

UNITED STATES OF AMERICA

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ARMED FORCES EPIDEMIOLOGICAL BOARD

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MEETING

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WEDNESDAY, MAY 22, 2002

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GAITHERSBURG, MARYLAND

The Board met at the Gaithersburg Marriott Hotel
9751 Washington Boulevard, Gaithersburg, Maryland, at
7:15 a.m., Dr. Stephen Ostroff, presiding.

BOARD MEMBERS:

STEPHEN M. OSTROFF, M.D., President

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JOHN HERBOLD, DVM

GRACE LEMASTERS, Ph.D.

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DENNIS F. SHANAHAN, M.D.

ROBERT E. SHOPE, M.D.

LtCOL. RICK RIDDLE, USAF

AFEB Executive Secretary

PREVENTIVE MEDICINE OFFICERS:

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MAJ. BRIAN BALOUGH, USA, MC
LtCOL. KELLY WOODWARD
LtCOL. MAUREEN FENSOM, CFMS
CDR. SHARON LUDWIG, USPHS
COL. J. GUNZENHAUSER, MC, USA
CAPT. K.W. SCHOR, MC, USN
CAPT. ALAN J. YUND, MC, USN
CAPT. B. WINKEL, MSC, USNR
CAPT. DAVID BROWN, L/RAMC

FLAG STAFF OFFICERS:

MADM (Sel) STEVEN HART, MC, USN
ADM. RICHARD WYATT

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

(7:15 a.m.)

DR. OSTROFF: Ms. Embrey is not here today, she is meeting this morning with the Deputy Secretary, and in her place we have Col. Terry Rousch, who is going to be sitting in as the designated Federal Official. He's not here yet?

LtCOL. RIDDLE: He won't be here.

DR. OSTROFF: Okay. Col. Gardner is going to be the designated Federal Official in his place. Welcome.

What I'd like to do before we get into the Preventive Medicine updates is just ask Dr. Herbold, since he has to leave early this morning, if he could make a couple of comments. One of the questions before the Board from the previous meeting in San Diego, for those of you who attended, you'll know what the acronym means, but for those who were not there, one of the issues that was before the Board was the PAPAS (phonetic) facility at Cape Cod, which is a phase-to-ray radar system where there are concerns in the community about an increased incidence of adverse health effects, particularly cancers related to that facility. And since the previous Board meeting, there has been a fair amount of activity with meetings that

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1 have transpired in San Antonio, and John has reviewed
2 a lot of material, and I'd like him to just update us
3 for a minute or two about his activities.

4 DR. HERBOLD: Just a quick review. On
5 behalf of the Environmental Occupational Health
6 Subcommittee, Dr. Shanahan, Dr. Campbell, Dr. Riddle
7 and I, in the company of one of the Directors of the
8 PAPAS Program met at the Air Force Research Laboratory
9 Directed Energy Division at Brooks Air Force Base
10 approximately a month ago. And the charge to the AFEB
11 was to answer the question as given to us by the Air
12 Force Surgeon General is, does PAPAS present an
13 imminent health threat to the civilians in the area of
14 Massachusetts Military Reservation, have asked us to
15 review the Statement of Work regarding ongoing
16 epidemiology studies that are being conducted by the
17 state and academics in the area, and also to answer
18 the question, do the current standards protect workers
19 and the public in lieu of some new theories regarding
20 directed energy and damage to human beings.

21 Our meeting in San Antonio was directed at
22 receiving a complete overview of the history of PAPAS,
23 a system that was put in place at the Massachusetts
24 Military Reservation area in 1979, and we will be
25 going to Cape Cod next month to look at the system,

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1 kind of hands-on examine the patient, and also meet
2 with local public health officials, Massachusetts
3 Medical Society, and other interested parties.

4 Dr. Shanahan, Dr. Campbell and I also
5 think we have learned a lot about the human as an
6 antenna and about the complexity of directed energy.

7 DR. OSTROFF: Thanks. Are there any
8 questions for Dr. Herbold?

9 (No response.)

10 Let me express the Board's appreciation
11 for taking time out of your busy schedule to move this
12 forward. There are plans for a number of us to go up
13 to Cape Cod in mid-June to see if we could further
14 address this issue and hopefully get a response to the
15 Department concerning questions that were put before
16 the Board.

17 Let me go ahead and get started with the
18 Preventive Medicine updates. Col. Diniega could not
19 be here this morning. He was here yesterday. And so
20 we will start with Jeff Gunzenhauser.

21 COL. GUNZENHAUSER: Good morning. It
22 looks like we're going to have a little trouble with
23 the slides.

24 DR. OSTROFF: We're technologically
25 challenged this morning.

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1 COL. GUNZENHAUSER: Well, I've got a
2 handout. If some of you didn't get it, it's over
3 there by the door.

4 Let me just try to provide you with a
5 quick update, we'll catch up with the slides here in a
6 minute hopefully.

7 There was an unprecedented outbreak of
8 meningococcal Disease at Ft. Leonard Wood, one of our
9 five Army installations that conducts basic training.

10 This outbreak involved five cases that occurred at
11 Ft. Leonard Wood. You can't see the slide, but these
12 occurred between 28 March and 27 April. They involved
13 four trainees, two from the Navy and two from the
14 Army.

15 Some of you may know that Ft. Leonard Wood
16 serves all DOD in providing initial training for all
17 the services in certain occupational specialties. In
18 this case, with respect to the second in time order,
19 occurred in a 12-year-old child of one of the training
20 cadres, and this was the only fatal case of the five
21 that we observed.

22 I've got a slide that shows the time line
23 and we'll get to that hopefully in a minute. The
24 first two cases occurred during a three-day period at
25 the end of March, and the last three cases were spread

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1 out over the following four weeks. All the trainees
2 eventually recovered and were returned to training,
3 and all the individuals were affected with a Group C
4 strain of the Neisseria meningitidis.

5 In accordance with DOD policy, all
6 trainees are vaccinated with the meningococcal vaccine
7 early during basic training. All of the trainees had
8 been vaccinated prior to the primary onset of their
9 illness. Navy trainees that actually started training
10 in Great Lakes in January, and had their vaccine on
11 January 16, prior to coming to Ft. Leonard Wood in the
12 middle of March.

13 The third training case was an Army
14 trainee who had been vaccinated in the Summer of 2001,
15 and the final case was a trainee that had been
16 vaccinated only a few days before becoming ill.

17 These facts raised some question about the
18 vaccine. As many of you know, the DOD serum involves
19 (inaudible) spores blood sera from HIV testing that's
20 performed as far as inspection valuation, but how that
21 sera can provide us with an opportunity to assess a
22 sera-like response to vaccine for the first three
23 military training cases.

24 I still don't have a slide, but I have a
25 slide that shows the serologic titer. So we've added

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1 a pre-vaccine titer, and few sero-preventative for
2 illness, and then subsequent titer for all three of
3 the trainees.

4 What slide 3 shows is basically we looked
5 at three of the polysaccharides, the C antigen, and
6 the Y, and the W 135 the antigen, and when we looked
7 at the serological response for the Y and W 135, there
8 was evidence there that all of the three trainees had
9 received vaccine, however, when we looked at the
10 serologic response to the C antigen, for the last two
11 trainees there was no response to the vaccine, and for
12 the first trainee there was an 8-fold rise in the
13 titer, but after illness it actually went up to 640,
14 another 8-fold rise, suggesting that the response was
15 probably not optimal.

16 We're still looking at these serologic
17 titers. The Navy, in addition to the Army, has
18 started studies that are ongoing at this time.

19 Back to the timeline, I just want to
20 comment that for each of the five cases Fort Leonard
21 Wood (inaudible) provided prophylaxis to all close
22 contacts within a couple of days, normally within
23 hours to those who were exposed.

24 Also, the fourth case had actually been in
25 close contact of the first trainee case and had

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1 received -- let's see if we can skip ahead to about
2 the seventh slide.

3 (Slide)

4 The fourth trainee, as you can see on the
5 bottom there, was actually a contact of the first case
6 and had received chemoprophylaxis at the end of March,
7 but that was three weeks prior to when he became ill,
8 so we think he probably got reinfected with the
9 organism sometime after receiving that
10 chemoprophylaxis. Let's go ahead to the next slide.

11 (Slide)

12 This time line is kind of complicated, but
13 what I want to point out is that after the third case,
14 an epidemiology team was sent from the Center for
15 Health Promotion and Preventive Medicine of the Army,
16 and at the time team departed, we learned that some of
17 the trainees had not been vaccinated at Fort Leonard
18 Wood, there were some logistics issues. Total, there
19 was about 1200 trainees not vaccinated, about 900 in
20 January and 300 in March. Efforts were immediately
21 made to vaccinate all the trainees. As of today, a
22 while ago, all of those on active duty have been
23 vaccinated. The team determined that the three cases
24 of some of these represented a rate of about 14 per
25 100,000 in the combined training of active duty

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1 population at Fort Leonard Wood, in accordance with
2 CDC guidelines for the management of any case or
3 outbreaks of meningitis may recommend extending the
4 vaccinations to include all individuals age 2 to 19 at
5 Fort Leonard Wood, including not only Department of
6 Defense beneficiaries, but also civilians in the
7 community who attended community schools or who had
8 regular contact with Fort Leonard Wood activities.
9 Next slide.

10 (Slide)

11 The fourth case involved a second Navy
12 trainee. Also in this case concern was going up so
13 that the vaccine program was extended to include all
14 individuals age 20 to 29. These numbers up there, we
15 estimated an additional 7500 vaccinations for those in
16 the 2 to 19 age group, and 4,000 more for the 20 to 29
17 individuals. And also we extended the
18 chemoprophylaxis to all Navy trainees and their cadre,
19 which was a particular training unit that was
20 affected. That's the white box up there shows contact
21 for each plus. There was over 200 persons there that
22 received chemoprophylaxis. Next slide.

23 (Slide)

24 This case was significant because this
25 individual had received vaccine only a few days before

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1 becoming ill. He actually arrived at Fort Leonard
2 Wood in January and had been among the trainees who
3 had missed vaccine, so he had just been caught up his
4 vaccine. Inherent to this case and in light of all
5 the measures that had been taken it was very
6 concerning.

7 As many of you know, vaccine prevents
8 disease, but it does not affect the carrier, at least
9 not to a significant extent. There was a perception
10 that a virulent strain of Group C meningitis was
11 persisting among the trainees and may cause additional
12 cases, and perhaps the only way to eliminate the
13 threat would be to provide mass chemoprophylaxis to a
14 large group. So, we consulted with an epidemiologist,
15 EIS officer who was in that state as well, and with
16 the head of the Meningitis Branch of the CDC, and the
17 Army elected to issue a mass chemoprophylaxis program.

18 One week after this case occurred,
19 ciprofloxacin was provided to approximately 6,000
20 military and civilian personnel. Those persons
21 received two doses, taken about 12 hours apart. A
22 two-dose regimen was selected to prevent cross-
23 contamination among individuals during the 24-hour
24 operation that was required to accomplish this effort.

25 (Slide) Next slide.

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1 Chemoprophylaxis was not given to all the
2 trainees in ciprofloxacin, and the Fort Leonard Wood
3 staff analyzed the separation of the various groups.
4 The red line here shows the location for training the
5 brigade at Fort Lewis. Two brigades that were
6 associated with all five cases are located on the left
7 vertical line, and two other brigades are located to
8 the right along the horizontal line, and it was felt
9 that the two affected training brigades on the left
10 were substantially isolated from the other two
11 brigades. Next slide.

12 (Slide)

13 So, accordingly, chemoprophylaxis was
14 provided to two of the four training brigades, those
15 two at the top, 1st Engineer Brigade and 14th Engineer
16 Brigade, for a total of about 5500 military personnel
17 and 800 civilians received treatment. Of note, only 7
18 individuals developed relatively minor reactions to
19 the medication, and they were released in short order.
20 Next slide.

21 (Slide)

22 A sample of approximately 10 percent of
23 those who received pre-prophylaxis had throat cultures
24 collected immediately prior to treatment and again
25 about a week later. This slide shows that while 6.5

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1 percent were carriers of Group C organisms prior to
2 the campaign, less than half a percent were carriers
3 of such organism one week later. Next slide.

4 (Slide)

5 In summary, the U.S. already has
6 experienced an extraordinary outbreak, the first of
7 its kind, of meningococcal disease among trainees
8 caused by a sero-group contained in the vaccine. No
9 one knows if the outbreak is over at this point.
10 Other U.S. outbreaks have extended for many months or
11 longer. We're hopeful, however, that if the effects
12 of the chemoprophylaxis lasts long enough, those
13 carrying the organism may complete their training and
14 move on hopefully minimizing the threat to this post
15 and the training environment. That concludes my talk,
16 I'd be glad to take any questions at this time.

17 DR. OSTROFF: Thank you. Can I ask one
18 question first? Can you comment on why so many
19 individuals missed getting the vaccine?

20 COL. GUNZENHAUSER: That's a rather
21 complicated story. I can give you some of the
22 background. During the mobilization, there was some
23 concern about vaccines that were in short supply,
24 being stockpiled at certain installations. Some
25 instructions were put out not to store vaccine at

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1 various installations. However, there were some
2 arrangements made for basic training centers to
3 receive most of what was allowed. I'm sure they had
4 vaccine. And for whatever reason, at the
5 installation, vaccine at one time that was on the
6 installation just didn't get to the basic training
7 center at the right time. In another incident in
8 March, they hadn't ordered the vaccine early enough in
9 order for it to get there. So, the constraints of
10 this limited supply stressed the system and resulted
11 in some lapses in vaccine being supplied.

12 I would comment that the 1200 trainees who
13 did get vaccine represented less than 20 percent of
14 the trainee population at any time. There's a total
15 of 26-27,000 trainees on an installation.

16 DR. OSTROFF: Pierce.

17 DR. PIERCE GARDNER: Two quick questions.

18 One, you had earlier that the first chemoprophylaxis
19 efforts were using multi-dose (inaudible), and then
20 later on you used the ciprofloxacin which was
21 generally single dose (inaudible) interested in policy
22 error, whether -- what the standard is. I think most
23 people would use the equivalent.

24 Secondly, the choice was made to initially
25 immunize the 2 to 19-year-olds, and then you extended

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1 it to 20 to 29-year-olds. Tell me a little bit about
2 why we stopped at 19 the first time.

3 COL. GUNZENHAUSER: The first question,
4 there's not really a particular policy for DOD to pre-
5 medicate or recommend post-exposure of
6 chemoprophylaxis. (Inaudible) was used early, that
7 was the local clinical call, which is the first
8 (inaudible). Later when we were (inaudible) the
9 larger group, we thought a single dose of (inaudible)
10 would be simpler logistically, so that's why we
11 switched to use that versus a broader chemoprophylaxis
12 campaign.

13 In terms of the thinking about extending
14 the vaccine, in the early part, we had two cases of
15 trainees and we had a single case in a child, a 12-
16 year-old. So, initially, we felt, well, let's just
17 protect those in school and those in a similar type
18 environment and the trainees. However, after the
19 third case, there was a contingency plan that if there
20 was another case, we would consider extending it to
21 the 20 to 29-year-old group. And the reason that that
22 was done was because looking at experience in the U.S.
23 for vaccine having been extended, those seemed to be
24 the groups that had been used when we tried to conform
25 with what the practice had been in the United States

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1 previously.

2 DR. PIERCE GARDNER: One of the remarkable
3 things about meningococcus is the age distribution
4 seems to me. Why it sort of stops at about age 40 to
5 45 whereas the other polysaccharide encapsulated
6 organisms like pneumococcus go up is one of the
7 mysteries. It's an interesting difference.

8 DR. OSTROFF: Bill.

9 DR. BERG: Bill Berg. Two questions. As
10 part of the mass prophylaxis, did you end up giving
11 ciprofloxacin to kids under age 18?

12 COL. GUNZENHAUSER: No, ciprofloxacin was
13 only provided to the trainee cadre and to the adult
14 work staff.

15 DR. BERG: My second question. One of the
16 issues that came up in the ciprofloxacin prophylaxis
17 for anthrax exposure at Post Office facilities was a
18 logistical one. Whose going to write the
19 prescriptions for all of those? How did you handle
20 that for the support civilians?

21 COL. GUNZENHAUSER: I'm not sure how that
22 was done. I know that locally there was a -- it was
23 actually a large operation setup gymnasiums, and
24 workers came in. They were provided information and
25 they discussed it with them there. I'm not sure

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1 exactly how they documented the prescriptions or
2 whether they discussed it with them, provided
3 pertinent information or provided the medication in
4 sort of a mass way.

5 DR. BERG: I was thinking there might be
6 some useful lessons learned there for if we have to
7 prophylax against anthrax again in the future. Just
8 the logistics of handling large numbers of people in a
9 short time were a bit of a challenge.

