11 passive system is fraught with difficulties. I think, if the  
12 Navy comes up with some great interventions, I'd like to know  
13 what they are, because we have the same problem.

14 Okay, I am the Coast Guard preventive medicine  
15 officer. I just want to remind, for the new members especially,  
16 that although the Coast Guard is not part of the Department of  
17 the Defense but part of the Department of Transportation, we are  
18 the fifth -- one of the five military services that is an armed  
19 force. We do work frequently with the DOD, in fact, almost  
20 continually with the DOD, especially in operations with the Navy.

21 The first thing I want to talk about is the  
22 Anthrax cleanup. The Environmental Protection Agency, which I  
23 didn't list up here, was actually the ones who were tasked with  
24 cleaning up the Anthrax-contaminated sites. They were activated  
25 under Superfund or CERCLA authority. The Coast Guard strike

1 teams, which have a great deal of experience cleaning up  
2 environmental kinds of Superfund activities, were notified by the  
3 EPA and requested to assist with the Anthrax cleanup.

4 Anthrax was classified as a disease-causing  
5 pollutant or contaminant. Of course, as you know from -- in the  
6 Superfund Act, that's one of the categories of environmental  
7 contaminants that are cleaned up. However, our strike teams had  
8 no experience with biological cleanup in the past. So this was a  
9 new and exciting experience for us.

10 We had 53 members of three different strike teams  
11 and at two different sites, both in D.C. and in Florida.

12 Our folks showed up in level B protective gear.  
13 What we found was that we were the most -- in the highest level  
14 of protective gear of anyone who showed up at the sites,  
15 including the EPA, who felt that level C was adequate. Because  
16 we were in level B, we were -- the strike teams; I say "we"  
17 collectively -- were sent into the hot zones preferentially  
18 although not exclusively.

19 There were, however, significant breaks in  
20 protocol. I won't go into those. They were largely accidental,  
21 of course, but they were of concern. We offered our strike team  
22 members the standard postexposure prophylaxis that all the  
23 cleanup members were offered. That is 60 -- I'm sorry, it should  
24 be 90 days of antibiotics. Sorry about that.

25 Then they were offered the Anthrax vaccine under

1 IND protocol. As you know, it's offered under IND protocol  
2 because the use of it, as opposed to exposure, prophylaxis, three  
3 doses, as opposed to six doses for pre-exposure use, is not  
4 included in the licensing. Therefore, it has to be under IND  
5 protocol.

6 Unfortunately, a fairly sizable majority of our  
7 strike team members refused the postexposure IND protocol  
8 participation, even though it's becoming fairly obvious that we  
9 will all be participating in the vaccine program again.  
10 Actually, our percentage was probably lower than, say, for  
11 instance, the D.C. postal workers, but we still had a significant  
12 number of personnel refuse.

13 To try to get a handle on why that happened and  
14 what were the various factors, I think a lot of us can guess at  
15 what they are. We did decide to send out a questionnaire, which  
16 I have included in your packet. I'd be glad to talk to people  
17 off-line about this if you have comments or questions. We  
18 haven't gotten any responses back. Our mail is going through  
19 irradiation before it gets to the building. So all the mail  
20 coming to Coast Guard headquarters, unless it comes by overnight  
21 delivery, is taking a long time to get to us, but I expect we'll  
22 have a fairly good response. The people in these teams are very  
23 motivated, highly motivated.

24 So that's the extent of what I wanted to report on  
25 the Anthrax cleanup.

1           The other topic that I wanted to talk about was a  
2           few activities of the STD prevention committee. I mentioned at  
3           our last meeting that I would try to devote some time in my  
4           reports to this prevention committee, of which I am an active  
5           member.

6           The surveillance subcommittee, I reported, was  
7           working on a report, which we are still working on, but I didn't  
8           really present any data, which I'd like to just present a little  
9           bit of data --                    you've got some handouts -- well, one  
10          handout, really, with more data. You can draw your own  
11          conclusions. When our report comes out, you'll see what our  
12          conclusions are. I've already alluded to them in previous  
13          presentations.

14          The reportable event -- this is sexually  
15          transmitted diseases -- are based on the tri-service reportable  
16          events list that Captain Yund was just referring to. They are  
17          collected through a variety of service-specific systems, which  
18          are named up there. The Coast Guard doesn't have a name. I'm  
19          open to suggestions for a surveillance system.

20          All of them are passive surveillance. What we  
21          find is the diagnoses may or may not be based on lab tests, which  
22          means that in the reportable disease surveillance system, if  
23          they're not based on confirmatory lab tests, they're set aside in  
24          a separate category.