10 COL. GUNZENHAUSER: There were many
11 incredible lessons from this experience. There's no
12 way to summarize it. We actually have some very active
13 lessons learned process right now. One you mentioned
14 is just one of the items that we're capturing.

15 DR. OSTROFF: Was it administered to these
16 people to find out if their titers against Type C were
17 adequate?

18 COL. GUNZENHAUSER: I think (inaudible
19 words). The answer to that question is yes. Any other
20 questions?

21 (No response.)

22 DR. OSTROFF: Thank you. Our next update
23 is, coincidentally, from Capt. Yund.

24 CAPT. YUND: Good morning, everyone. Jeff
25 Yund, from Navy BUMED. First slide, please.

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1 (Slide)

2 I have three topics, the first of which is
3 related to some presentations and a question to the
4 Board that will appear this afternoon. Next slide.

5 (Slide)

6 We had an interesting cluster of cases at
7 the Marine Corps Mountain Warfare Training Center.
8 Eight cases were reported to Navy Environmental
9 Medicine Unit No. 5 in San Diego since the beginning
10 of the calendar year, and that against a background of
11 no cases in recent memory of the clinicians who were
12 there, or who had recently left. Seven of these
13 individuals needed to be evacuated to a civilian
14 hospital for management, and there's been an
15 investigation of the situation by Cdr. Scott Sherman,
16 from NEPMU-5, and so far two of the eight cases have
17 been eliminated as really not consistent with Sickle
18 Crisis, but of the remaining six three have been
19 confirmed and three are being considered probably.
20 Next slide.

21 (Slide)

22 I won't read it, but there's the
23 definition of a probable case, and the confirmed
24 definition is simply the probable definition plus CT
25 evidence of splenic infarction. And, again, it's

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1 three of each of those. Next slide, please.

2 (Slide)

3 During this period, there have been about
4 3300 Marines trained at the Mountain Warfare Training
5 Center. Scott Sherman estimates simply from
6 population prevalence data that about 55 people were -
7 - out of this 3300 -- were sickle positive. So,
8 again, this is a rough estimate, but there aren't data
9 to show exactly how many were, but a significant
10 percentage of them appear to have developed this
11 illness. Of course, there's a lot of strenuous
12 exercise at altitude, but questions that are current
13 to us are how come now and how come so many in such a
14 short period of time, especially against a background
15 of apparently no cases in recent years. Next slide.

16 (Slide)

17 We don't have the answers yet, but Scott
18 Sherman has proposed that we do several things at
19 Mountain Warfare Training Center, and one is identify
20 the sickle trait positive individuals before training,
21 and that there be some risk communication and
22 education that's provided similar to what we do at
23 Great Lakes in recruits, and that includes some
24 increased emphasis on hydration during training
25 evolutions. Scott recommended that there be

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1 availability of supplemental oxygen at or near the
2 training sites, and then also that we initiate a 24-
3 month prospective study to follow all of the sickle
4 trait positive trainees who go through Mountain
5 Warfare Training Center, and learn as much as we can
6 over the next couple of years. And that's the end of
7 that topic. I'll move on to the next slide.

8 (Slide)

9 This is an update from a topic that you
10 heard a bit about at the previous meeting. We know
11 that NHRC has a study that's preliminary -- next
12 slide, please.

13 (Slide)

14 -- preliminary results that found an
15 elevated risk of major birth defect in women who
16 received the anthrax vaccine in first trimester of
17 pregnancy, and there are a whole flood of issues
18 around that. Next slide, please.

19 (Slide)

20 One, of course, what is the quality of the
21 immunization data. What about the accuracy of the
22 pregnancy dates, and also questions arose later about
23 the determination of major birth defect. Next slide,
24 please.

25 (Slide)

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1 Some of the things that are going on right
2 now, Megan Ryan has six full-time people in St. Louis,
3 and they've identified about 12,000 outpatient health
4 records out of the original 30,000 women in this
5 study, and so far they've extracted data from about
6 1500 of these records. And what they have found so
7 far in comparing immunization data between the paper
8 record which is being considered somewhat the Gold
9 Standard, and the electronic record, they have given a
10 window of plus-or-minus 1 day, the agreement is strong
11 between the two sets of data, and given a wider window
12 of plus-or-minus 7 days, the agreement is very strong
13 between the two sets of data. This is just
14 preliminary, just an initial indication of the level
15 of agreement between the paper and electronic data.
16 Next slide, please.

17 (Slide)

18 On to the birth or major birth defect
19 diagnoses, dysmorphologists at the National Center for
20 Birth Defects and Developmental Disabilities think
21 that it would be a good idea for them to review the
22 entire first-year-of-life health records for 280
23 infants who were considered to have a major birth
24 defect based on the registry that NHRC runs. And
25 Megan has gotten approval for retrieving those records

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1 from NHRC Institutional Review Board. Letters request
2 260 sets of records that in military hospitals will go
3 out this week or next week. There are an additional
4 20 sets of records in civilian hospitals which will no
5 doubt be a little more difficult to find, but she will
6 try very hard to get all of those, also. Next slide.

7 (Slide)

8 The team at St. Louis will probably be
9 there through July. It's turning out that a small
10 percentage of the 12,000 records are probably going to
11 be unavailable for one reason or another, but they are
12 expecting to have certainly over 10,000 records to
13 look for.

14 As far as the first-year-of-life health
15 record retrieval, that's going to take a bit longer,
16 Megan is not really sure, but she suggests that or
17 estimates that it could very easily take 6 to 12
18 months. Next slide, please.

19 (Slide)

20 I want to give you a little bit of
21 information about the meningococcal meningitis
22 outbreak from the Navy perspective. We have a
23 slightly different problem with this outbreak. Next
24 slide.

25 (Slide)

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1 If you just go to the last bullet here,
2 two Navy cases were both among 250 recruits that were
3 immunized with quadrivalent meningitis vaccine on 16
4 January, with a Lot No. UB093AA, according to our log
5 books at Great Lakes. The next slide is the shocker.

6 (Slide)

7 Aventis-Pasteur says that was Yellow Fever
8 diluent. So, as you can imagine, when we got that
9 word there were a lot of chills going up and down Navy
10 spines. We settled down a little bit because of
11 information on the next slide.

12 (Slide)

13 It turns out that UB095AA was the lot
14 number recorded for quite a few weeks prior to the
15 16th of January. 093AA appears only on one day, that
16 was 16 January, in fairly poor handwriting. And then
17 095AA was the lot number that was recorded for quite a
18 few weeks after the 16th of January. In addition to
19 that, both of the Navy cases have serological evidence
20 that they did receive vaccine.

21 So, our working hypothesis at this point
22 is that they really got 095AA, not 093AA, and that it
23 was a transcription error. But we would like to see
24 some data that would give us a better warm-fuzzy that
25 that was the case. Next slide.

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1 (Slide)

2 Next slide.

3 (Slide)

4 If you look on the second bullet there, I
5 think what would really reassure us is some serologic
6 data, and these sera that I'm referring to on the
7 slide were collected yesterday, and we have 40 or more
8 sera from each of five groups. First is the 250
9 people who were logged at 093AA. We have 40 also for
10 the similar number 095AA, and also 40+ from three
11 other lot numbers of vaccine. We'll be obtaining pre-
12 samples from the Armed Forces Serum Repository, and
13 the sera will be tested at CDC, and what they will
14 determine is mass concentration of specific antibody
15 against the four components for antigens in the
16 vaccine. So, we hope to learn a little bit more about
17 certainly what the people on the 16th of January
18 received, and maybe answer some questions about if
19 there have been, as you heard in the previous
20 presentation -- have been some questions about what's
21 going on with the vaccine, is there something about
22 the vaccine, about the C-component of the vaccine, and
23 with CDC's help we may be able to gather some more
24 information. I think that's the last slide.

25 (Slide)

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1 If there are any questions, I'll be glad
2 to try to address them.

3 DR. OSTROFF: Questions from the Board?

4 DR. LEMASTERS: I have two questions.
5 Grace Lemasters. The first one is, why are these
6 being hand-entered when you can on a database system
7 you can just enter those numbers for 100 people,
8 there's no transcription error problem once it's done.
9 It just seems that it would be so much more efficient
10 and avoid mistakes in the past. I wonder if you could
11 go to a more automated system.

12 CAPT. YUND: Yes, ma'am. Great Lakes is -
13 - that's certainly one of the lessons learned from the
14 Navy's experience in aftermath of this outbreak. And
15 Naval Hospital Great Lakes is working toward moving to
16 such a system for documenting lot numbers.

17 DR. LEMASTERS: Seems like it should be
18 across-the-board, right? I mean, not just in one
19 location.

20 CAPT. YUND: Yes, ma'am, that would be
21 ideal.

22 DR. LEMASTERS: And the other question I
23 had concerns the study on birth defects and AVA. It
24 looks like she is dabbling in health records of the
25 280 cases of major birth defects, and I was wondering

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1 if she was going to match those with a set of controls
2 in order to look at patterns? Looks like she only has
3 the cases as of now.

4 CAPT. YUND: Yes, ma'am, that's the case.

5 I discussed this last night with Megan, and this was
6 an arrangement that was worked out with the
7 dysmorphologists at CDC. It was thought that, first
8 of all, there are criteria for major birth defects are
9 going to be fairly strict. It's going to be a high
10 bar. And so it was thought that the vast number of
11 individuals, of infants who were not diagnosed with a
12 major birth defect, there would be a very low rate of
13 failing to pick up a major birth defect, and that most
14 of the information would be -- if there is a change in
15 the diagnosis of major birth defect, that most of that
16 we have in the group who were diagnosed with a major
17 birth defect.

18 DR. LEMASTERS: So the question is -- I'm
19 not sure what the question is she's trying to answer.

20 DR. NESS: Can I comment on that, having
21 been involved in all those conference calls and
22 discussion. The issue is an issue of classification
23 within the presumed cases, and essentially specifying
24 the appropriate congenital malformation diagnosis
25 within presumed cases. So there's really not a need

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1 to kind of look at the non-cases. This is a question
2 of, as you say, raising the bar of specificity within
3 that particular group because the CDC was concerned
4 that there was actually an over-ascertainment of
5 cases.

6 But the other thing that I wanted to ask
7 was, given the fact that 1500 records have now been
8 reviewed and, in fact, the capa of statistics are very
9 high in correlating the date of vaccination -- with
10 recorded date of vaccination. I'm wondering why
11 you're continuing that process. I mean, from my
12 perspective, I'd say stop. That's a lot of people
13 doing that work over a prolonged period of time, and
14 I'm sure that those researchers could be used
15 elsewhere. It's highly unlikely that those scores are
16 going to change significantly with the entire cohort -
17 - ascertainable cohort being available.

18 CAPT. YUND: Well, I think that's a good
19 point. One comment I would offer is that the number
20 of records that are available in St. Louis, the
21 12,000, is only a subset of the 30,000 births that
22 were looked at, and if we sort of fold up shop and go
23 away now, it will be very difficult to go back later
24 and gather more. So, I think Megan's thinking is
25 that they are there, they are set up, the funds have

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1 been allocated, let's get as much as we can out of the
2 effort. She's looking at other things in the health
3 records also, besides just the agreement between the
4 paper and electronic immunization. She's finding that
5 there's some information in the health records about
6 the pregnancy date. So there's more of interest
7 besides the simple immunization dates, and she'd like
8 to get everything she can out of St. Louis while she's
9 there.

10 DR. OSTROFF: Let's go first to Dr. Berg,
11 then Greg, then Col. Gardner.

12 DR. BERG: Bill Berg. I have a comment
13 and then a question. I think the meningococcal
14 vaccine experience is a cautionary tale for the birth
15 defect study. There's a high capa between the written
16 records and the electronic records, and you alluded to
17 the written records being the Gold Standard. Even
18 early on in the discussions, there were questions
19 about how accurate are the written records. And long
20 before there were electronic records, there were ways
21 in which the system could inadvertently introduce
22 errors. So I would not want us to take away the idea
23 that just because there are high capa values, that
24 we've solved this problem. I think the NHRC ought to
25 go back and look at how accurate the written records

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1 are, and the meningococcal vaccine instance sort of
2 provides a bit of a spur to that.

3 My question, which is on an entirely
4 different topic, for several Board meetings now we've
5 raised the question to the Navy about the Navy's
6 underreporting of disease as part of the routine
7 disease surveillance effort. Where does the Navy
8 stand on improving its routine disease reporting?

9 CAPT. YUND: Our routine disease reporting
10 happens through our Medical Event Reports and a system
11 that's called Navy Disease Reporting System. We have
12 a working group that's composed of some staff from
13 NEHC, BUMED, the Army Medical Surveillance Activity
14 where we have a Navy staff member, and this is a
15 problem that we're looking at very hard. I don't
16 think we have any improvement in reporting to show
17 yet. This is one part of an effort of a Navy
18 Preventive Medicine-wide self-assessment task force
19 that we've embarked on. I think it's one of the
20 important aspects of that task force, and we are
21 committed to improving the reliability of that data.
22 At this point, I don't have data to show you that
23 we've gotten there yet.

24 DR. BERG: I'd just like to remind you
25 that that was the answer you gave us last meeting

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1 also. I understand it's tough, but it will be nice to
2 see a little progress.

3 DR. OSTROFF: Dana.

4 COL. BRADSHAW: Dana Bradshaw, from DOD
5 Global Emerging and Infectious Threats Response
6 System. Bill Geddes (phonetic) and I are there, and
7 we just actually had a Navy Preventive Medicine
8 Resident from USUHS that's going to be looking
9 specifically at S&E reporting and putting in some
10 correlations there. But over and above that, I think
11 for all three services what we are looking at is the
12 electronic systems, trying to get correct laboratory
13 data -- I think we've mentioned this before. One of
14 my jobs there is actually trying to look at that and
15 actually trying to get correct laboratory data. We're
16 doing mapping of the different CACS2 systems. They've
17 done 30 of those right now, and we're looking at some
18 software methods to do that as an interim until CACS2
19 gets around. Hopefully that will actually help all
20 three services eventually, but there's hurdles in
21 terms of trying to get the laboratory data classified
22 and standardized, et cetera, and how they extract it.

23 DR. BERG: I understand all the high-tech
24 stuff, but what I'm referring to is a slide of about
25 three meetings ago in which the Army reporting started

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1 out slow, came up, and then peaked. The Air Force
2 came up, went down a little bit, came up. The Navy
3 went up and then down. And so, yes, the electronic
4 stuff is going to help, but in the meantime the Navy
5 reporting simply is -- for whatever reason, has not
6 been up to the standards of the Air Force and the
7 Army.

8 DR. GREG: Greg Gray. With respect to the
9 proposed prospective study of young Marines receiving
10 cold weather training at Pickle Meadows, unless the
11 outcomes are very objective like the CT scan, my
12 concern is that if you don't have a control group, you
13 might find morbidity that is due to many of the
14 different stressors there, and basically implicate
15 your population group as not being fit. So, I just
16 want to encourage you to consider the control group
17 that doesn't have the sickle cell trait in your
18 training morbidity evaluations.

19 CAPT. YUND: Sir, I think that's a great
20 idea, and I'll pass it on to the people who are
21 planning the study.

22 DR. OSTROFF: Can I ask just quickly, what
23 altitude is Pickle Meadows at?

24 CAPT. YUND: Six to 10,000 feet, I'm
25 informed.

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1 DR. OSTROFF: Col. Gardner.

2 COL. GARDNER: With respect to the
3 validation of the immunization status of the pregnant
4 women, you've done the 12,000 look at the total group.

5 What about the 280 cases? How many of them really
6 got the vaccine, the anthrax vaccine? It seems like
7 280 is a lot easier to handle than 12,000.

8 CAPT. YUND: Well, it's a lot easier to
9 handle than the 12,000, but we won't have as many of
10 the 280 as we're going to get until we get through the
11 12,000. I mean, they are going through the records in
12 a fairly efficient way, that being going through the
13 entire facility by the color coding system of the
14 health records, which means by the last digit of the
15 Social Security Number, and they are pulling all of
16 the requested health records in that fashion. For
17 them to go through and identify the 280 patients alone
18 I think would be an inefficient way for them to get at
19 the data.

20 COL. GARDNER: Well, I agree that you need
21 to look at the validity of both the numerator and the
22 denominator, but you're talking 5 or 10 percent
23 changes in the denominator which are not going to make
24 a huge difference. But if those 280 cases all come
25 from the 10 percent misidentified in the denominator,

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1 then you've got no results, and I think that's why you
2 need to look at the numerator specifically and usually
3 first. That's the easy part. And then that's the
4 part that ought to be addressed immediately. It seems
5 to me you can get that real quick.

6 CAPT. YUND: I'll pass that suggestion on
7 to the Navy.

8 DR. OSTROFF: One last comment about that
9 issue, I remember many of us that were listening to
10 this story last fall were somewhat incredulous that
11 these women could have been getting vaccinated in
12 their second and third trimesters, and I'm really
13 disturbed to hear that there is so far this high a
14 correlation between what was in the electronic
15 database and what's turning out to be the case, and
16 I'm just baffled as to how that conceivably happened.