25          We have no way, really, of determining which

1 diagnoses, if any, are based on any lab test or what the result  
2 might have been.

3 We also don't have antibiotic susceptibility data  
4 on any large scale in any of the services.

5 Actually, these are out of order. I meant to  
6 present this one first. It doesn't really matter.

7 Chlamydia. There are a number of studies -- I  
8 have a summary list of results of targeted studies in the  
9 military. There are quite a few, but this is the best we can do  
10 for prevalence data is these targeted studies. There's no  
11 program, no overall arching program that directs what studies  
12 need to be done. They're done at the determination of the  
13 research facility or the researchers on what looks like it's  
14 going to be an important issue.

15 Anyway, chlamydia in recruits -- you have female  
16 Army and Marine Corps -- that is, as they came into the service,  
17 with 9 to 11 percent with chlamydia. Male Army, 5%. These,  
18 remember, are from a variety of targeted studies. Some other  
19 studies show female Navy -- this is post recruit training,  
20 sometime in their Navy career -- a 3-to-7-percent prevalence.  
21 Army personnel -- females who are asymptomatic, it was found in  
22 one study, had a 7% prevalence of chlamydia. Males in the Marine  
23 Corps, a 3-to-5-percent prevalence.

24 There are other studies, other sexually  
25 transmitted diseases, but I think you can see that, not



1 surprisingly -- well, perhaps surprisingly to some people -- we  
2 really do have a sexually transmitted disease problem in the  
3 military. It hasn't been under a lot of discussion for a number  
4 of years, although this committee has addressed it. I just  
5 wanted to present some of the data we have.

6 Subject to your questions, that concludes my  
7 presentation.

8 DR. OSTROFF: Thank you very much. Let's take one  
9 or two questions.

10 I will say that this issue of the -- what to do  
11 about the people involved in the environmental cleanup with the  
12 Anthrax has been a sustained problem because these are  
13 individuals that have potential repetitive exposures. We have,  
14 not only in the Coast Guard but also in some of the other federal  
15 agencies that have been involved in the cleanup -- but in  
16 particular, people in the private sector that literally have  
17 gotten stuck on antibiotics for months or more already and have  
18 lots more yet to go because they've been involved in all this  
19 cleanup. That's why we were -- I mean, if there's any group that  
20 really needs to get the vaccine, these are the people.

21 DR. POLAND: I agree. I do wonder, since you are  
22 going to do a survey, will you have any idea of compliance with  
23 the antibiotic recommendation?

24 CMDR. LUDWIG: If you take a look at the survey,  
25 if I remember correctly, I did ask them when they finished taking

1 their antibiotics -- yes, question number 8, did you take  
2 antibiotics and, if yes, what date did you stop? Question number  
3 9, if you stopped -- and then I have why. Then I have the same  
4 question repeated, it looks like. Anyway, I am trying to get at  
5 that.

6 Fifty-three members -- I mean, we'll have a sense  
7 of what's going on with this population. I'm not sure we can say  
8 anything about the postal workers or the other federal employees  
9 who -- or private --

10 DR. POLAND: And when you said your rate was  
11 lower, the rate of refusal of Anthrax vaccine?

12 CMDR. LUDWIG: Yes, I think our rate of refusal  
13 was quite a bit lower than the post office.

14 DR. OSTROFF: It was low everywhere.

15 CMDR. LUDWIG: It was very low in the post office.  
16 Ours was probably -- I think about 25% took the vaccine.

17 DR. OSTROFF: Oh, then you're --

18 DR. POLAND: Okay, so the office --

19 CMDR. LUDWIG: The rate of --

20 DR. POLAND: Seventy-five percent refused the  
21 vaccine, in other words.

22 CMDR. LUDWIG: Right.

23 DR. OSTROFF: Let's take one more question and  
24 then we'll have to move on. Otherwise we'll never --

25 DR. CATTANI: Jacqui Cattani. I wondered if you

1 can still change this questionnaire. It seems to me that it's  
2 good to ask whether people stopped taking antibiotics because of  
3 side effects, but one of the issues that has occurred, I know, in  
4 Florida and some of the individuals that have been on prophylaxis  
5 is the incidents and type of side effects that actually occur.  
6 There may be a significant number of people that continue to take  
7 the antibiotics but experience side effects. I can't see that  
8 you would actually pick it up from this questionnaire. So you  
9 might ask them, yes, if you stopped, why did you stop but also,  
10 if they continued taking them, did they experience any side  
11 effects or what side effects they experienced.

12 CMDR. LUDWIG: Yes. I can't change this  
13 questionnaire, but it's a small enough population I can get the  
14 question out there to them.

15 DR. OSTROFF: Yeah. Let me just point out very  
16 quickly -- I mean, we are monitoring and doing a two-year follow-  
17 up of all approximately 10,000 people who were placed on 60 days  
18 of chemoprophylaxis. So we actually do have all of this  
19 information. It's more than we want.

20 Let's move on. I think we next have the British  
21 medical liaison, Colonel Staunton.

22 COL. STAUNTON: Ladies and gentlemen, good  
23 morning. Firstly, I'd like to introduce myself so that you know  
24 who I am and, very briefly, my background.

25 My name is Michael Staunton. I started working

1 here in the United States at the office of the Army Surgeon  
2 General at the beginning of September.

3 My background has been in family medicine, also  
4 public health medicine and command and staff work.

5 It's my privilege to convey to you today the  
6 greetings and gratitude of the United Kingdom Armed Forces  
7 Surgeon General and also the directors general of the medical  
8 services. That's General Bob Menges (ph), Surgeon Admiral  
9 Jenkins, General Joliff (ph) and recently appointed to the Air  
10 Force, Air Vice Marshal Warrick Pike (ph).

11 Now, during my brief time here, I've had the great  
12 privilege of visiting many establishments and seeing the day-to-  
13 day work and cooperation that goes on between our armed forces.

14 I know we've worked particularly closely on the  
15 Gulf War illness issues. Now, our language can sometimes be, it  
16 seems to me, a barrier and a hindrance rather than a help,  
17 because although Captain David Brown, who works on the Gulf War  
18 Syndrome, is not here today, I noted that he refers to himself as  
19 the Gulf War health officer. Now, it seems to me there may be  
20 some conflict in terms of how we sometimes look at things. So my  
21 job is actually, in some ways, to smooth out some of these  
22 differences and to help with the translation.

23 The area I've been particularly, I have to say, on  
24 a personal level -- I will be pushing very hard -- I would like  
25 to endorse the millennium cohort study. I think here is perhaps

1 even an area where we could work well together.

2 The other areas of concern that I have are very  
3 simple. I wish to be a conduit, if you will, for our own  
4 studies, for our own concerns, for insuring that our military  
5 personnel on both sides of the Atlantic receive quite the best  
6 treatment that we can give, the best health surveillance.

7 So I will invite all of you -- and this is my main  
8 message today -- to inquire of me or to contact me regarding any  
9 areas which you believe that I can be of assistance in insuring  
10 that we work as closely together as possible. Thank you.

11 DR. OSTROFF: Thank you very much. Any questions  
12 or comments?

13 (No audible response.)

14 DR. OSTROFF: We appreciate you being here very  
15 much. We definitely look forward to working with you.

16 COL. STAUNTON: Thank you.

17 DR. OSTROFF: Colonel Fensom, who usually gives  
18 the update for Health Affairs Canada is not able to attend. We  
19 have Dr. Jeff Whitehead to do her update.

20 DR. WHITEHEAD: Good morning. Colonel Fensom  
21 couldn't make it. I work in the epidemiology cell of Force  
22 Health Protection. So I was invited to come down here because I  
23 have some projects which are very similar to some of the ones you  
24 have on your agenda.

25 So I'm just going to go through those briefly and

1 then we can ask questions later on.

2           So these are the ones. The first one, prospective  
3 health data analysis capability, that has some similarities to  
4 your recruit assessment program. The second one, the Anthrax  
5 vaccine long-term safety study -- by "long-term" I should say we  
6 mean beyond the short-term effects of, let's say, redness or  
7 swelling in the arm. Then the last two are linkage projects,  
8 which I'm going to talk about, which are attempts to try and get  
9 some grasp of some of the health effects on people after they've  
10 left the Canadian forces. I'm sure that's a problem that you  
11 have in this country as well.

12           So let's talk about this one first. It's called  
13 the capability because this is something that's going to stay in  
14 place forever. There's three parts to this. All three parts  
15 share one thing. The underlying objective is to try and get some  
16 idea of what the risk factors are for post-deployment illnesses.

17  
18           The first one, the recruit questionnaire, you'll  
19 find there are significant similarities to your recruit  
20 assessment program. That isn't by chance. We're  
21 actually -- we're very grateful for the assistance we've gotten  
22 from a number of people here who have kept us in contact by e-  
23 mail, fax and phone.

24           Let me just talk a little bit about the recruit  
25 questionnaire. At this point it actually serves two functions.

1 There's a research side in terms of we're asking about risk  
2 factors for post-deployment illness -- possible risk factors, I  
3 should say. There's also a health surveillance side to it.  
4 We're asking about things like smoking, alcohol intake, use of  
5 seatbelts.