17 DR. NESS: I think, though, actually when
18 you said that the total you're getting from these
19 records also that (inaudible words) because I think
20 that's essentially now affecting the work on a more
21 important issue with a less important issue.

22 DR. OSTROFF: Thank you, Jeff. Our next
23 presentation is Capt. Schor.

24 CAPT. SCHOR: Good morning on this fine
25 Navy/Marine Corps day, this the Marine Corps update.

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1 At the request of Dr. Ostroff, I'm just going to talk
2 about one of the main efforts that I've been working
3 on and reporting on to this Board over the last
4 several meetings. Next slide, please.

5 (Slide)

6 About over the last month, I've been
7 briefing the leadership of the Marine Corps. And as
8 many of you may not realize, all of the medical care
9 to the Marine Corps is provided by the Navy, but it
10 sort of works out like this. Bureau of Medicine and
11 Surgery owns the hospitals, the docs that work on the
12 ships are owned by the Fleet, and the docs that work
13 with the Marine Corps are owned by the Marines. So,
14 my office at Headquarters Marine Corps, and my boss,
15 Adm. Huffstetter, the Medical Officer of the Marine
16 Corps. We're advisors. We're in a true Public Health
17 position. We own nothing. The only budget that we have
18 is our very meager TAD budget. So we're advisors to
19 the Commandant and the leadership of the Marine Corps.

20 So, over the last month, we have been providing
21 briefings to one-stars, two-stars, three-star generals
22 and one four-star general, the Assistant Commandant of
23 the Marine Corps. The following slides are selected
24 from those briefings.

25 We have been working on injury

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1 attrition/injury prevention in the Marine Corps. That
2 has been raised by the Marine Corps when Gen. Case,
3 the Vice Chairman of the Joint Chiefs of Staff several
4 years ago, said, "How many Marines are we breaking?"
5 So I started to try to answer that using Preventive
6 Medicine resident help to do the research, and this is
7 sort of the cycle that this has gone on, and this is
8 what we proposed to the leadership. Next slide,
9 please.

10 (Slide)

11 We've taken this approach. We've tried to
12 emphasize as a strategy that if you want to have a
13 data-driven approach, and the leadership understands
14 that. When they go out to Parris Island or the Depot
15 in San Diego where you were last meeting, and they ask
16 the Commanding Generals, and generals don't know how
17 many Marines become injured or ill during the
18 crucible, for instance, they can only estimate it.

19 I'm taking a true Public Health/community
20 health approach by saying this is by Marines, for
21 Marines. So, they are advisory in this, we are not
22 reading the charts, Marines are, we're a half a step
23 behind, as I think we should be.

24 And, finally, we have put a spin on this.

25 It says we're going to treat Marines as athletes, as

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1 athlete warriors, that they want to be called. They
2 see themselves as world-class athletes, and in many
3 cases and many times they are.

4 The second bullet is draft UNS. Some of
5 you want to know what acronyms mean. That's a
6 Universal Needs Statement. That simply means that we
7 are getting this wedged into the combat development
8 process of the Marine Corps from the get-go. That
9 means that corporate Marine Corps is going to look at
10 this as a community and say we want this or we don't
11 want this. And we're going to ask for a few sheckles
12 of funding here. Next slide, please.

13 (Slide)

14 This is the single data slide that I
15 presented to the leadership. Some of this has been
16 presented in the past to this Board. Cdr. Fred
17 Landro, who has recently finished his Preventive
18 Medicine training, has collected this data from the
19 Physical Evaluation Board. This is very high on the
20 injury pyramid. I would have placed this just below
21 "death" on the injury pyramid for the Marine Corps.
22 These are Marines that are considered too broken to
23 remain in the Corps. They're either given a severance
24 or a disability tax-free payment.

25 During those four years of complete data

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1 capture -- and all this data on this slide is
2 administrative, none of it is medical, so I have used
3 the Marine Corps' data and other supporting boards'.
4 Over half are musculoskeletal codings, 42 percent are
5 degenerative arthritis, which could be a key process
6 or a coding issue with some of the Disability Rating
7 Systems which are not ICE-9s, we don't have those kind
8 of ICE-9s. And, interestingly, 75 percent of these
9 Marines are broken, so to speak, 10 percent or less.
10 Now, the Disability Rating System is very arcane and
11 very strange, but I look at that as a preventive
12 fraction. If they are only that broken, maybe the
13 Marine Corps can retain them through other means.

14 That bullet that says that in on year
15 about 1100 Marines are lost. That's very meaningful
16 to the leadership of the Marine Corps. A MEU, Marine
17 Expeditionary Unit. That's the pointy end of the
18 spear of the Marine Corps. That is the Marine Corps
19 element of an amphibious task force. Those are the
20 guys and gals that are out there from the East Coast
21 to the West Coast. And very interesting gender
22 disparity, female Marines are about 6 percent of the
23 Corps, and they have at least twice the rate, and in
24 some of the MOS and some of the ranks, it is up to 8
25 times the rate. Very interesting disparities. We

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1 don't know why.

2 I tried to capture some data from sort of
3 the industrial side of training in the Marine Corps
4 that some of you saw out at San Diego, and these are
5 kind of rough estimates, but it looks like they
6 separated about 700 recruits because of injury. If
7 you use the fact that it costs about \$7,000 per copy
8 to recruit a Marine and get them on the yellow
9 footprints at San Diego or Parris Island, that's about
10 \$5.5 million, that's probably a very low estimate, and
11 it takes using two weeks per recruit of recruiter time
12 -- and that's a very low estimate also -- that's about
13 27 recruiter years of effort.

14 The average lost training days was from
15 data developed in the mid-'90s from NHRC, Naval Health
16 Research Center. It looks like about 54,000 lost
17 training days per recruit. Now, that's a squirrely
18 figure. We don't know exactly what the right number
19 for that is, but at least it's a benchmark. Next
20 slide, please.

21 (Slide)

22 This, as I said to the generals, is the
23 one slide that I would pick to try to summarize our
24 program. I've used levels across the top. On the
25 very top of that, I tried to put some terms that are

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1 meaningful to the leadership. ORM is Operational Risk
2 Management. Every leader in the military and in the
3 Marine Corps, as they prosecute a mission given to
4 them, has to consider what the risks are of that
5 mission as they go through options analysis.

6 The middle part of that shows -- what
7 we're trying to show is a handshake between putting
8 athletic trainers in the operating forces, the
9 warfighters, in the training cadre, in working for the
10 Marines, and the partnership between Navy Bureau of
11 Medicine and the supporting hospitals. And you see
12 down below that in some of these cases we're trying to
13 get primary prevention working by policies,
14 procedures, training, changing the training, changing
15 how we train gunnery sergeants, the drill instructors,
16 those sorts of efforts, and that's going to be the
17 hard part to change in the Marine Corps, as we all
18 realize. And then this partnership in secondary and
19 tertiary levels of prevention. Next slide, please.

20 (Slide)

21 There's three elements to this next slide.
22 The core of this is what we're going to call the
23 Program Management Office. Now, that name may change,
24 maybe Center of Excellence. Those are the folks that
25 execute the contracts for the trainers, hire them, and

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1 also develop the data because we don't have an
2 institutional database for this, sort of to do the
3 epidemiology of this. Next slide.

4 (Slide)

5 The second part of this are the athletic
6 trainers and the athletic training rooms, and the
7 training in a session pathway and also the operating
8 forces, the warfighters.

9 And the third part -- and this is
10 absolutely critical -- is the handshake with Navy
11 Medicine. Those are called SMART Clinics. I think
12 you may have seen one of those, I'm not sure, in San
13 Diego. But those are sports medicine and
14 reconditioning therapy clinics. Those are any
15 reconditioning therapy clinics, the sports medicine
16 docs, podiatrists, kind of one-stop shops that treat
17 the broken recruits and try to return them to training
18 as fast as possible. That's been developed over the
19 last ten years. And so that's the heavy clinical side
20 of that. Next slide, please.

21 (Slide)

22 This data is historical and primarily
23 based on the SMART type clinics. SOI, School of
24 Infantry. Every Marine is a rifleman, as the Marine
25 Corps says. After they go through recruit training,

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1 they go up to Lejune or Camp Pendleton and spend,
2 depending on what their MOS or specialty is, they may
3 spend four weeks, they may spend 11 weeks, training to
4 be riflemen. And that's the impact of the Camp
5 Pendleton, the impact you see in savings that have
6 been accrued through SMART Clinic type approaches.

7 Next slide, please.

8 (Slide)

9 These are kind of best-guesses. I mean, I
10 think they are reasonable, to look at decreasing the
11 total force, injury attrition, disability attrition
12 under PEB, Physical Evaluation Board, system. And
13 that's to give the leadership some sense of the
14 impact. And saving 200 Marines a year is very
15 important to the three-stars and four-stars. That
16 means a lot. Total force of the Marine Corps is about
17 172,000.

18 Recruit attrition. The industrial
19 training base of the Marine Corps, it's very much an
20 industrial model. Recruits in, Marines out, that sort
21 of deal. Saving 140 recruits a year is probably a
22 conservative estimate. 5.4 years of recruiter time is
23 a low estimate. \$1.1 million of expenses. We may not
24 decrease the number of Marine Corps recruiters that
25 are out there in the hinterlands, but we may make

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1 their job a lot easier. We may decrease the
2 psychological stresses on them. We may decrease their
3 suicide rates. There are suicides amongst recruiters
4 because of the pressures they are under to recruit a
5 target. So, improving their quality of life through
6 decreasing injury attrition is a very important goal.

7 This whole issue of what's the right
8 number for lost training days -- you know, if a Marine
9 gets a stress fracture, they are put in a
10 rehabilitation platoon and they work with them. The
11 average duration in a training platoon is about 45
12 days, but the Marine Corps will try to retain them if
13 they are motivated recruits and it looks like they're
14 going to make a good Marine. They don't want to lose
15 those recruits. So, that's how tough the recruiting
16 scene is.

17 So the way ahead is next month the
18 generals of the training and education command are
19 convening an initial work group to put this together,
20 to put a structure together, and so we're going to
21 move out from my office's approach to this and put
22 this very Marine Corps "face" on this effort. Subject
23 to your questions, that's my brief.

24 DR. OSTROFF: Thank you. I'll open up
25 your presentation to the Board. Carol?

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1 DR. RUNYAN: I'm curious to know more
2 about your data, the rates and circumstances of these
3 injuries. Obviously, your primary prevention is only
4 as good as your understanding of what is happening to
5 create the injuries. Can you say a little bit more
6 about how that?

7 CAPT. SCHOR: Absolutely. Parris Island
8 collects different data than San Diego, for instance.
9 They collect different goals. That's all internally
10 report. There is no system to tie in data collection.
11 That's where we want to get to with this report.

12 Also recognize that different people keep
13 different data, some of it is medical and some of it
14 is administrative, and we look to merge those two
15 databases together. So the leadership of the Marine
16 Corps, the generals that own those bases, have access
17 to develop an injury tracking system, a surveillance
18 system that collects this data. It does not exist
19 now. The central access to this kind of data is very
20 difficult getting. You have to go to the bases and
21 try and get the data, and almost do record searches.
22 It's amazing, just can't get there.

23 DR. RUNYAN: I'm wondering if that's
24 something that the Board might be able to help with in
25 thinking through how to do that and helping it along.

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1 CAPT. SCHOR: I would hope that as this
2 effort goes on, we could come with a proposal for data
3 elements that we would like to track in an appropriate
4 manner, and ask for the opinion of the Board. I
5 appreciate that interest of the Board.

6 DR. CAMPBELL: My question is along those
7 lines. It would be nice to have data about when in
8 the training process these injuries occurred. And my
9 second question is about the difference between the
10 females and the males. If these data exist, can you
11 somehow compare the mechanism or the timing of the
12 training of the injuries of these two classifications?

13 CAPT. SCHOR: We have only begun to peel
14 the layers of this onion. We have not even gotten the
15 ICE-9 diagnoses to compare those gender differences.
16 The database just allows us to look at their
17 occupational specialty, their rank, their gender, and
18 some of their other personnel data. To merge that
19 with the medical report that gets them separated is
20 something that we have to link up, and it's not done.

21 It is a paper-based system at this point. There's no
22 electronic database. We'd love to get there -- gotta
23 have the money, gotta have the manpower.

24 DR. OSTROFF: One question that I would
25 have is I think it's laudable to be setting these

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1 goals for these 20 percent reductions, et cetera.
2 Have you set a target date to achieve them?

3 CAPT. SCHOR: That's what we're going to
4 discuss next month, to try to get some sense of the
5 target date. Of course, the leadership of the Marine
6 Corps would like this fixed yesterday. They don't
7 realize the difficulty of merging medical and
8 administrative databases, so I don't have a goal for
9 that. I would think that within the first year or two
10 we could see that level of reduction.

11 DR. GRAY: Greg Gray. One thing that
12 seems easy to do that you already have in your system
13 is the outpatient clinical encounter tracking sheets
14 that we saw in the various clinics. And it would seem
15 to me that you might be able to adapt these to capture
16 some of the data that you're after. And you might be
17 able to employ these in the various different settings
18 apart from the outpatient clinic where some of this
19 treatment is occurring early and not being captured.

20 CAPT. SCHOR: Absolutely.

21 COL. GARDNER: We've seen over the years
22 along these same lines a lot of ad hoc -- and I won't
23 say "half-hearted", but certainly unfunded -- attempts
24 to try to collect data and look at data and injuries,
25 but I've never seen any systemic resource approach

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1 established. I mean, as far as I know, there's no
2 full-time person given that job to track these data,
3 and that's where -- I mean, you can't make progress if
4 you can't measure the progress.

5 CAPT. SCHOR: Well, that's --

6 COL. GARDNER: -- it's the systemic
7 process of actually getting the data so you can track
8 it with some full-time people devoted to that effort.

9 CAPT. SCHOR: Our proposal has a budget
10 time to it. The Assistant Commandant is going to the
11 Governing Board of the Marine Corps, Resource
12 Governing Board of the Marine Corps, to try and get
13 funds even next year, which is very quick in the DOD,
14 as we heard yesterday, and we want to -- we are
15 fighting to have funded support for this data
16 collection, perhaps through support through Naval
17 Health Research Center or other consultations. We
18 don't have the billets and the bodies to shift within
19 the Navy or Marine Corps.

20 COL. GARDNER: And that's the point, most
21 of what we see is based upon projects that could be
22 given to students because we can get them for free.

23 CAPT. SCHOR: That's how I have to
24 operate. We're trying to get some resources against
25 that. And the leadership seems to support that at

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1 this point.

2 DR. OSTROFF: Ken, thanks very much.
3 We're going to have to move on, but we'll look forward
4 to updates. I think the Board is very interested in
5 this issue, and certainly seared in my mind is that
6 entire platoon on crutches that we passed by in San
7 Diego, and we'd certainly like to see that no longer
8 be the case.

9 The next presentation is Col. Woodward,
10 from the Air Force.

11 LtCOL. WOODWARD: Good morning. I'm
12 LtCol. Kelly Woodward, from Air Force Medical
13 Operations. Next slide, please.

14 (Slide)

15 I'm going to give you a brief snapshot of
16 three policy issues that we're working -- and program
17 issues that we're working right now on many issues
18 being worked in the Air Force. I'll give you a
19 snapshot of two implementation policy issues and then
20 one program execution issue. Next slide, please.

21 (Slide)

22 The first implementation policy issue is
23 regarding the Hepatitis-B vaccine for Recruits
24 Program. As you may or may not be aware, we now have
25 a Health Affairs policy to implement Hepatitis B

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1 vaccine amongst all new recruits in the military, and
2 services are going about implementing that policy. Of
3 interest to you all is the AFEB made this
4 recommendation I believe in 1998, and so we are now
5 implementing this program. But I wanted to just point
6 out that there are several issues in terms of how we
7 implement this policy and this program, and you see
8 them listed there.

9 First of all, there's much discussion
10 about whether or not to screen recruits prior to
11 immunizing them with the Hepatitis B series, and the
12 variables that are really at play there are really
13 cost issues for the most part, but some logistics
14 issues of how training, the very vigorous training
15 cycle and how much opportunity you have to screen and
16 then vaccinate, but what we have found in the Air
17 Force is that we believe that the sero-prevalence rate
18 of Hepatitis B surface antibody is going to be
19 somewhere around 20 percent. We don't have hard data
20 on that, and we'll know, though, in the next couple of
21 months when we start the program, but for the Air
22 Force, in our cost model, it's going to be cost-
23 savings to screen at a prevalence rate somewhere
24 around 5 percent. So, we're planning on screening,
25 but it's mainly a cost question and a logistics

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1 question.