6 Now, our legal advice was that we had to get  
7 informed consent to collect this data and to use it for research  
8 and to link it, actually, to the medical record. We'll also be  
9 linking it to personnel and environmental records.

10 We don't see that as a problem. In fact, we have  
11 more of a concern that recruits will tend to sign anything  
12 because of the peer pressure. So we're still in discussion, how  
13 do we make sure that they don't feel that they have to sign it,  
14 that people around there aren't going to give them a hard time?

15 We're aiming for a questionnaire about 45 minutes.  
16 We'd like to have them in the first three days of recruit  
17 training, before they even get their uniforms, but it looks like  
18 we're probably stuck at the end of the first week, by which time  
19 they're starting to get into sleep deprivation. That's a  
20 problem. They fall asleep while we're doing the survey  
21 sometimes.

22 Of course we're asking about health risk factors,  
23 a number of psychological scales. We tend to try and use  
24 questions from Canadian population health surveys that so we'll  
25 be able to compare recruits with the population from which

1 they're drawn. Now, if we don't have that, then what we're doing  
2 is the next closet thing, which we think are American recruits.  
3 So that's why we're trying to use some of the same questions that  
4 you have on your recruit assessment program.

5 We did a pilot last month in English and French.  
6 It's still a little long. It has to be cut down to size. I  
7 think I was having a good day when I gave that implementation  
8 date there. I haven't had that many good days since then. So I  
9 think we're probably looking at April, May, if we're lucky, if  
10 everything goes according to plan and, of course, it never does.

11 The second part of this prospective project is  
12 really an existing medical questionnaire which is not optional.  
13 This is one that you have to fill out with a periodic health  
14 exam. As it exists now, there's a symptom checklist. There's  
15 questions on smoking and alcohol, things like that. What we've  
16 done is we've expanded the area on psychological health, and also  
17 we've asked specific questions about deployment history, because  
18 our administrative records are not very accurate in that area.

19 Another thing we're doing, of course, is we're  
20 making it into a machine-readable input so we can put it into a  
21 database easily.

22 The last part we're just getting started on.  
23 That's the optional periodic health exam questionnaire. What  
24 we're trying to look at there is organizational and social  
25 factors. So we're going to be looking at stuff like unit



1 cohesion, unit morale, family discord. That may be an area where  
2 we get into problems with consent. As people get into the  
3 military, they're less likely to agree to this type of thing.

4 Now, the Anthrax vaccine long-term safety study,  
5 that's simply a chart review of symptoms and diagnoses of those  
6 who received the Anthrax vaccine. It was in 1998. They were  
7 going to the Gulf. This was compared with a group that was  
8 deployed to the Balkans. We planned to revisit this group at  
9 five-year intervals. We've contracted this out to a university  
10 research group. They should be completed by the end of this  
11 year.

12 Now, the Gulf War linkage project. This is a plan  
13 we have to link our Gulf War cohort, which I should mention is  
14 quite a bit smaller than yours and the U.K.'s, and link that in a  
15 comparison group to the Canadian cancer registry and the Canadian  
16 mortality database.

17 One thing we've learned from this, though, is it's  
18 a very lengthy process. The data may be held centrally, but it's  
19 actually all the provinces that own it. So we had to go and get  
20 their approval. So we're now two years into this and we  
21 won't -- we probably will have the results this summer, but  
22 that's a long time. I'm sure you're all aware that, when someone  
23 comes after a deployment and raises a concern about an increased  
24 risk of cancer, it's not good enough to say, "Well, I'll get back  
25 to you on that two years from now." That just doesn't fly.

1           So, if we can go on to the next slide, that's  
2 what's led to the last thing I want to discuss, which is what we  
3 call the omnibus record linkage project. Our idea here is just  
4 to pre-link all members of the Canadian forces that were in from  
5 1990 on to these two databases, these nationally held cancer  
6 registry and mortality databases. Then the idea is that, if a  
7 concern is raised, you can quickly pull up this information and  
8 you can answer some of those key questions. Of course, you have  
9 to redo the linkage, but it's always the administrative burden in  
10 front, getting the okay, that takes the time. So we should be  
11 able to do that quite quickly once this is okay, because the  
12 linkage takes no time at all.

13           That still leaves us with a gap in terms of  
14 people, once they do get out of the military, we have no idea  
15 what symptoms they have. We have no idea what their  
16 hospitalization is like, because once they're out there into the  
17 provincial health care systems, they're very hard to track at  
18 that point. We have no system in place. In fact, we're even  
19 limited by contacting them by things like privacy legislation.  
20 Those are things we're going to work on for another day.

21           That's the things I wanted to tell you about just  
22 in case you have any interest in what we're doing and we can  
23 compare notes.

24           The next slide is -- the last one is just contact  
25 information. I'm the point of contact for any of these probably

1 for the next little while. We only have one other epidemiologist  
2 in this cell. She's going on maternity leave anytime now. So,  
3 at least until the end of this calendar year, it's probably best  
4 to contact me if you want any information on these things that  
5 we're doing. Thanks.

6 DR. OSTROFF: Thank you so much. I'm intrigued  
7 that there's an Alta Vista Drive in Ottawa.

8 Any questions?

9 (No audible response.)

10 DR. OSTROFF: Thank you so much. What we're going  
11 to do now is move on to Colonel Egerton to give us an update on  
12 the survey that was discussed at great length at the last board  
13 meeting of the September 11th events at the Pentagon. Thank you  
14 for coming.

15 COL. EGERTON: Good morning. I'm pleased to have  
16 this opportunity to present the progress of the Pentagon post-  
17 disaster health assessment that was developed at the United  
18 States Army Center for Health Promotion and Preventive Medicine  
19 and administered to Pentagon personnel shortly after the events  
20 of 11 September.

21 This was a complete team effort. Two team members  
22 are here today, Lieutenant Colonel Jim Wells and Nikki Jordan.  
23 They're in the back. Please direct all questions to them.

24 (Laughter.)

25 COL. EGERTON: This slide describes the CHPPM

1 responsibilities in the survey process. The primary  
2 responsibility for deploying the survey was delegated to the  
3 North Atlantic Regional Medical Command. The operations plan  
4 called for NARMC to conduct a pre-survey campaign throughout the  
5 Pentagon using printed as well as electronic media to advertise  
6 the survey. Tri-service teams were trained by CHPPM personnel  
7 under the direction of Lieutenant Colonel Greg Black and Major  
8 Tony Cox and then released within the Pentagon and throughout  
9 satellite locations containing Pentagon personnel.

10 A total of 19,450 personnel were contacted until  
11 NARMC concluded their operations on 16 November. The custodial  
12 responsibility of the survey then moved to the DeLorenzo (ph)  
13 Tricare Health Clinic. Those personnel took charge of the survey  
14 until it closed on 15 January of this year.

15 An interim report was published in established  
16 Pentagon communications and through e-mail in December. A total  
17 of 4,764 persons completed the survey online and in paper format.

18 Response rates were probably affected by a variety of reasons,  
19 like the ongoing deployment, the Anthrax situation and increased  
20 operations tempo within the Pentagon.

21 The web-based format that we used was developed by  
22 PKC and used problem knowledge coupler technology.

23 This slide summarizes the demographics of the  
24 respondents. The median age of respondents was 43 years age.  
25 The mean age was 42.8 years. Respondents ranged in age from 17

1 to 88 years of age. 38.4% of the respondents were female.  
2 Active duty response was more heavily Army and Air Force. Four  
3 thousand six hundred and eighty-seven respondents indicated their  
4 location at the time of the attack and 3,608 were actually able  
5 to quantitate their distance from the point of the attack.  
6 Thirteen percent didn't know how far they were from the collapsed  
7 portion of the Pentagon, and 15% reporting that they were within  
8 the collapsed area is most likely an overestimate due to the  
9 subjective nature of the question that we asked.

10 This slide describes the respondents' answers to  
11 the questions dealing about potential exposures. A majority of  
12 the respondents reported exposure to light smoke. Sixty-four  
13 percent of respondents reported smoke exposure for 30 minutes or  
14 less.

15 Questions were asked relating to health status,  
16 and a majority, 79%, rated their health status as very good to  
17 excellent prior to the attack. Respondents reported on new  
18 health problems, old health problems perceived to have been made  
19 worse since the attack, and they also responded to health  
20 problems at any time since the attack.

21 Sixteen hundred ninety-two respondents answered  
22 yes to either having an old health problem that was made worse or  
23 a new health problem or they may have indicated in the course of  
24 the survey that they had a problem, a health problem that  
25 resulted as -- since the attack on 11 September. Fourteen

1 hundred and seventy-two of those respondents actually were able  
2 to describe their problems; 220 didn't answer. Three percent who  
3 were at or near the Pentagon indicated that they were injured  
4 during the blast. A hundred and fifteen of those were able to  
5 describe how they were injured.

6 Now, it's noted that 20% of those respondents gave  
7 some conflicting information, that is, that they might have  
8 answered that they were injured early but then reported that they  
9 were not injured later on in the survey.

10 Also, a lot of respondents seemed to indicate that  
11 smoke inhalation and depression and anxiety were injuries as  
12 opposed to health problems.