2 Another issue of interest is the pediatric
3 versus adult vaccine issue. It turns out in the Air
4 Force, enlisted in basic training or enlisted
5 trainees, about 40 percent are 18 or 19 years of age,
6 and it turns out the labeling for Hepatitis B vaccine
7 pediatric dosing, pediatric vaccine is up to age 19,
8 and that vaccine is considerably cheaper than adult
9 preparation, so there is some discussion about whether
10 or not at which age to use pediatric versus adult but,
11 again, it is in the logistics issue.

12 And then, finally, mixing products amongst
13 different adult-pediatric products along with a series
14 of Hepatitis B, which could happen as they move
15 through our system, and also issues of combination Hep
16 A/Hep B vaccine. These are just some of the issues
17 that we're discussing in terms of implementing the
18 Hepatitis B vaccine program.

19 (Slide)

20 Another issue that is just now coming to
21 our plate is an issue of influenza vaccine for
22 trainees. We vaccinate trainees each year now for
23 influenza, but we now see clearly that the current
24 this year's vaccine expires -- all vaccine expires
25 around June 30, and we don't expect to have next

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1 season's vaccine available at our training sites
2 before late September probably, so we have a
3 significant gap in available vaccine.

4 Interestingly, we started looking into
5 what is really the risk in the summer months, and
6 certainly in the United States, the second bullet,
7 there have been 6 -- I think maybe more than 6 --
8 Influenza A outbreaks between May and September in the
9 United States, not in military populations.

10 There was an outbreak in recruits at
11 Lackland Air Force Base in July of 1999. It started
12 amongst some unvaccinated recruits, and there were
13 significant lost training days at that site, so it did
14 have a lot of morbidity -- no fatalities -- but there
15 is -- we believe a risk still exists, so we are
16 addressing this issue through two parallel actions.
17 First of all, pursuing with manufacturers the issue of
18 can we get the expiration date extended, which has
19 been done in the past, but it has some significant
20 possible issues.

21 The second one is in the event that we
22 can't do that, what are we going to do to manage the
23 risk, and it's through surveillance and perhaps
24 planning a contingency, if there is an influenza
25 outbreak, we'd be ready to respond promptly.

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1 We do want to emphasize the whole
2 Hepatitis B issue and for this that as was mentioned
3 yesterday in regards to Title X, we are not in any way
4 promoting off-label use of biologics. Next slide,
5 please.

6 (Slide)

7 Final issue I just want to briefly talk
8 about is Deployment Health Surveillance and Readiness,
9 that is, that the Air Force is stepping up to have a
10 comprehensive program to do both surveillance of
11 deployment-related illnesses to tell us for sure that
12 comprehensive countermeasures are implemented across-
13 the-board. Next slide.

14 (Slide)

15 Just to give you an idea, we just started
16 this initiative and we are going to systematically
17 look across our programs to assure that we capture all
18 the processes across the deployment health continuum -
19 - pre-deployment, deployment, post-deployment -- and
20 then ensure we have all of the enablers in place to
21 make sure things get done, such as policy guidance,
22 tools, measurement, and then analyses to reinforce the
23 implementation.

24 I just wanted to give you a flavor that we
25 take this very seriously. Dr. Shanahan raised a

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1 question yesterday about are we doing the
2 surveillance. We will step it up so that we expect
3 success. Next slide.

4 (Slide)

5 Just in summary about deployment health,
6 we take this very seriously, both surveillance and
7 medical countermeasures for our troops, and we have a
8 lot of issues to work through. We need to develop
9 better tools, and we need to measure our capability to
10 implement these programs, and then improve our
11 performance. Next slide.

12 (Slide)

13 That's all. Thank you. Any questions?

14 DR. OSTROFF: Kelly, thanks. Questions
15 from the Board?

16 DR. PIERCE GARDNER: I have two questions.
17 One is I am surprised at the prevalence of antibodies
18 in Hepatitis B was as high as 20 percent. These are
19 pretty much people who have not been immunized with
20 the routine pediatric process (inaudible words). It
21 seems high (inaudible words).

22 The second question is, I think the
23 developed formulation at 4 times (inaudible) the
24 pediatric dose. (Inaudible words.)

25 LtCOL. WOODWARD: Regarding the answer to

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1 the second question -- well, let me answer the first
2 question first. I may have misrepresented. Based on
3 ascertaining a history of whether or not our new
4 recruits have had -- was believed to have had Hep B
5 vaccine, and we got up to 20 percent. I apologize,
6 that was not sero-prevalence. The data actually from
7 CDC says that it ought to be more like around 40
8 percent because of the nationwide strategy of
9 vaccinating starting in infancy, now catch up in
10 adolescence, that CDC, from that immunization survey,
11 our attempt to try to extrapolate that, it ought to be
12 about 40 percent, but we don't believe it's that high
13 at all.

14 DR. PIERCE GARDNER: I don't believe we've
15 been immunizing in infancy for 19 years, and I think
16 these immunization by condition is (inaudible words).

17 LtCOL. WOODWARD: That is, again, the CDC,
18 the number from there, and they estimated for an
19 immunization survey that it could be very high in
20 terms of people who had the series. I guess that
21 would be mostly by age 4, and catch up in adolescence
22 which is the (inaudible words).

23 The second question about Hepatitis B
24 vaccine, the adult preparation has twice in it of the
25 pediatric and, by the way, the 1999 people did address

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1 of using pediatric dose in young adults up through age
2 29 and recommended they thought it would be equally
3 effective up to age 29.

4 DR. OSTROFF: Other comments?

5 (No response.)

6 Thanks very much. We have to move along.
7 Our next presentation is from the Joint Staff, and we
8 have Maj. Jeff Gillen.

9 MAJ. GILLEN: Good morning. Next slide,
10 please.

11 (Slide)

12 I'd like to give a brief update on the
13 anthrax vaccination program as the Joint Staff knows
14 it. First thing was the Institute of Medicine report
15 that came out. The basic take-aways from the
16 preliminary report were that it was recognized that
17 AVA is a safe and effective vaccine. We have so many
18 strains of anthrax. So that's good for our take-away.

19 And that there's no evidence of adverse events
20 occurring at high rates in the general public.

21 The current success of the anthrax
22 vaccination program is that it's at the Secretary of
23 Defense, he's working with Federal partners, the other
24 agencies, and we're just waiting for a release of the
25 policy at this point. There's nothing more I can say

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1 about the policy, it's just that we're working the
2 issues with our sister agencies across the federal
3 programs. Next.

4 (Slide)

5 The other topic of concern is smallpox.
6 Some of the background on the smallpox program is that
7 CDC has an approved FDA IND. It controls almost all
8 the stocks of Dryvax vaccine, and we're working with
9 Health and Human Services to establish DOD's
10 requirement for a set-aside. We're also drafting
11 through the Army's Surgeon General's Office to
12 establish DOD supplement, that's coming together this
13 week. And the Joint Staff is expected to receive it
14 approximately the first couple of days of June for
15 coordination through the commands, as well as the
16 services.

17 The Department of Defense has tried 5
18 million doses of VIG vaccine, and currently OSD -- at
19 the OSD level, they're developing their vaccination
20 policy on how they want to implement their policy on
21 vaccination for smallpox, and that's ongoing as we
22 speak.

23 One last thing on smallpox. There was a
24 meeting yesterday up in Health Affairs, and one of the
25 things that was brought up last night and again early

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1 this morning was making recommendation to have the
2 AFEB review the CDC's vaccination program for whether
3 or not revaccination is still effective or would be
4 effective. That's not -- that's probably coming, but
5 it's not -- I revalidated that this morning. I wasn't
6 aware of that. That is likely to happen very shortly.

7 I was also asked late yesterday to give a
8 quick update on investigation of new drug protocols.
9 The anthrax, the Department of Defense has an anthrax
10 post-exposure treatment protocol. We've received no
11 comments from FDA within the last year, which we would
12 call passive approval, and that has been -- the
13 current status is that it's with the United States
14 Army Surgeon General as they develop a final
15 implementation plan.

16 We have three other treatment protocols
17 that are in the works -- PB, Bot Tox and smallpox.
18 The Joint Staff, my office coordinated with the
19 commands and the services on all three, who turned it
20 over to Health Affairs, who then turned it over to --
21 it's with MRMC, and they are preparing the final
22 package to send to FDA.

23 The dates are a little fuzzy because the
24 principal that I was going to contact was here
25 yesterday, so -- but as we know they are ongoing

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1 initiatives and working, and that the Army is working
2 those implementation plans as well.

3 That's all I have from the Joint Staff.
4 I'll be happy to answer questions.

5 DR. OSTROFF: Thank you, Jeff. Questions
6 from the Board?

7 (No response.)

8 I have one. Since the anthrax policy is
9 imminent, do you have a rollout plan in place?

10 MAJ. GILLEN: To execute?

11 DR. OSTROFF: Not to execute, but to
12 inform and educate the potential recipients on the
13 policy?

14 MAJ. GILLEN: The anthrax vaccination
15 immunization program office, AVA, is working those
16 plans as we speak, with the services and commands.
17 They are still in draft. Once the policy is signed,
18 they can circulate that. But after it is signed by
19 Secretary Rumsfeld, we believe that within 30 days
20 we'll have all those plans together and be ready to
21 start the vaccination program.

22 DR. OSTROFF: Thanks. Other questions?

23 (No response.)

24 We'll certainly look forward to hearing
25 more about the smallpox issue. Thank you.

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1 Our next presenter is Cdr. Ludwig.

2 CDR. LUDWIG: Good morning. As you can
3 see, I'm Cdr. Sharon Ludwig, from Naval Staff
4 Headquarters. Next slide, please.

5 (Slide)

6 I'd like to report this morning on the
7 fifth tuberculin outbreak that's come to my attention
8 in three years. Three of them I have reported on
9 here, and truly I am getting tired of the same
10 subject, and I would like to, at the end of this
11 presentation, propose a radical change in the policy
12 that I potentially will bring as an official question
13 for the Board, so I'd like to have some support for
14 it. Next slide, please.

15 (Slide)

16 Oh, by the way, I do apologize I don't
17 have handouts. I actually only gave the hard copy
18 this morning. I was preparing two reports at the same
19 time, one to give here and one that I need this
20 evening for Key West to give to the folks down there.

21 And in my attempt to get everything sorted out, I
22 copied the same report twice and had to redo this
23 report last night. So you don't have some of the nice
24 pictures and you don't have the hard copy, but on the
25 Web site you can get the presentation.

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1 Anyway, the outbreak report that was sent
2 to me was an excess positive tuberculin skin test at
3 Key West, Florida, that's a group that turns out to
4 have a population of about 333 people, but at this
5 time I didn't know the population numbers. What was
6 reported to me was 25 tests interpreted as positive,
7 of about 150. Eighteen of them so far have been
8 evaluated at the Base Clinic by a Navy physician, I
9 think, who comes into the clinic at Key West, and
10 almost all of them have started on LTBI treatment,
11 Latent Tuberculosis Infection. Next slide, please.

12 (Slide)

13 By the way, I just want to mention that
14 when they told me that these 25 were interpreted as
15 positive, the size was not initially given, no size of
16 the reaction, they just said 25. And at the Navy
17 Clinic, again, the size of the reaction had not been
18 re-evaluated, it was just accepted that there were 25
19 positive tests. Next slide.

20 (Slide)

21 Three groups of people were involved in
22 the investigation -- the local (inaudible words), and
23 then they called the Atlantic Area Environmental
24 Health personnel and the Monroe County Health
25 Department to be control on this. Next slide, please.

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1 (Slide)

2 The county investigated and, first of all,
3 said that the temperature tuberculin skin test
4 positive was not excessive, and they were relying on
5 numbers from CDC that they -- in the general
6 population. Apparently you can expect 5 to 10 percent
7 sensitivity rate. Now, I've never been sure, as I've
8 read this, whether that means that they accept an
9 incidence of TB infection between 5 and 10 percent as
10 normal, let's say, or whether they expected it, but
11 many of those may be false-positives. I'm not sure
12 that anybody really knows the answer to that question,
13 although many of us have pretty strong suspicion.

14 Anyway, the county found no common
15 exposure. There were actually 11 separate that were
16 affected. It was 25 people were scattered among the
17 number of units, which had really no overlap in their
18 duties and their exposures, and there were no active
19 cases found in the evaluations. In fact, the entire
20 county that includes the Keys averages about four
21 incident cases per year. And all of those -- we went
22 over the incident cases for the past five years, and
23 all were either recent incidents from high prevalence
24 areas or had the known exposure long ago and far away.

25 Next slide, please.

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1 (Slide)

2 The county investigation, again, did not
3 address the question of what type of reaction is
4 considered positive. In fact, she admitted to me that
5 was one question she had forgotten to ask. They did
6 suggest they could retest all the people using the
7 Tubersol test to see if they could reduce the
8 incidence of false-positives, and Aplisol had been
9 given (inaudible). Next slide, please.

10 (Slide)

11 The folks down there -- the Coast Guard
12 people who looked into this whole situation before
13 they called me found that 7 of 17 people who were
14 retested were still interpreted as positive tests, but
15 you'll notice it goes from 17 to 7. The ones who were
16 started on the LTBI treatment were continued. Nobody
17 was (inaudible words). Next slide.

18 (Slide)

19 When I got involved, I found that of 25
20 initial 25 TST+ interpretations, 20 were over 10mm but
21 less than 15mm, and only 5 were over 14mm. Of 17 that
22 were retested with Tubersol, only 1 was over 15mm, 1
23 had increased from 14 to 15mm, and of the 8 who were
24 not retested, only 1 was above 15mm, and those three
25 stars are what I now consider (inaudible words). Next

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1 slide.

2 (Slide)

3 Two cases gave a reading of positive, not
4 necessarily a TB infection. In my investigation, I
5 evaluated the risk factors, including the frequency,
6 length and quality of any potential exposures that
7 they had had, and determined that the 15mm should be
8 their cutoff for a positive. So, of all of these
9 supposed positive-TSTs, it turns out that they were
10 boiled down to 3 out of what turned out to be 268
11 tests administered, which left a rate of a particular
12 two-month period of 1.1 percent. Even with the 10mm
13 cutoff, the rate turned out to be 7.5 percent,
14 obviously still within that 5-10 percent that CDC says
15 on the general population. However, all of this is
16 very reassuring to me that we weren't probably dealing
17 with an active case anywhere, or even an exposure to
18 an active case on a migrant interdiction or something.

19 It hasn't been all that reassuring yet to folks down
20 there, and that's why I'm going. Next slide, please.

21 (Slide)

22 It's still common perception then that
23 10mm is the cutoff, and there is really a lack of
24 understanding or appreciation about the risk-base
25 evaluation for TSTs. Even once I explained the risk-

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1 based screening, there is still a strong perception
2 that Coast Guard work is greater risk. Next slide.

3 (Slide)

4 And my job really is going to be point out
5 why it is not an increased risk despite the exposure
6 to people possibly from high-risk areas, from areas
7 with a high prevalence of active tuberculosis. There
8 really isn't time because the red light is blinking
9 madly at me, I'm not going to go into all the details.

10 However, I do want to mention that I believe that the
11 psychological impact of the work these people do on a
12 daily basis. Interdicting migrants and law
13 enforcement and other things where they come into
14 contact with people who are probably dirty, different,
15 and out on the sea for a long time, who are
16 undernourished and in poor health, the psychological
17 impact is not to be minimized. And so it's a very
18 careful consideration we have to deal with in those
19 situations.

20 The historical perception, of course, is
21 that TB is an infector. We still do know that it is a
22 dangerous disease, and with some of the recent changes
23 in dealing with TB, we cannot make lightly of. Next
24 slide.

25 (Slide)

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1 My conclusions really are that there's no
2 further investigation indicated in terms of looking
3 for an active case, as has been the case so often
4 among myself and the rest of the Preventive Medicine
5 Service. However, as I mentioned, there are several
6 concerns, and I won't read them to you, you can read
7 them.

8 Finally, the policy issue that I would
9 like to propose is to discontinue all tuberculosis
10 testing except for in the military -- well, in the
11 Coast Guard, except for at accession for basic
12 training, and when there is a strong suspicion of
13 significant exposure, still leaves a number of
14 questions how to evaluate the risk that various units
15 or various individuals undergo. I think that the
16 amount of time that I've spent, and others have spent,
17 on this issue is something that may call for some kind
18 of radical proposal. I'm the only person in the Coast
19 Guard, and I don't think that my time is best spent
20 re-evaluating TB positives, and there are so many
21 other issues that are not reported on.

22 (Slide)

23 I did rewrite an instruction a few years
24 ago, and found that that was totally inadequate for
25 what is really known to (inaudible words) about

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1 tuberculosis. And that ends my presentation.

2 DR. OSTROFF: Thank you very much. Let me
3 open it up to the Board, if there are any comments.
4 David?

5 DR. ATKINS: David Atkins. Were these
6 positive tests, had they been tested at accession and
7 they were negative?

8 CDR. LUDWIG: Correct. All these people
9 did have a history of their previous tests, and they
10 were, I believe, all zero before. And, of course, one
11 of the lingering questions is why all these
12 conversions, apparent conversions, at one time, and I
13 have a list of possible explanations that I'm going to
14 go through, including exposure to nontuberculo
15se microbacteria. And I don't think anybody here can say
16 for sure what causes that, but it does happen, we see
17 it from time to time.