13 Of the 118 respondents who answered that they were  
14 trapped during the attack, all but three were able to quantitate  
15 the amount of time that they were trapped. A majority of these  
16 respondents were trapped for less than ten minutes. Causes for  
17 being trapped are shown in the third bullet.

18 The survey asked respondents about the amount of  
19 time it took to evacuate the building. A majority of the  
20 respondents were able to evacuate in ten minutes or less. The  
21 reasons for not evacuating were also noted, like not knowing that  
22 an attack had happened, the lack of awareness or assisting with  
23 rescue efforts.

24 Of 114 respondents who noted injury during the  
25 evacuation, 109 were able to describe the cause of their

1 injuries. Nineteen respondents had conflicting responses, and  
2 many injuries that were reported were not physical.

3 This slide describes the self-reported functioning  
4 since the attack on September the 11th. Over 20% of respondents  
5 reported that daily functioning was at least somewhat impacted by  
6 personal or emotional problems. Twenty-eight percent of  
7 respondents reported symptoms associated with a high risk for  
8 PTSD depression, panic attacks or alcohol abuse. We asked  
9 specific questions in the mental health portion that were -- that  
10 correlated with high risk for these particular conditions. We  
11 also used problem knowledge couplers in the web-based version  
12 that linked these questions and also gave messages to respondents  
13 who answered these positively, cluing them that they might want  
14 to seek assistance.

15 Over 862 respondents expressed that they had some  
16 concerns, and of that group, 414 of them actually asked to be  
17 contacted. We were able to group their concerns into the  
18 categories that are listed. To give you an example, the mental  
19 health category included stress, sleep or eating disorders and  
20 anxiety, among other things. The building safety category looked  
21 at emergency response preparedness, building security. People  
22 expressed concerns about that. The administrative category,  
23 people expressed concerns about complaints on admin decisions,  
24 for instance, being told to go back to work too soon, things like  
25 that. Family member concerns were particularly of note. People

1 were concerned about the attack of the -- I mean, the effects of  
2 the attack on their family members.

3 Four hundred and fourteen referrals were passed to  
4 the mental health response team. That's Operation Solace. The  
5 breakdown of those referrals is listed here. To date, most of  
6 those persons have been contacted either personally, by phone or  
7 electronically.

8 We learned a lot of lessons in doing this. We had  
9 a very short timeline to get this survey deployed. Some of the  
10 lessons learned I'd like to discuss now. We solicited input from  
11 a variety of sources and showed the survey to a variety of  
12 persons, this board included, to get input. Trying to coordinate  
13 that in the short amount of time that we had in order to get the  
14 survey deployed was an adventure. We're looking at maybe  
15 institutionalizing a more streamlined version of being able to do  
16 that.

17 There were difficulties with the web-based version  
18 of the survey. Once we deployed it within the Pentagon,  
19 unforeseen difficulties -- incompatibilities with the networks  
20 and the browsers within the Pentagon. There is absolutely no  
21 uniformity of informatics within the Pentagon.

22 (Laughter.)

23 COL. EGERTON: It's literally a tower of Babel.  
24 The standardization of the systems in the building, as I said, is  
25 virtually nonexistent. That made the web-based version not work



1 in a lot of areas. That probably cost a lot of participants  
2 because of frustration with making the survey work online, which  
3 was our preferred method of having the survey completed.

4 We were able to get an expedited approval through  
5 OMB with the help of the Tricare Management Agency's Department  
6 of Health program analysis and evaluation.

7 We're attempting to chronicle this process for  
8 institutional memory for those who would attempt to do something  
9 similar to this in the future.

10 We wanted tri-service participation in this  
11 effort. We were able to achieve this in development and the  
12 review process of implementing the survey; however -- and we  
13 received report from the three surgeons general -- three service  
14 surgeons general; however, when we deployed the survey, the  
15 deployment teams were decidedly Army and Air Force. We didn't  
16 have very heavy Navy participation.

17 This was a voluntary survey. As such, respondents  
18 were not contacted about results unless they specifically  
19 requested to be contacted. That was one of the rules that we had  
20 to agree to in order to get the survey deployed within the  
21 Pentagon.

22 This is the future direction of the survey. Of  
23 particular note is that we plan completion of the technical  
24 report by the end of April.

25 That concludes this presentation. We're ready for

1 any questions.

2 DR. OSTROFF: Thank you very much for that  
3 presentation. I concur with you that this was not an easy thing  
4 to accomplish.

5 I have one question for you. In terms of -- and  
6 maybe Colonel Engler would weigh in as well. In terms of the  
7 mental health issues, is there any way to separate out how much  
8 of the mental health burden is directly related to what happened  
9 on September 11th versus all this stress of the war effort that's  
10 occurred subsequently?

11 COL. EGERTON: That is a very good question, and  
12 I'm not sure that I can answer that completely to your  
13 satisfaction. I'm not sure that we can do that based on the  
14 types of questions that we asked, but it's definitely a  
15 consideration. So, when we do the complete analysis, that would  
16 be -- and with the help of the mental health team that helped us  
17 formulate the questions, that would be a consideration to look  
18 at.

19 AUDIENCE MEMBER: I can speak to that a little bit  
20 by saying that the mental health questions -- many of the mental  
21 health questions that we rolled into this survey came -- are  
22 those that are PHQ or prime MD questions that are used in the  
23 millennium cohort study. One of the goals that we had since we  
24 felt the millennium cohort study had a nice set of mental health  
25 assessment questions -- they weren't entirely complete from our

1 perspective as it related to this particular event, but since a  
2 lot of them were previously validated questions and so on, that  
3 we wanted to make it as much as possible overlapping with that so  
4 that we would eventually have normative data to compare it to,  
5 normative military data to compare it to.

6 At this moment, I don't think that we could say  
7 how much reflects an added burden -- just how much of a burden  
8 there is at that moment in time, but eventually, as we have  
9 millennium cohort study data to compare to it, I think we may be  
10 able to sort some of that out. It also speaks to the need to do,  
11 as Colonel Egerton was saying earlier, develop sort of a  
12 standardized package of these kinds of questions.

13 DR. RUNYAN: Carol Runyan. I appreciate the  
14 difficulties in doing this kind of work, although the 25%  
15 response rate is concerning in terms of drawing conclusions.

16 I wonder if, at the very least, if you could do  
17 some analyses to examine the extent to which the 25% who  
18 responded are representative of the population queried, at least  
19 in terms of their location in the building or other variables  
20 that -- to give some reassurance of the extent to which they may  
21 be representative.

22 COL. EGERTON: I appreciate the question now. I  
23 believe Colonel Wells can probably speak to that a little bit  
24 more directly. We are looking at that.

25 COL. WELLS: We have a good GIS section at CHPPM.

1 They're working with us to locate in the building little dots by  
2 floor where the respondents were. So that helps that standpoint.

3

4 As to the average demographics of our respondents  
5 versus the employees at the Pentagon, we haven't gotten a  
6 breakdown of employment records from Pentagon -- Washington  
7 headquarters service that runs the Pentagon employees yet.

8 DR. RUNYAN: Well, I guess the other issue is  
9 whether there is still the possibility of doing some follow-up.  
10 I suspect that memory of the events is not as major an issue as  
11 in a lot of surveys and that maybe you could still increase your  
12 response rate.

13 AUDIENCE MEMBER: Do you want to address the  
14 follow-up issue?

15 COL. EGERTON: One of the other conditions that we  
16 needed to agree to in order to get this survey rapidly  
17 implemented was that we wouldn't go back and do follow-up. It  
18 cripples us to a great degree, but that was -- the concern was  
19 that we would over-survey personnel.

20 DR. RUNYAN: It wouldn't be resurveying. I didn't  
21 mean to resurvey the people you've already surveyed but to try  
22 and increase the response. It would still be the first time  
23 those individuals responded. I may not have made myself clear.

24 COL. EGERTON: Okay. We did try to attempt to  
25 increase response by going back to personnel within the initial

1 implementation phase. We sent teams back to try to encourage  
2 people to do this. We did have endorsement throughout the  
3 leadership within the Pentagon. We also sent out reminders  
4 electronically. We sent out reminders in hard copy to persons.  
5 Given the nature of the Pentagon, I'm sure that the -- pretty  
6 much postulating things here, a lot of folks who either felt that  
7 they weren't directly affected didn't see the need to do the  
8 survey, were far removed from the actual affected area in the  
9 Pentagon, just chose not to do the survey. We pushed the  
10 envelope as far as we could within the time limit that we were  
11 given in order to get the survey done.

12 AUDIENCE MEMBER: I think there may be some  
13 administrative issues around this that I don't fully appreciate,  
14 but there seems to be a false dichotomy that plays out in the  
15 military, in any case, around the difference between surveillance  
16 and research that has implications for the question.

17 The false dichotomy is that surveillance doesn't  
18 necessarily require human use review and research review and  
19 surveillance entails surveying everyone involved, as opposed to,  
20 if you get into using smaller representative samples, then it  
21 falls into a research rubric. I think these are -- like I say,  
22 I'd call it a false dichotomy, but what it -- my sense is -- I  
23 felt this way early on -- was that, if they had gone with a  
24 smaller, more systematic sample, perhaps over-sampling for some  
25 of the more affected groups, that they could have done -- it

1 would have been possible to do a much more intensive follow-up  
2 effort and possibly even a longitudinal study and still have it  
3 serve the purpose of population surveillance in population  
4 indices.