18 DR. OSTROFF: Well, let me just comment on
19 that. We do know from surveys that were done in
20 military personnel back in the '60s with the highest
21 incidence of exposure to nontuberculos microbacteria
22 is in the southeastern United States, particularly in
23 Florida, so that does happen. However, I know from my
24 experience with the Coast Guard that very often the
25 PPD tests on accession were not recorded as zero, they

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1 were recorded as negative, and that's problematic
2 because, in point of fact, the TB test interpretation
3 is an increase of 10mm in size, and if you record it
4 as negative, as you know, very often what you'll have
5 is people with 2 or 3mm, or 4mm, or 5mm, and that's
6 not the same as putting down on the record that it's
7 negative, and that's been one of the constant problems
8 with the Coast Guard.

9 I don't think you're going to be able to
10 get away with the policy of not doing periodic skin
11 testing. I can't see that happening. I myself was
12 involved a number of years ago in writing some of the
13 policies regarding the AMIO, and I don't think it's
14 going to be acceptable to personnel, to the force, not
15 to do some sort of skin testing after what are
16 considered to be high-risk circumstances, particularly
17 for a place like Key West.

18 CDR. LUDWIG: Yes, sir. All of those
19 issues in terms of potential explanations for
20 (inaudible), and there are many more that I go into in
21 terms of not just the fact that they are reported as
22 negative rather than some number of millimeters or
23 0mm. There are many other issues.

24 One of my policies that I suggested when I
25 made policy recommendations, things I'd like to keep

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1 but people would just not accept (inaudible words),
2 and one of the reasons why I proposed to the Navy
3 (inaudible), and at the next meeting I might be able
4 to present --

5 DR. OSTROFF: And coupled with that is
6 that there have been circumstances where people really
7 were exposed to individuals on these ships with active
8 tuberculosis, so there is a legitimate reason to do
9 it.

10 CDR. LUDWIG: One of the photographs that
11 I had in my original presentation had a nice picture
12 of a migrant interdiction, and you see people in the
13 background, if you look you can see that (inaudible)
14 had masks on.

15 Evaluating the risk, I do recognize that
16 they -- I think that we can all admit that it's
17 probably very likely that they have encounters with
18 people that have tuberculosis. We never bring people
19 inside the ships, it's always on deck, always -- so
20 there's air and ultraviolet light. Their face-to-face
21 contact with any person at most would be a couple of
22 minutes at a time. There are some other instances,
23 too, I don't want to take the time for it now, but in
24 terms of keeping it in mind for the (inaudible).

25 DR. OSTROFF: Thanks. Dana.

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1 COL. BRADSHAW: One thing you might think
2 about since there's still some discomfort at the local
3 level, there are tests now available, and it might be
4 something you can go back with. For instance, if
5 they've still got 18 people on the LTBI, perhaps they
6 could cross-check with a (inaudible) test. You might
7 get a lot more specific information about what's
8 actually going on, including some information about
9 the line of bacteria exposed to.

10 The other question is, are we able to
11 identify whether or not any of these that were
12 (inaudible words) more and more interdependent in five
13 years, that would be one thing.

14 Also, I think we already have support from
15 the AFEB for just doing -- not doing continual TBC
16 testing for people that just put into CONUS to do
17 (inaudible) because the problem I think for the Coast
18 Guard is defining what really is a risk for people
19 that are interacting with refugee populations or
20 people that they are bringing on-ship. But the
21 (inaudible) test might be helpful in that respect.

22 We're going to do probably in the Air
23 Force (inaudible) risk-base training, and we've
24 grappled with whether we should do any random sampling
25 just to get an idea of our (inaudible).

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1 DR. OSTROFF: Thank you very much. Let's
2 go on to the next presentation. This is one that
3 we've not heard before. Capt. Winkel, from Reserve
4 Affairs.

5 CAPT. WINKEL: Thank you. My name is
6 Bernard Winkel, from Reserve Affairs. This is the
7 office that deals with the policy legislation issues
8 with the administration and utilization of the Reserve
9 community. I want to thank Col. Riddle for the
10 opportunity of presenting to the Board, and for this
11 first presentation I'd like to just go over some
12 general information about the Reserves and some of the
13 medical issues of the Reserves. Next slide.

14 (Slide)

15 Next slide.

16 (Slide)

17 Looking at this slide reminds me of the
18 commercial "It's not your father's Oldsmobile",
19 meaning the changes. I've been in the Reserve
20 community myself, I guess, from 1980 to 2001 when I
21 returned to active duty for a three-year period, and
22 it has been quite a change in utilization of Reserves,
23 as you can see from that chart, going from .9 duty
24 days up to 13.5. The change has been primarily with
25 getting out into the field and providing contributory

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1 support to local commands. Initially, a lot of their
2 training was done at the Reserve Center site, and
3 that's changed considerably. I mean, when I left the
4 Medical Reserve when they were doing same-day surgery
5 at many of the local NTFs, as one indication of how it
6 really has changed in using these resources. Next
7 slide.

8 (Slide)

9 Here you can see the actual decrease in
10 manpower over that same period, so we really are doing
11 more with less, as the slide shows. The output has
12 increased 13-fold whereas the personnel support has
13 gone down by 25 percent. Again, Active Duty has gone
14 down by 35 percent, so a lot of our services have been
15 incorporated into the Active Commands.

16 What enables us to do this is, again, I
17 think, the Reserve community has gotten much more
18 flexible and doing flex-drills. It's not only just
19 weekend, it's during the days, during the evenings,
20 it's 24-hours-a-day. You go for a few hours. It's
21 just a lot of flexibility incorporating the manpower
22 into the Active Commands. Next slide, please.

23 (Slide)

24 This gives you, again, just an idea about
25 how it falls out with the numbers. The Selected

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1 Reserves group -- these are the people that are the
2 active drillers, either at Reserve Centers in a lot of
3 coordinated units, or they're individuals that drill
4 with Active Commands. In IRR, the green group, are
5 people that are not actively drilling but this is a
6 group that's available, they have special skills, and
7 are available to the various Reserve Components. Each
8 Reserve Component uses them in different ways, some
9 use them more than others, but they are available.

10 Next slide, please.

11 (Slide)

12 Again, this gives you an idea of the total
13 numbers. This is as of fiscal year '01. The Army
14 National Guard, obviously, is the largest with the
15 351,000, Army Reserve, Navy Reserve, Marine Corps, Air
16 National Guard, Air Force Reserve, and Coast Guard.
17 So that gives you, again, some idea of the numbers
18 we're talking about. Next slide.

19 (Slide)

20 Again, this breaks it down by various
21 military actions. Right now, we're demobilizing a
22 number of people, so we're probably about 77,000
23 instead of the 88. But that, again, gives you a rough
24 idea of how the numbers break out. Next slide.

25 (Slide)

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1 Again, deployment. The basis of the
2 commonality between Active and Reserve Components. At
3 pre/post assessment, very important, that was an issue
4 that was brought up yesterday. With the Reservists,
5 when they are demobilized and they go back into the
6 civilian world, we don't get to see them as often.
7 And when the medical complications come up which may
8 be related to deployment, it becomes more complicated.

9 So that's why the pre/post assessments are certainly
10 important to us. Again, we sometimes are obviously
11 exposed to the same types of things during deployment
12 as an Active Component. We have the same readiness
13 requirements, training, medical, et cetera. Next
14 slide, please.

15 (Slide)

16 Some of the differences. Again, one of
17 the major ones is limited access to MTF care. What
18 happens is that typically Reservists get their health
19 care through their civilian health care providers.
20 Many of them certainly live and work large distances
21 from MTFs whereas if you're Active, your Command are
22 typically co-located with support systems and have
23 access to military health care. Obviously, you have
24 limited access to the Reservists. They typically have
25 15 days of AT, then 2 days a month. Again, how that's

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1 taken -- again, it varies, depending on the Reserve
2 Component and the flexibility. It's no longer just on
3 the weekend, they may drill during the day and
4 evening, whenever they need it. Next slide, please.

5 (Slide)

6 Again, some of the challenges. When we
7 talk about immunizations and some of the necessities,
8 I mean, we get individuals into the Reserve or they're
9 new accessions. If they're new accessions, they
10 typically go through the Recruit Depots and then
11 they're exposed to everything that a Recruiter gets.
12 So, that's not a problem.

13 How it becomes (inaudible) issues and
14 things of that nature to get the individual to get the
15 treatment that they need. Again, different service
16 components are handling that in different ways. The
17 Navy uses the MTF. The Army, they've established some
18 arrangements now with (inaudible) program, which is an
19 arrangement with HHS and the facilities as a way of
20 keeping up. And, again, that's a big change. I mean,
21 ages ago when I first got into the Reserve after
22 coming off of Active Duty, we used to have our
23 physicals -- typically a lot of physicals were done
24 right at the Reserve Centers, and depending on what
25 the Reserve Center had, you either got part of that

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1 physical or you got an FNA, which meant "facility not
2 available" on your physical, so they were not -- often
3 not the most complete. That's changed -- well, it's
4 changed. I mean, now the physical is the same as the
5 Active Components now, I mean, especially since the
6 Gulf War, we want to maintain medical readiness to the
7 same standards.

8 Then follow-up difficulties, there's a
9 concern when an individual backs away from the health
10 care facility. They are involved in their civilian
11 lives and they live a distance from a facility, so
12 that's a challenge.

13 Data entry, the chart is not always
14 available, and they get treatment from a civilian
15 provider, that may not always get access to the
16 individual's chart or record. Again, provider access
17 to clinical guidelines -- I'm talking about civilian
18 providers that the individual may use. Now there are
19 some guidelines that -- DA-DOD guidelines for post-
20 deployment health concerns that recently was set up.

21 Well, that's basically it. I know I
22 promised to get through quickly, I know we've fallen
23 behind. Any questions on some of these issues?

24 DR. OSTROFF: Thank you. Let me just
25 comment by saying I recently was at one of the

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1 overseas bases, and I realize the incredibly important
2 role that the Reservists play in that setting.
3 However, from the health care point of view, they were
4 certainly a major challenge. In the two weeks that I
5 was there, we had four Reservists who had major
6 cardiac emergencies, including one that required
7 bypass surgery because many of them had neglected to
8 bring their cardiac medications with them when they
9 were deployed overseas. And it just makes me wonder
10 what screening is done of these individuals to make
11 sure that they are deployable.

12 CAPT. WINKEL: Well, that is a challenge.
13 They've had annual physicals. I mean, those people
14 that are drilling with organized units -- I mean, that
15 shouldn't be the case. I mean, we have the pre-
16 deployment assessments which when somebody is going on
17 Active Duty or considered for deployment their record
18 should be reviewed and updated, and they should be
19 checked periodically. Where it does become a
20 challenge is with that IRR group, they are not seen or
21 they may be seen once a year for a pre-assessment. So
22 there are more unknowns in that community. And,
23 again, we're trying to get a better handle on
24 monitoring their medical state there. You're
25 absolutely right, that is.

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1 One of the things we're doing is that each
2 component is on a Web-based data system where the
3 medical information can be entered and where the
4 Reserve Center or where the Command can have access to
5 it as a more effective way of monitoring because right
6 now a lot of it is hard-copy medical records and
7 things like that. If it's Web-based, I think it's
8 much more effective and an efficient way to keep up
9 with that information.

10 DR. OSTROFF: Thanks. I think that it's
11 not always the case with the Reservists that they fit
12 the definition of young, fit and healthy that we heard
13 about yesterday. Thank you very much.

14 We're running a little bit late, but our
15 next presenter is Capt. David Brown, from the British
16 Defense Forces, and I'm sure he has a presentation
17 that many of us have been looking forward to hearing
18 about given the recent events at Ogrum (phonetic).

19 CAPT. BROWN: Good morning. I'm David
20 Brown. I'm a Reserve operation physician, like the
21 other (inaudible) working in the area of dealing with
22 one's health. (Inaudible words) with Health Affairs
23 and also with the Veterans Administration (inaudible
24 words).

25 I did have some slides to give you, but

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1 unfortunately they didn't (inaudible words). Instead
2 of talking (inaudible words), I can just concentrate
3 on two tape recordings. The first thing I want to
4 talk about very briefly is our anthrax vaccination
5 program. Our program commenced in May of last year.
6 It is a voluntary program which consists of four shots
7 -- first shot, second one after three weeks, third one
8 in another three weeks, the next one after six months,
9 next one after a year. And it's intramuscular as
10 compared to the subcutaneous (inaudible).

11 We previously vaccinated against anthrax
12 during (inaudible), it was about three or four years
13 ago, and we began as one big program, and the update
14 was very low (inaudible words). When the decision was
15 taken to reinstitute the vaccination program last
16 year, a lot of attention was paid to the health risk
17 communication aspects of this, trying to get the
18 update increase. And certainly up until now, that
19 seemed to be aimed (inaudible words), an operation we
20 have against Iraq and which took place in Saudi Arabia
21 and also in Turkey.

22 The update started off very, very poor.
23 We're looking at perhaps 18 or 19 percent of those
24 (inaudible words), despite a large education campaign
25 aimed at (inaudible) the medical officers and also

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1 (inaudible words). And the update of vaccination was
2 very, very touchy. We're looking at some, on ships,
3 the risk was very low, you find perhaps 2 or 3 percent
4 of people onboard that need to be vaccinated whereas
5 for some of the other units it would be 30-40 percent.

6 However, after events in the U.S. last year, we're
7 not surprised that the update (inaudible words). In
8 the last three months, it has leveled out to a
9 consistent level about 45 percent is what we're going
10 to get now. Overall, (inaudible words).

11 Okay. That's the first topic I was just
12 going to mention. I would say it's fairly relevant to
13 (inaudible words) anthrax vaccination. The second
14 issue is very, very briefly, a recent event affecting
15 one of our vehicles that was in Afghanistan, last week
16 we started to receive reports about an outbreak of
17 diarrhea and vomiting in this hospital. The hospital
18 consists of 70 personnel. It's a very small unit
19 (inaudible words). Of the initial cases, two were
20 very seriously ill and, indeed, (inaudible). One of
21 these cases was evacuated through the U.S. system to
22 Ramstein, Germany, the other one back to the U.K.

23 There was a total of 18 cases identified
24 in the first two days. I say two were evacuated very,
25 very quickly, back to Europe, and a further six

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1 slightly later. Over the next few days, 20 further
2 cases developed, but their symptoms were much less,
3 this was just really diarrhea and vomiting, and an
4 infection referral team was sent out from the U.K. to
5 look at this particular incident.

6 Our initial suspicion centered on shigella
7 or E.coli and, indeed, there were reports that
8 shigella had actually been identified by a check at
9 the site. Not being able to confirm those reports,
10 when I talked to the general staff this morning, they
11 didn't know anything about them. Instead, what we
12 have isolated is another like virus which has
13 responsible for a number of outbreaks in the U.K. over
14 the last few months, also known as (inaudible). And
15 the isolation of that is being carried out by
16 (inaudible) authorities in the U.K., and they haven't
17 been able to find anything else. So, that being said,
18 (inaudible) the medical staff went out to (inaudible
19 words).

20 I'm here to say that the disease has now
21 settled down, there have been no further cases since
22 19 May, and as of this morning the field hospital is
23 open for business and receiving no new cases.

24 DR. OSTROFF: Thanks very much. I'm not
25 aware of Norwalk causing disease. I mean, I'm

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1 wondering if what happened wa that there was also some
2 Norwalk floating around and because once this was
3 recognized some of these latter, more mild cases, were
4 the ones that you had good samples on, whether you
5 were missing something else in these more severely ill
6 individuals at the beginning -- I mean, because that
7 would be highly unusual to have meningeal signs and
8 symptoms from Norwalk.

9 CAPT. BROWN: Yes.

10 DR. OSTROFF: I'm curious. The response
11 to this in both the British media and in Parliament
12 has been quite vigorous, to say the least.
13 Particularly, I saw several articles that commented on
14 the degradation of infectious disease capability
15 within the British military. I don't know who would
16 be politically correct to comment on that, but --

17 CAPT. BROWN: You probably thought I
18 wouldn't, but I will anyway.

19 (Laughter.)

20 CAPT. BROWN: It's normally a very small
21 medical unit, so you wouldn't normally expect
22 (inaudible words). We do have a very, very limited
23 amount of (inaudible words). We do rely very heavily
24 on the civilian Public Health Service for a lot of our
25 support. I don't think it would have made any

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1 difference at all in this particular outbreak.

2 DR. OSTROFF: Any other questions?

3 (No response.)

4 Thank you very much for that update. Can I
5 ask one question concerning the anthrax vaccination,
6 the voluntary -- is that the license schedule for the
7 vaccine that's being used in the U.K.

8 CAPT. BROWN: That is the license schedule
9 for the vaccine.

10 DR. OSTROFF: And it's licensed for use
11 intramuscularly?

12 CAPT. BROWN: It's licensed for use
13 intramuscularly, as I say, on a four-shot basis
14 (inaudible words).

15 DR. OSTROFF: Okay. Thank you. Our last
16 presentation is by LtCol. Fensom from the Canadian
17 Armed Forces.

18 LtCOL. FENSOM: Thank you and good
19 morning. (Inaudible words), and I'd like to also say
20 that I promise not to get into (inaudible), I really
21 just have some information from our Center, and I want
22 to begin by thanking the Board for the warm reception
23 you gave Dr. Whitehead, who presented at San Diego.
24 Historically, it has been the Washington-based
25 clinician who has participated in the Board.

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1 (Inaudible) and myself have felt it would be more
2 valuable to bring some of our people down from Ottawa,
3 and I consider this a very valuable exchange forum.
4 So, as a result, I proposed to our headquarters that
5 (inaudible words), so thank you very much for the
6 great reception there and with the Board's
7 concurrence, I'd like to make that a routine.

8 Just a few info items from north of the
9 border post 9/11. One of the things that has happened
10 is an expansion in the capacity for (inaudible)
11 research facility (inaudible) training for first
12 responders during a chem/bio (inaudible), and since
13 then we've had a number of groups from the States come
14 up and train civilians (inaudible words) in the
15 environment, and this has been valuable. We're
16 planning to do a lot more of that. It's my
17 understanding the central facilities is available in
18 which folks can train for chem/bio agents in an
19 exercise scenario.

20 We also, on the military side, recently
21 approved starting up an immediate response chem/bio
22 unit with capabilities for detection, containment and
23 follow-up treatment, and these folks are planning to
24 do some training with your folks out at Aberdeen. So,
25 that will provide us a bit of that capability for

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1 (inaudible words).

2 (Inaudible) Canadian force, we have a
3 couple of ongoing studies which we hope will be
4 presented to the Board in the '03 time frame. One of
5 them is an extensive survey and we're going to ask the
6 question of the survey personnel also having those
7 structured interviews in detail. We're hoping that
8 will give us a good benchmark on mental health issues
9 where, of course, that may be of interest to you.
10 We're also doing a in-depth profile psychologically of
11 our troops in Afghanistan. This was done pre-
12 deployment. It will be redone post-deployment all the
13 way up to the two-year mark, with the intention of
14 hopefully getting us any information that might be of
15 use in terms of vulnerability to (inaudible) to
16 stress-related problems on deployment, and also to try
17 to evaluate in at least a semi-scientific way some of
18 our (inaudible words), that is, with regards to post-
19 deployment stress issues.

20 We're also currently involved in
21 investigating a small cluster of problems in
22 (inaudible) amongst air traffic controllers on our Air
23 Force bases. We're collaborating to use that with the
24 Surgeon General's staff to look at that because the
25 expectation is that this is a random method. We'll

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1 certainly let you know if anything turns up there.

2 And for those of you who followed the Sgt.
3 Kipling case which was our Air Force sergeant who was
4 court-martialed for refusing the anthrax vaccine.
5 Fortunately, the appeal of the original decision came
6 back in favor of the Department of National Defense,
7 so we're now back to a steady state of (inaudible
8 words). Our operational vaccine policy for anthrax
9 remains unchanged. It's a compulsory program, but
10 it's only activated when that necessity is considered
11 to be warranted, and right now the only folks that are
12 included in that are the Special Forces who are
13 (inaudible) people in Afghanistan.

14 (Inaudible words) that we have this year
15 our first Canadian military position in the USUHS
16 program, and we're also very pleased with that. We're
17 hoping to continue that on an ongoing basis, and I
18 think over the next decade we will get us a cadre of
19 folks (inaudible words). So that's all I have in the
20 way of comments. I'd be very pleased to answer any
21 questions.

22 DR. OSTROFF: Thank you. Any questions
23 from the Board?

24 CAPT. BROWN: I have one -- Capt. Yund, is
25 he still here? Any follow-up on the leukemia

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1 (inaudible)?

2 CAPT. YUND: There was a 15th case in
3 December. No additional cases since then. The study
4 that's jointly underway by CDC and HSDR involving a
5 large -- I think four controls per base -- and
6 environmental sampling at the homes. The data has been
7 collected. I'm not sure if there's been any
8 announcement of any results of the analysis of the
9 data.

10 CAPT. BROWN: Thank you.

11 DR. OSTROFF: Okay. Let's take a ten-
12 minute break if we can, and try to be back right at
13 9:30. We're running a bit behind schedule, so for the
14 next session I will have to crack the whip in terms of
15 people keeping on time, but thank all the presenters
16 for some very interesting discussions.

17 (Whereupon, a short recess was taken.)

18 DR. OSTROFF: If we want to finish on
19 time, we have to get moving, so why don't we progress
20 to the next series of presentations. This series of
21 presentations relates to questions before the Board
22 related to Sickle Cell Disease and Trait, and they are
23 particularly timely based on the presentation that you
24 heard from earlier in the morning concerning the
25 cluster of potential adverse events related to Sickle

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1 Cell Trait in California. And so with that, let's get
2 started.

3 The first presentation is by LtCol.
4 Corcoran.

5 (Laughter.)

6 I'm sorry -- LtCol. Corcoran.

7 LtCOL. CORCORAN: That's okay. I'm Dr.
8 Corcoran, the physician working on clinical policy for
9 the Assistant Secretary of Defense for Health Affairs.
10 Next slide, please.

11 (Slide)

12 Right now we have a directive that
13 dictates physical standards for appointment,
14 enlistment, or induction into the Armed Services.
15 This is a fairly recent phenomenon, in fact. The
16 first time a directive subject more at the Department
17 of Defense level was 1986. The present two standards
18 that we have here were actually published in the
19 Summer of 2000, but the history goes back far further
20 than that. In fact, the first standards that were
21 published were published by the Army, and the other
22 two services, the Air Force and the Navy, used those
23 standards published by the Army for enlisted up until
24 the first Department of Defense Directive was
25 published.

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1 Another interesting little fact is that up
2 until 1986, all three services had separate standards
3 for officers. Next slide, please.

4 (Slide)

5 Basically, why do we have these things?
6 GAO pointed out that it cost the military roughly
7 around \$35,000 to both induct and train your average
8 enlisted soldier -- this probably underestimated --
9 but in any event, \$35,000. So, we don't want them
10 dropping out early. And, also, we want the individual
11 who can spend more time doing their duty than spending
12 time in doctors' offices and inside hospitals, and we
13 want them to be able to avoid them. Next slide,
14 please.

15 (Slide)

16 So, the warfighter commander's mission is
17 to fight and win wars. He has to have healthy people
18 to be able to do that. Next slide, please.

19 (Slide)

20 The point I want to make here, the history
21 of military medical management standards has been
22 characterized by increasing uniformity in their
23 application and implementation. The most recent
24 example of this actually was done by AFEB recommended
25 to the ASDHA last year that we go ahead and eliminate

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1 screening for officers for -- the only point of this
2 slide is that there is an increased uniformity of
3 application of the standards as we go along. Next
4 slide, please.

5 (Slide)

6 There is a Steering Committee, a Working
7 Group, and an Analysis and Research Activity that was
8 put in place in 1996, with the intention of
9 integrating the medical and personnel communities and
10 providing policy guidance and establishing standards
11 for accessions. And so I, in fact, am the co-chair of
12 the AMSWG, Accession Medical Standards Work Group, and
13 I represent the medical side and she's the co-chair,
14 also she represents the personnel side. AMSARA, you
15 will hear from Col. Krauss, who is the head of AMSARA,
16 you'll hear her talk later. But AMSARA has provided
17 us with more evidence-based feedback to base our
18 accession standards on. Next slide, please.

19 (Slide)

20 Basically, we have a division that is
21 primarily focused on doing examinations on enlisted
22 entrance into the military and one on officers. I'll
23 address this first. U.S. Military Entrance Processing
24 Command, through their 65 military processing
25 stations, does roughly around 400,000 examinations per

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1 year. The vast majority of those are enlisted,
2 although they do do some officers, depending on what
3 the service need is. Next slide, please.

4 (Slide)

5 DODMERB has a contractor, and it does
6 exclusively officers. They don't do any enlisted
7 examinations. They have a contractor who does those
8 examinations. And they roughly around 25,000 exams,
9 although recently their mission was expanded to
10 included not only ROTC scholarship and non-scholarship
11 programs, we expect that their numbers will rise, and
12 unfortunately the next will decrease a little bit.
13 Next slide, please.

14 (Slide)

15 In terms of the specific standard that
16 touches upon our problem today, here it is, and let me
17 just go through that with you here. The cause for
18 rejection for appointment, enlistment or induction
19 are: E1.2.1. Anemia. Any hereditary, acquired,
20 aplastic, or unspecified anemia that has not been
21 permanently corrected with therapy. You will notice
22 that Sickle Cell Disease is not specifically
23 mentioned. It is not. There is no laboratory screen
24 for anemia with two exceptions. Medical
25 qualifications, since the military utilizes only a

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1 history of physical exams, the two exceptions being,
2 and only for enlisted side, HIV screening and urine
3 drug screening at the time application. Next slide,
4 please.

5 (Slide)

6 And also in terms of trait, to re-
7 emphasize, specifically the directive and instruction
8 did not disqualify individuals with sickle cell trait
9 for appointment, enlistment, or induction, and the
10 Assistant Secretary of Defense Health Affairs has been
11 put on record as saying, "It is not appropriate to
12 screen for a condition that is not disqualifying per
13 the Directive and Instruction". And that was as
14 recent as March of this year. Next slide, please.

15 (Slide)

16 So now we get into the questions, and you
17 have these, so I won't go over these in-depth. Next
18 slide, please.

19 (Slide)

20 This is how we presently screen by using a
21 history on the enlisted side, by using DD Form 2807-2,
22 which is the Medical Prescreen, which does ask
23 specific questions: Have you ever had or do you now
24 have anemia -- the 51, by the way, is line 51 of the
25 document. And if the applicant says, Yes, I have had

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1 this condition or I have it now", the recruiter is
2 supposed to call MEPS before sending the applicant to
3 the MEPS for the actual physical examination. They
4 would write on the prescreen that they need further
5 evidence, and so forth and so on.

6 I'd like to point out that DD Form 2808 is
7 the Report of Medical Examination, it does have a
8 block for Hemoglobin hematocrit, but I understand that
9 there is no required screening test for this. This
10 form is a dual purpose form. It is used for other
11 things. Next slide, please.

12 (Slide)

13 DODMERB uses a different form, although it
14 still comes through Department of Defense. DD Form
15 2492, Report of Medical History, it doesn't ask
16 specifically about anemia, but there are a number of
17 questions on that form that if a person has sickle
18 cell anemia or other condition, they would certainly
19 not have checked the answer yes, and I won't go
20 through all those for the sake of time, but that
21 particular form does conclude with "Have you ever
22 consulted or be treated by clinics, hospitals,
23 physicians, or other practitioners for other than
24 minor illnesses", and it also asks, "had any injury or
25 illness other than those already noted?" So, although

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1 sickle cell per se does not show up on either the
2 enlisted group or the officer group, in fact, if a
3 person has significant clinical disease and if they
4 are being honest, they would certainly be screened out
5 with those forms. Next slide, please.

6 (Slide)

7 The purpose of this question is that there
8 is acknowledgement that there are a number of
9 individuals who have successfully completed a military
10 career even after coming to the attention of
11 authorities that they, in fact, have Sickle Cell
12 Disease. In other words, did they pass six months of
13 service condition? Yes. And so they met a board.
14 The board determined that they were fit for duty.
15 These are indeed individuals who actually have Sickle
16 Cell Disease. Next slide, please.

17 (Slide)

18 Another question to the Board is if a
19 testing program is recommended at accession, would
20 universal screening be indicated, and then what is the
21 ethical responsibility of the DOD concerning
22 counseling, and then, finally, what is the absolute
23 risk of sudden death during training for an individual
24 with Sickle Cell Trait?

25 I think that when you look through the

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1 literature, I was struck by seeing Dr. Kark's role of
2 risk being quoted. And oftentimes, more times than
3 not, it seems to me that absolute risk is not
4 discussed. And so I think it's important that we not
5 only consider what the role of risk perhaps is, but
6 also what the absolute risk is. Next slide, please.

7 (Slide)

8 These are the last two questions. When in
9 the basic training cycle have exertional deaths
10 associated with Sickle Cell Trait occurred, and have
11 exertional deaths associated with Sickle Cell Trait
12 occurred after basic training? All the services
13 encourage ongoing aerobic fitness and mandate an
14 annual fitness test. Army utilizes a two-mile run,
15 the Navy less, the 1.5 mile run, and the Marines do a
16 3-mile run. The Air Force, of which I'm a member, we
17 use the (inaudible).

18 (Laughter and simultaneous discussion.)

19 LtCOL. CORCORAN: There are very few
20 deaths that occur after basic training. Why is that?

21 Is there something unique about the initial training
22 of military groups, and that's also something we'll
23 get to the bottom of when we're all done with this
24 today. That concludes my first presentation. I have
25 another one called a 30-year history, but I'll turn

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1 the mike over.

2 DR. OSTROFF: Thanks. Our next presenter
3 -- and I think what we're going to do is hold
4 questions and discussion, except for clarifications,
5 until we get through the presentations -- is from
6 Terrence Lee, who is at CHPPM.

7 MR. LEE: Thank you very much. I'd like
8 to give you some background on relatively recent
9 events that probably precipitated the current interest
10 in Sickle Cell Trait Disease. As you may or may not
11 know, the AFEB actually discussed Sickle Cell Trait in
12 1995 and 1996. Questions back then were a little bit
13 different than today's questions.

14 The questions I received is mostly from
15 the Army Safety Center, and I'll try to answer
16 questions, but the Safety Center Surgeon is here today
17 to help me answer questions. Next slide.

18 (Slide)

19 Not surprisingly, the current interest
20 stemmed out of a fatality or several fatalities. The
21 first one occurred in August 1999, and this individual
22 was in fitness training, which means that he was
23 actually below par physically, and he didn't enter
24 basic training formally yet. He was in a group that
25 initially trained and once he reached a physical

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1 level, then he entered basic training. Ten days after
2 he had arrived on post at Fort Jackson, he went on a
3 morning run at 5:30. After less than a mile, he
4 stopped running, began to walk, ran a little bit more,
5 dropped out at ten minutes after 6:00, and at that
6 point he was seen by several drill instructors, he
7 started to lose consciousness. They started pouring
8 water on him. He arrived at the hospital at 6:30,
9 with a high temperature of 107.6. He was transferred
10 to another hospital, and later on died from
11 rhabdomyolysis and impaired renal function. And a
12 Sickle Cell test was positive.

13 And the Army Safety Center did their
14 homework, and they realized the association between
15 Sickle Cell Trait and (inaudible) death from
16 (inaudible). And this case was reported to the Safety
17 Center Commander, but no immediate action was taken.
18 At this time it was considered an isolated case. Next
19 slide.

20 (Slide)

21 That was August 1999. In the year 2000,
22 there were several more sudden exertional deaths.
23 Case No. 2 was a hypolukemia case, actually, Sickle
24 Cell Train unknown. Case 3 was also unknown Sickle
25 Cell Trait. Case 4 was Sickle Cell Trait negative.

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1 Case 5 was Sickle Cell Trait negative. Case 6 was
2 Sickle Cell Trait positive, cardiac arrest. Case 7
3 was also Sickle Cell Trait positive, rhabdomyolysis.
4 And this person was reported to have been using
5 laxatives. And Case 8 was Sickle Cell Trait positive,
6 rhabdomyolysis.

7 I have details of these cases on a chart
8 which is at the end of your handout. Next slide,
9 please.

10 (Slide)

11 So, the Safety Center, at an in-process
12 review to the Chief of Staff of the Army, brought this
13 case up and the eight sudden exertional deaths, four
14 were Sickle Cell Trait positive, and the Safety Center
15 asked if it may be advisable for the Army to routinely
16 screen for SCT. At this point we've been working with
17 the Office of the Surgeon General on this. And since
18 this time, there have been additional deaths. There
19 has been actually five, three more in 2000 and two in
20 2001. At this point I was going to go into the
21 etiology, but Col. Krauss will deal with that later on
22 after lunch, and I'll had the mike back over to LtCol.
23 Corcoran who will be going over a review of DOD
24 policy.

25 DR. OSTROFF: Thanks. Can you clarify

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1 where those additional deaths were in terms of
2 location?

3 MR. LEE: Yes. The sudden deaths were at
4 Fort Campbell, Fort Drum, Fort Leonard Wood, Fort
5 Leonard Wood, and Fort Meade, and they were not --
6 actually, none of those were trainees, none of those
7 were basic trainees.