5 You know, for whatever reason, like I say, my  
6 sense is that, if it went that direction, then it would have  
7 fallen out of the realm of surveillance and then there's other  
8 associated sort of bureaucratic issues that rise up around that.

9 DR. OSTROFF: Other comments? I'd just make one  
10 comment in response to what you said, which is that -- you know,  
11 the definition of surveillance, per se, is ongoing systematic  
12 data collection. It's not a onetime survey. It would be hard to  
13 consider this surveillance.

14 The difference, you know, where we work, we do a  
15 lot of this emergent response of this nature. We don't consider  
16 it research. That's the main difference. We consider it part of  
17 the public health response. We don't usually route it through  
18 the human subjects.

19 AUDIENCE MEMBER: I think you're preaching to the  
20 choir.

21 DR. OSTROFF: Yeah.

22 AUDIENCE MEMBER: Just an observation that I had  
23 as a relative outsider who's consulting on just the medical  
24 health portion of this survey is our feeling -- those of us who  
25 are thinking about the mental health part of it, our feeling from

1 the beginning was that this really needed to be longitudinal and  
2 that, if we focused only on a survey that tried to do this in the  
3 whole population of people at the Pentagon, you were going to end  
4 up with just what we see, an exceedingly low response rate,  
5 unable to say anything about the larger group of people  
6 (indiscernible).

7 DR. OSTROFF: One more -- we'll take two more and  
8 then we'll have to stop.

9 DR. SHANAHAN: I just wanted to comment. You  
10 know, this has been an impediment for as many years as I can  
11 remember in the military. I think that eventually we could take  
12 some action, maybe encourage through HA to try to address this  
13 head on. I know that there's been a lot of research that's been  
14 attempted over the last decade or two that's been thwarted by  
15 some of these administrative snafus that exist for other reasons.

16 Because there are a lot of regulations in place which regulate  
17 these kinds of surveys and surveillance mechanisms, it takes  
18 fairly high-level action to get some of it turned around. If we  
19 could generate interest within HA, it may be something that we  
20 could take on as the board.

21 AUDIENCE MEMBER: I completely agree, and that's  
22 why I said this.

23 DR. OSTROFF: Let's let Dr. Berg have the last  
24 word.

25 DR. BERG: I just want to endorse what Dennis

1 says. This is a problem that has been ongoing. It is getting  
2 worse. CDC is working on a white paper, sort of drawing the  
3 distinction between public health surveillance and research.  
4 That might be a useful starting point. I think in any case, as  
5 Dennis suggested, calling this to the attention of HA may help  
6 set some guidelines that will have some teeth to them.

7 DR. OSTROFF: Greg's taking notes.

8 DR. BERG: He always does.

9 DR. OSTROFF: I think Commander Russell has been  
10 gracious enough, so that we can try to stay on time, to defer his  
11 presentation on the pneumococcal vaccine until tomorrow morning.

12 So we're now ready to take the break. I'm going to turn it over  
13 to Colonel Riddle to give us a couple of comments about how we're  
14 going to organize ourselves to get up to the MCRD.

15 LT. COL. RIDDLE: We have a few other folks that  
16 signed up out there on the holding list. I did call. We  
17 increased our reservations at the Bay View and I talked to  
18 Captain Hann. We'll make do. So I think we're bumped up to  
19 about 39 or 40 people. So what we're going to do is, if we could  
20 meet everybody over in front of the lodge that's going to go on  
21 the tour and we'll carpool to MCRD. We'll go into the Bay View  
22 Restaurant. We have reservations there at the Bay View, a very  
23 nice setting. Then we have to be over at the clinic at 1:30 to  
24 catch the bus for the tour. We're going to tour MCRD, look at  
25 the Marine Corps recruit training process and then come back to



1 the clinic and have about 30 minutes at the clinic to go over the  
2 actual execution of the recruit assessment program that they're  
3 doing over there.

4 So the drivers are going to be myself, Dr.  
5 Ostroff, Dr. Gunzenhauser, Major Balough, Dr. Ludwig, Dr. Berg,  
6 Dr. Shanahan and Dr. Gray. So we'll all have ID cards and that  
7 should facilitate our entry.

8 So, if I could meet with the drivers when we  
9 adjourn here and then, if we could leave from in front of the  
10 lodge in five minutes.

11 (Meeting recessed for the day.)

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