8 COL. GARDNER: None of them were Sickie
9 Cell Trait either?

10 MR. LEE: Two of them were Sickie Cell
11 Trait.

12 DR. OSTROFF: Thank you. LtCol. Corcoran.

13 LtCOL. CORCORAN: This is really actually
14 very fascinating, this journey I'm about to take you
15 on, and I personally had no idea just how far back
16 this went. Next slide, please.

17 (Slide)

18 In 1968 and '69, there were four
19 unexpected SCT+ African American deaths reported in
20 the New England Journal of Medicine, which was
21 published in 1970, and they occurred at the Army Ft.
22 Bliss Base at 4,060 feet. And, basically, I looked at
23 that article closely, and they really -- because they
24 didn't have anything else to really say it killed
25 them, they thought, well, they are also SCT+, so

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1 that's how we'll reflect it. Next slide.

2 (Slide)

3 Then in the summer of '72, two black
4 cadets at the Air Force Academy were hemoglobin
5 electrophoresis positive Sickle Cell Trait,
6 experienced severe rhabdomyolysis and renal
7 insufficiency during strenuous exercise at 7,000 feet.

8 Next slide.

9 (Slide)

10 In '72, the ASD for H&E issued an interim
11 proscription for admittance of cadets with SCT, and
12 thereafter Air Force policy excluded applicants with
13 Sickle Cell Trait from the Air Force Academy. Next
14 slide, please.

15 (Slide)

16 Well, the Navy was looking at this and
17 they said, "Hmm". When they saw that going on, they
18 decided in September of '72 to require testing for
19 hemoglobin S of all Navy and Marine Recruits. They
20 couldn't identify any specific risk when they ran, but
21 they felt it was enough smoke, perhaps fire, here.
22 So, they did that. But understand that they weren't
23 the first ones to test. In fact, the Air Force policy
24 since 1956 was to screen all flight duty candidates
25 for Sickle Cell Trait because of alleged hazards

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1 related to clinic infarction or hematuria in the
2 presence of hypoxia. Next slide, please.

3 (Slide)

4 The ASD for H&E also asked the National
5 Academy of Sciences National Research Council to
6 advise DOD on this issue. Next slide, please.

7 (Slide)

8 They came back actually in 1973 and stated
9 the following: "Except for pilots and copilots,
10 persons with sickle cell trait should not be
11 restricted from flight duty. Such persons" -- and I
12 think they refer to the ones for flight duty, they are
13 not referring to pilots and copilots" -- "Such persons
14 should be informed of the potential risk, but should
15 be allowed to take that risk if they wish".

16 they also had some verbiage in their
17 discussions that the services looked at and said,
18 "Aha". However, the position of the armed forces was
19 that all flight crew members are essential to the
20 mission of an aircraft, therefore persons with sickle
21 cell trait are disqualified from flight status". Next
22 slide, please.

23 (Slide)

24 The NAS-NRC also advised DOD to screen all
25 accessions and those with sickle cell disease be

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1 excluded and those with sickle cell trait be
2 restricted, and specifically the pilots and copilots,
3 and they recommended further research to define the
4 exact nature and extent of the problem, and also
5 provide genetic counseling. Next slide, please.

6 (Slide)

7 So, in 1974 the Department of Defense put
8 out a draft DODD and they mandated the universal
9 testing, however, it never made it through the
10 coordination process because of disagreement. So the
11 bottom line was, few, if any, of the recommendations
12 were ever implemented. Next slide, please.

13 (Slide)

14 So, to summarize, in the 1970s we had
15 these different occupational specialties for which
16 sickle cell trait was disqualifying. You can read
17 that list there -- basically all occupational
18 specialties where there was a risk of hypoxia. Next
19 slide, please.

20 (Slide)

21 So at the beginning of the 1980s, blacks
22 were excluded from several military occupations, there
23 was no uniform policy for testing among the services,
24 and there were several black flight personnel who had
25 been previously cleared, already engaged in aviation,

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1 when they were found out to be sickle cell trait
2 positive, they were grounded. Next slide, please.

3 (Slide)

4 Well, as you might expect, that didn't set
5 well. And there was initiation of a class action
6 lawsuit against the Air Force for the wrongful
7 disenrollment of a black student from the U.S. Air
8 Force Academy, who you remember was the only Academy
9 that excluded sickle cell trait positive individuals,
10 and this really brought national interest to this
11 issue, and it also brought congressional interest to
12 this issue. Next slide, please.

13 (Slide)

14 As a result of that, the Air Force
15 Secretariat asked the Assistant Secretary of Defense
16 Health Affairs Office to look at this issue for them,
17 and they did. They contacted the original NAS members
18 and all the NAS members said "we still believe what we
19 told you back in 1973". And, furthermore, I was
20 looking through some background papers that led to the
21 policy I'm about to discuss, and it was clear that
22 they felt that a review of available information
23 provided no justification for maintaining restrictions
24 on pilots and copilots. They pointed out that the FAA
25 had no restrictions on pilots or copilots for civilian

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1 pilots and, furthermore, in that background paper the
2 following statement was made: While the foregoing
3 policies, outlook and actions were in part not
4 discriminatory in intent, they have been
5 discriminatory in practice because sickle cell trait
6 is, with limited exceptions, confined to blacks. Next
7 slide, please.

8 (Slide)

9 So 16 January 1981, Deputy Secretary of
10 Defense directs the services to eliminate any
11 occupational or Academy standards which restrict
12 individuals with sickle cell trait. Additionally,
13 they issued the DOD Directive 6465 which mandated
14 universal testing for hemoglobin S. Next slide,
15 please.

16 (Slide)

17 Informally, the services set a cut-off of
18 greater than 41 percent of hemoglobin S. If you were
19 less than 41 percent hemoglobin S, then you were
20 permitted to do just basically any kind of occupation.

21 If you were greater than 41 percent hemoglobin S, you
22 were still restricted. Next slide, please.

23 (Slide)

24 Also, the Department of Defense asked
25 USUHS to look into this and develop a tri-service

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1 study, and Walter Reed became involved, and also
2 Howard University was involved. Next slide, please.

3 (Slide)

4 Well, it was still a contentious issue and
5 it was still on the hotseat. Then in January '85, the
6 Assistant Secretary of Defense Health Affairs states,
7 "no credible scientific evidence has emerged either
8 within or without Department of Defense in the last
9 four and one-half years that would justify any
10 continued restrictions whatsoever on sickle cell trait
11 bearers". At that point, the Deputy Secretary of
12 Defense removes all military occupational specialty
13 restrictions on sickle cell trait bearers. However,
14 this was not the end of restrictions, as it also went
15 on to say that you could still -- to the services,
16 "You could still restrict an individual who while
17 serving in his or her occupational specialty
18 encountered problems related to sickle cell trait, and
19 that person could be excluded. Next slide, please.

20 (Slide)

21 The Tri-Service Sickle Cell Trait study
22 was then canceled. Next slide, please.

23 (Slide)

24 Well, things were quiet for a period of
25 time, and then in 1994 the Air Force again asked for a

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1 review of the sickle cell trait screening policy after
2 experiencing three recruit deaths. So, Under
3 Secretary of Defense for P&R sponsored a Sickle Cell
4 Working Group, and that Working Group recommended
5 universal sickle cell trait screening, that it counsel
6 all positives on risk for exercise related death, and
7 allow the option for voluntary discharge. This was
8 remarkably parallel to the Air Force position. Next
9 slide, please.

10 (Slide)

11 Well, the Army did not concur with that
12 recommendation. Navy concurred, but they requested
13 testing at basic military training sites, and the Air
14 Force requested testing at MEPS. Because of this
15 contentious -- this disagreement, ASDHA asked the AFEB
16 to look at the issue and to make some recommendations.
17 Next slide, please.

18 (Slide)

19 AFEB did so, and basically they advised
20 ASDHA against routine screening for sickle cell trait.
21 They felt that screening and counseling alone would
22 not significantly reduce either the death rate or the
23 relative risk of death in the sickle cell trait-
24 positive group. Next slide, please.

25 (Slide)

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1 USD P&R issued that hemoglobin S testing
2 should not be mandated for military accessions, and
3 basically went along with the AFEB recommendation.
4 Also, directed that DODI be modified to reflect that
5 hemoglobin S testing for sickle cell trait shall not
6 be conducted at accession. However, this end of
7 testing. It also went on to say hemoglobin S testing,
8 however, may still be conducted for individuals being
9 considered for specific high-risk occupations, but
10 must be conducted after entry into the military. Next
11 slide.

12 (Slide)

13 Also, that same policy memo stated that
14 "medical history screening guidelines at accession
15 appear to be able to successfully exclude entry into
16 the military of most individuals with Sickle Cell
17 Disease". Next slide, please.

18 (Slide)

19 In the 1999-2000 period, five Army
20 recruits who are sickle cell trait-positive die during
21 training. At that point, the OTSG Army re-examines
22 the policy concerning sickle cell trait screening.
23 The Safety Centers, including Army, Navy, Air Force,
24 Coast Guard, and Marines, send a letter to Under
25 Secretary of Defense P&R July of 2001. Next slide,

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1 please.

2 (Slide)

3 And they requested that DOD policy be
4 changed to test all recruits for Sickle Cell Disease
5 and sickle cell trait at initial accession. They
6 asked that DOD standardize counseling and tracking
7 guidance and continue research on sickle cell trait.

8 Next slide, please.

9 (Slide)

10 In terms of when we drafted our response
11 to that Safety Center letter, AMSARA did a very
12 preliminary analysis -- we were under a time
13 constraint -- and they concluded that perhaps there
14 was a possibility that the efficacy of present DOD
15 screening methods at accessioning may be inadequate
16 for identifying Sickle Cell Disease individuals. At
17 that point, Assistant Secretary of Defense asked AFEB
18 to once again revisit this issue. And that concludes
19 my presentation.

20 DR. OSTROFF: Colonel, thank you for a
21 really terrific presentation. I thought the smallpox
22 issues was complicated. Our next presentation is by
23 Dr. John Kark, from Howard University. He's one of
24 the world's experts on this disease, and he has
25 published extensively on the topic, and we thank you

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1 for joining us today.

2 DR. KARK: A pleasure.

3 (Slide)

4 This slide describes -- this is some of
5 the people who worked with me on this. John Gardner
6 who is from USUHS, Frank Ward is an intern at Walter
7 Reed, and Renu Virmani is the Chief of Gastric
8 Pathology at Armed Forces Institute of Pathology, and
9 one of the best scientists in this area.

10 I've been involved in a lot of this
11 history because I came to the Army as an hematologist
12 specializing in red cell disease in 1973. The entire
13 1994 I was associated with Howard University Academy
14 for Sickle Cell Disease throughout my career in the
15 Army, and since then. And some of that work included
16 the subject I'm going to talk about today on the
17 epidemiology of exercise related death, and some
18 studies we did on pilot candidates or helicopter pilot
19 candidates. We did some altitude chamber studies.
20 Next slide, please.

21 (Slide)

22 This slide just reminds of the
23 pathophysiology of Sickle Cell Disease. It's a single
24 point mutation in the beta globin chain, there are two
25 globin data that make up hemoglobin, and that's what

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1 allows this strange in the deoxy state, the hemoglobin
2 started being disorganized and floating around in
3 solution, organized itself into long strands which are
4 very rigid and make the inside of the cell rigid so it
5 won't perform, and in the deoxy state, these cells
6 assume strange shapes shown on the right there, and
7 become very rigid, and they can occlude blood vessels.

8 Fortunately, the ability for enough cells to get
9 together to occlude a vessel happens very seldom, and
10 it's more or less a random event.

11 One of the big puzzles about Sickle Cell
12 Disease is that people, although millions survive the
13 level for SS, it's in the 40s, the natural history of
14 the disease, but there are large tracts of people who
15 are quite healthy with Sickle Cell Disease, and my
16 guess is it's around 15 to 20 percent who have very
17 rare events, and these occlusive events are
18 unpredictable. Next slide.

19 (Slide)

20 Probably the best attempt to explain some
21 other features might determine the severity. It's a
22 concept that the paths of sticky proteins of sticky
23 cell surfaces allow them to adhere to endothelium, and
24 Hamil (phonetic) published a study about 1983, I
25 believe, which shows the adherence between

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1 endothelium, and the clinical severity for and some
2 correlation between the two. Next slide.

3 (Slide)

4 So this just says what the pathophysiology
5 of what Sickle Cell Disease is, and the second line is
6 the important one here, that in order to get the
7 formation of polymer and GUOs in hemoglobin S, the
8 rate increases exponentially with the S concentration,
9 probably to the 15th power, a low pH is helpful, high
10 temperature, and variations can change, in effect, the
11 tendency to sickle. And this is relevant to explain
12 the circumstances under sickling complications occur.

13 High risk for specific organs such as the spleen and
14 the renal medulla. Next slide.

15 (Slide)

16 The hemoglobin AS genotype, the S is less
17 than 50 percent. It doesn't compete as well as the
18 normal beta combined in the alpha globulin, so in some
19 way that's destroyed. In Sickle Cell Disease, the S
20 is greater than 50 percent, most of the time it's
21 greater than 70 percent, and the common genotypes of
22 SS, about half in Sickle Cell Disease, SC and SA.
23 There are a whole bunch of genotypes S with other
24 hemoglobins. In the median hemoglobin S, with 4
25 globulin genes is 42 percent, but alpha thalassemia,

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1 in which one reportable or more, is pretty common --
2 which I'll get to in a later slide -- in African
3 Americans, so there are means also of 32 and 26
4 percent, and a fraction of that is just spread out
5 over a wide range.

6 In sickle failure, it's normal CBC with no
7 anemia, hemolysis is undetectable, even though we can
8 find sickle cells in genus nigerial blood or mainly
9 during exercise or alpha exposure.

10 Microscopic sickling is generally only
11 significant in the loops of Henle of the renal medulla
12 and under rare circumstances in the spleen and in
13 drainage of vitreous humor. Next slide, please.

14 (Slide)

15 So now we come to the process of screening
16 that I've labeled steps 1, 2 and 3. The first step is
17 to use a sickle cell screening test in which you place
18 a drop of blood in a phosphate buffer which slices the
19 blood, the hemoglobin S release an excess of its
20 unique property and precipitating in high phosphate.
21 This test has high specificity and sensitivity and
22 it's sensible as an initial screen.

23 The second step is to do a CBC. This will
24 be normal in uncomplicated sickle trait. There will
25 be anemia with an increased RDW in nearly 100 percent,

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1 but not quite 100 percent, of sickle cell disease.
2 And at the same time, a quantitative hemoglobin
3 electrophoresis in alkali, which is pretty good at
4 detecting S.

5 A third step which I like to do, but I'm
6 not sure it's standard in the military, is to obtain a
7 reticulocyte count because that will be elevated in
8 nearly 100 percent of Sickle cell disease, but normal
9 in uncomplicated sickle trait. Unfortunately, that
10 test has a wide variance. Next slide.

11 (Slide)

12 This slide shows the clinical
13 complications that are proven to be associated with
14 sickle cell trait because there's been a tendency to
15 attribute ever complication you see in sickle cell
16 disease with trait, but actually trait is so much more
17 benign. One can't accept that causal relationship
18 unless you demonstrate a true association.

19 A reason that this comes up -- and I
20 didn't have a slide about this -- is that when you
21 biopsy tissue or a person dies and the tissue becomes
22 deoxygenated, there will be trivial or unimportant
23 agonal sequence, so you should see greater occlusion
24 of vessels with sickle cell pretty widespread at
25 autopsy. It doesn't mean that that is what caused

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1 death or the injury that you're looking at. So it's
2 very hard from histology to know whether sickling
3 played a role in something or it didn't. So, the
4 syndromes that are associated are age-related loss of
5 maximal urinary concentration. It's very common, for
6 example, by age 30 about 85 percent of the people with
7 sickle trait have that. It may not be severe enough
8 to cause a physiologic limitation. Episodic hematuria
9 which, fortunately, usually results at the most in one
10 major event with major anemia in a lifetime,
11 fortunately not too persistent beyond that in most
12 people. Mild increase in urinary tract infection in
13 pregnancy is probably of trivial importance. Altitude
14 and exercise related splenic infarction can be very
15 disabling, usually is self-limited, it does occur in
16 military people because of the heroic nature of
17 exercise in military operations, very unpredictable.
18 There is an increased risk of hyphema when there's
19 trauma to the anterior chamber of the eye because of
20 the difficulty of the sickle cells getting out of the
21 vitreous humor. And then there's a very rare renal
22 medullary carcinoma that can be fatal and,
23 unfortunately, it occurs in teenagers and young
24 adults. And today we're going to discuss the most
25 important complication in the military, there's an

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1 unexpected exercise-related death in recruits and
2 young athletes. Next slide.

3 (Slide)

4 In 1981, there were some deaths in the
5 Army that prompted the Army to ask me to investigate
6 this problem, and it occurred to me that the recruit -
7 - at that point, it was just an observation about 12
8 cases -- and it occurred to me that recruits formed an
9 ideal group to look at this because you could
10 enumerate exercising population of several million
11 people, you could study all the deaths without
12 restriction to any particular type so that you didn't
13 have to identify sudden deaths and limit yourself to
14 those. You didn't have to even limit yourself to
15 deaths that were obviously exercise related.

16 And the third most important thing, all
17 the deaths had adequate data because during most of
18 the time period of this study it was general policy to
19 do a very thorough investigation on the grounds that
20 there might be a congressional examination of the
21 death. So, eyewitness accounts, clinical records,
22 autopsy -- a full autopsy is performed -- full
23 toxicology, and there was investigative report and
24 behavior issues and circumstances of the events that
25 led to the death. And it was not routine -- it never

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1 has been routine for some specialist in pathology for
2 a few of these cases, but it turns out to be very
3 important -- at the time I began the study all Army
4 cases will be referred to the AFIP. That's been
5 replaced now by the medical examiner's office, which
6 is really associated with the AFIP.

7 And, finally, the evaluation included body
8 temperature and blood tests adequate to detect
9 exertional heat illness, and occasionally urine is
10 helpful, but that's never been the case, and at the
11 present day only about 5 percent of the people who
12 suffer sudden death have been approved to get that
13 kind of evaluation, so 95 percent do not. Next slide.

14 (Slide)

15 In the first study, we looked at a
16 population of 2 million recruits who trained from '77
17 to '81, and it turned out all the sickle cell related
18 deaths but one occurred in people who had no
19 underlying pre-existing disease whereas the
20 predominant cause of death in this population is pre-
21 existing heart disease. And if you look at the group
22 who had unexplained deaths that were autopsied, the
23 group with trait consisted of about 37,000 recruits
24 and we only found -- we did include a small percentage
25 of nonblack people -- the incidence of trait is about

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1 8 percent in the African population and about .08
2 percent in the nonAfrican population, mainly in people
3 from the Mediterranean area and Saudi Arabia and
4 India. And those without Hb S were 429,000, and came
5 up with a relative risk of 30, which was a shock to
6 me. I was expecting to see a very small increment.
7 Next slide.

8 (Slide)

9 So this shows you the death rates. You
10 can also just look at All Deaths, All Races, and you
11 look at the relative risk factor and it comes out
12 about the same, at 28. And these rates, I believe,
13 are per recruit training cycle. So at that time, we
14 had rather a high absolute risk. This is represented
15 in the literature as a very low absolute risk, but
16 what it is is it's a very high risk for a very short
17 time, in a relatively small population. So the
18 numbers of deaths are not huge, but the risk is
19 remarkably high for the short period of intensive
20 training involved. Next slide, please.

21 (Slide)

22 Here I've compared the death rates using
23 annual numbers with the deaths that have been
24 published in the civilian literature from Paul
25 Thompson, using Rhode Island joggers. His population

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1 were 30 to 64 years old, and he just focused on
2 coronary deaths. In his group he had one, I believe,
3 and the rest were all coronary artery disease. And he
4 showed a rate of about 13 deaths per 100,000
5 person/years of jogging. These are people who jog
6 probably twice a week or three times a week.

7 The baseline, at best, I think was around
8 1 to 2 per 100,000. We did figure it was almost 17-
9 fold lower in another line of what we studied. His
10 people, by the way, were Caucasian.

11 In recruit deaths, which were all black
12 individuals with sickle trait, that's about -- that
13 number was 244 per 100,000 per year, and for recruit
14 deaths who I presume had AA, the rate was 8.98, so it
15 was pretty high for the recruit. Whether he had
16 sickle trait or not, they're close to the death rate
17 of middle aged people jogging. It shows you how severe
18 the conditioning process is.

19 In the column on the right, it had the
20 same rate per 100,000 per hour, and you see that the
21 recruit death is about 10-fold of that you see of
22 middle aged people for the short period of 8 weeks or
23 so of basic training, and for the AA individual it's
24 still pretty significant, .09, from the middle-aged
25 people who are jogging.

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1 That's the absolute rate. Now, it's hard
2 to say what the absolute rate is at any one moment in
3 time, it varies a lot over time, partly because of the
4 small numbers of cases, so the rate isn't very stable.

5 It's hard to say at any moment in time whether the
6 rate will increase. Next slide.

7 (Slide)

8 This shows a detailed analysis of the
9 cause of death, the trait in the left column and the
10 non-trait in the right. The major point is that about
11 half of them, 7 of them had a form of disease related
12 to rhabdo, with or without heat stroke, and nearly the
13 same number, 6 versus 7, had unexplained sudden
14 death. At autopsy, no explanation was found. In
15 looking at the AA individual, they are fairly similar,
16 although there's a tendency for the heat stroke to be
17 more common in the AA group than it was in the group,
18 there's no real difference. And then if you look at
19 deaths attributed to pre-existing disease, there was
20 only 1 sudden cardiac death. It turned out that
21 person also had some evidence of heat illness that
22 preceded the sudden cardiac death, and 10 individuals
23 with AA hemoglobin had pre-existing heart disease.
24 Next slide.

25 (Slide)

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1 So, in determining the cause of death, we
2 found that new standards were required for diagnosis
3 of exercise-related death. It kind of really
4 surprised us. There was a major revision of a local
5 autopsy diagnosis for 47 percent -- actually it should
6 be 53 percent of our cases, and 51 percent of another
7 survey done of Navy recruits by Wagner.

8 Forensic pathology review corrected
9 mistakes attributing death to agonal changes that were
10 really not significant, such as sickle cell crisis,
11 aspiration of gastric contents, drowning after cardiac
12 arrest in water. This constituted 11 of our cases, of
13 the 41 cases.

14 Cardiovascular pathology review corrected
15 6 errors of overinterpretation and 4 errors of
16 underinterpretation, or another 10 cases. In internal
17 medicine review identified 5 episodes of heat illness
18 missed by the local pathologist based on body
19 temperature and chemistries that were obtained in the
20 final illness. By the way, you can obtain a useful
21 body temperature in the first 24 hours post-death.
22 Next slide.

23 (Slide)

24 So, standards should be required for
25 investigating exercise-associated deaths in the

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1 military, and are not required. In fact, we're moving
2 away from good studies now compared with earlier time
3 periods. There was a thorough investigation which
4 includes medical and command issues pertinent to
5 management of exercise and risk of heat illness. I
6 think the best example is maybe the Navy JAG manual
7 investigation in the '70s and '80s was really
8 excellent. Now we're not so good, at least the part
9 we get isn't so good. I don't know that they retained
10 some of it.

11 100 percent of timely referral of cases
12 with all pathologic and clinical materials to the
13 Office of the Armed Forces Medical Examiner is really
14 required. Right now I'd say that it's about 40
15 percent referral, which is really terrible because a
16 pathologist who is not skilled in thoracic or cardiac
17 vascular pathology can't make an accurate diagnosis in
18 these cases.

19 100 percent measurement of body
20 temperature and some lab tests for rhabdo can be done
21 on all sudden deaths, all exercise-related deaths, and
22 this could be done either pre-mortem or at least at
23 the point when the code is called. And it's a pity
24 that this isn't done. I think this should, of course,
25 include a screen for sickle cell trait, including

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1 hemoglobin electrophoresis. Next slide.

2 (Slide)

3 Now, looking at the exercise-related
4 deaths which were idiopathic. I understood that some
5 of the sickle trait individuals had heat illness, and
6 you can see how that would lead to sickling. But the
7 other half of the cases had an idiopathic sudden death
8 and we didn't know what this was. There was no
9 difference in clinical picture by hemoglobin
10 phenotype, so we're going to have to look at some
11 epidemiologic features to decide what it was. Next
12 slide.

13 (Slide)

14 So, looking at the cases of sickle trait,
15 this shows you the breakdown at the point -- I
16 enumerated about 94 cases of exercise-related death,
17 and I kind of set of 18 control at the bottom from the
18 recruit population. You can see the sickle trait
19 accounted for 10 out of 25 heat illness cases, and 7
20 out of 15 idiopathic sudden death, and 2 of them were
21 captured in the explained cardiac death group. Both
22 those two had features that suggested that they
23 actually an initial heat illness before they had the
24 sudden cardiac arrest. Then I had 6 patients who had
25 explained noncardiac death, meaning cerebral

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1 hemorrhages and asthma, and 12 people who died at
2 rest, no named injury to speak of. Next slide.

3 (Slide)

4 This slide shows a marked difference in
5 our survey -- this is the point when we had about 94
6 cases -- versus the eight most prominent large
7 civilian athlete surveys. You can see that explained
8 cardiac death was found in about 84 percent of the
9 athletes survey versus 44 in the military , and the
10 types of death were quite different. The athletes
11 frequently have hypotrophic cardiomyopathy and that's
12 pretty rare in our population. The difference there
13 probably is the age at which the genetic expression of
14 this occurs, which is generally higher than the age of
15 any of the recruits.

16 Explained non-cardiac death is about the
17 same. Exertional heat illness, we attributed 27
18 percent of our deaths to that, and they only
19 identified 1 percent. Idiopathic sudden death, we had
20 about double the rate. And then sickle cell trait is
21 not a separate cause, but it's a finding that occurs
22 in mainly, as you saw before, mainly those people with
23 explained non-cardiac death or heat illness. It was
24 20 percent in our series and only .2 percent in
25 athletes. Now, the numbers in brackets come from a

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1 paper by Van Camp published in '96, which correlates a
2 little better with our work and was a very well done
3 paper. They found 15 percent of deaths from heat
4 illness, and 5 percent with sickle cell trait. I
5 think that's, in part, because the military population
6 differs from athletes. They are younger. They're
7 selected in a different way. And partly because there
8 is more outdoor stress and use of not very palatable
9 canteen water. Next slide.

10 (Slide)

11 One of the questions is whether or not the
12 method you can do a pathogenesis of these deaths, or
13 whether it's just an innocent marker for some other
14 genetic problem that is causing the deaths. To look
15 at this issue, I used an established method. 30
16 percent of African Americans have alpha-thalassemia,
17 and the main effect of this on those with sickle trait
18 is simply to lower the S fraction without causing much
19 anemia. So if the S fraction is less than 35 percent,
20 they are otherwise well. If that is true, that should
21 protect them against events that are related to
22 sickling because the rate is highly dependent on
23 concentration.

24 We collected 47 cases of exercise-related
25 death or near death with sickle trait, and if the

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1 hemoglobin S percent was negative, we expected to find
2 14 cases with alpha-thal and therefore an S of less
3 than 35 percent. What we did find was that the lowest
4 two cases had 35 percent or more, and none below this.

5 So, statistically, one case developed alpha-thal
6 instead of 14, and so there was at least a 10-fold
7 reduction in cases with alpha-thal.

8 Individuals with sickle cell trait are
9 protected by alpha-thalassemia. Next slide.

10 (Slide)

11 Gupta and co-workers from NIH published a
12 paper establishing that any complication associated
13 with trait can be attributed to polymerization of
14 hemoglobin S if its incidence is reduced by alpha-
15 thalassemia.

16 So, we have to say then that sickle cell
17 trait associated exercise-related death, whether due
18 to heat illness or sudden idiopathic arrest is largely
19 due to polymerization of hemoglobin S.

20 Sickle trait is not simply a marker for
21 risk but contributes to pathogenesis of the exercise-
22 related death by vascular obstruction from red cells
23 stiffened by deoxyhemoglobin S polymer. Not that
24 isn't to say that there couldn't be additional genetic
25 effects that are related to S, but the major effect is

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1 not the genetic link to death. Next slide.

2 (Slide)

3 This just discusses briefly the
4 complicated terminology of exertional heat illness.
5 The left side of the slide is moderate heat illness,
6 and the right side are the manifestations of severe,
7 and what you look for is hypothermia beyond the
8 ability of the body to cool down, dehydration,
9 nephropathy, lysis of mainly muscle cells but
10 sometimes the liver -- that's why I used the term
11 "cell lysis" -- and encephalopathy, which is a
12 nonreversible encephalopathy highly associated with
13 hyperthermia. The syndromes that we see here are
14 distributive shock, acute renal failure, very severe,
15 breakdown of muscle, release of potassium in uric acid
16 and phosphate, and a lactic acid production, and heat
17 stroke with regards to coma, and failure of neurologic
18 systems. Next slide.

19 (Slide)

20 Just a reminder, I'm sure you're all
21 familiar with the Wet-Bulb Globe Temperature Index,
22 the heat index. This shows you how we derived it.
23 Next slide.

24 (Slide)

25 I want to look back again at the common

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1 characteristics of the sudden exercise-related deaths,
2 especially the idiopathic ones. These were mainly
3 related to 1-3 mile runs, which is the highest
4 metabolic activity that's sustained that recruits
5 engage in. Most of these actually occur during summer
6 months, they are early in the morning, when the WBGT
7 was less than 75 and considered safe. There was no
8 significant environmental heat stress in most of these
9 cases.

10 Now, at the time those standards, they
11 were based on marching with around a total time --
12 marching was the main exercise, and that was around 5-
13 6 MEPS, volume is somewhere around 12-13 MEPS, and
14 therefore I felt there might be a substantial risk in
15 the range of 75 to 80 degrees. But even more
16 important was prior-day heat exposures led
17 unrecognized heat illness contributing to sudden
18 death. Now, because these were summer month events
19 and, of course, the most likely candidate would be
20 uncorrected dehydration or salt loss. Next slide.

21 (Slide)

22 So we turned our attention to an
23 epidemiology study of heat illness in recruits, and we
24 looked at a 12-year period, probably longer than that
25 now, down on Parris Island, to obtain all the cases of

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1 heat illness, and this shows an analysis of about
2 1,500 cases. You would expect an increase in, May
3 through September, the hottest months of June through
4 August. Next slide.

5 (Slide)

6 To look at the time peak, about 70 percent
7 of cases are occurring between 7:00 and 9:00 a.m., and
8 that's when recruits do their running, especially in
9 the hot season when the drill instructors want to get
10 everything done and avoid immediate heat exposure. So
11 we looked at that time period in about 950 cases.
12 Next slide.

13 (Slide)

14 And the bars on the left axis show the
15 rates -- on the left Y-axis. and the faint yellow
16 shows the total number of cases, and then the X-axis
17 rose from 60 degrees to 90+ for the heat index. And
18 you can see that the rates go up to about 80-85
19 degrees and then start to fall. The case number falls
20 off very rapidly from 80 degrees on up, and that's
21 because the drill instructors are doing their job.
22 And so most of the heat illness from heat exposure
23 related to temperatures around 75 degrees to 80
24 degrees. At 79 degrees, the rate is about 10 times
25 over the baseline, so we feel that's a significant

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1 risk if you wanted to take a simple view of it. Next
2 slide.

3 (Slide)

4 This shows the heat illness as a function
5 of prior day maximum, with the same information, but
6 now we're looking at the highest temperature the prior
7 day. And, again, by 75 degrees, you are 10-fold above
8 the baseline, and as you go up to 85 degrees, the risk
9 remains high. It turns out that about nearly two-
10 thirds of the cases that are occurring now in the
11 decade of the '90s at Parris Island are occurring
12 because of heat exposure the day before. So that
13 gives the largest factor of pre-exposing to heat
14 exposure, and the risk becomes greater as we expected.

15 Next slide.

16 (Slide)

17 So we wanted to look at the effect of
18 sickle cell trait also on rates of nonfatal exertional
19 heat illness, so we collected all the cases at Parris
20 Island for a three-year period, and we found that the
21 incidence of heat illness was .55 percent of 1,500
22 recruits with sickle trait, and it was up .54 percent
23 of 36,325 black recruits without hemoglobin S. And
24 the same for the nonblack. So, sickle trait did not
25 appear to alter the risk of non-fatal exertional heat

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1 illness. We think that sickle trait becomes a factor
2 only when severe heat illness has occurred, and taking
3 a severe case that one could recover from and changing
4 it into a fatal case. And probably the mechanism is
5 that the heat illness would call acidosis, low oxygen,
6 dehydration and high body temp, all of which promote
7 sickling. We think that when a person has a severe
8 episode of heat illness, the physiologic effects of
9 that promote sickling, and then you get obstruction,
10 extension of the lesion, and a fatal event. Next
11 slide.

12 (Slide)

13 Now I'm going to turn to some epidemiology
14 studies that we've done. The first one will reflect
15 that exertional heat illness is a risk factor right
16 beside related sudden death. The problem I have is
17 not having a basis to capture all facets of heat
18 illness and look for this risk, so I had to take
19 myself to Parris Island. And I knew that the study
20 was too small to look at sickle cell trait as a
21 factor, and then probably too small for mortality
22 alone as an end-point, so I'm going to look at
23 threatened as well as actual sudden deaths, and I'm
24 going to define sudden death as any condition that
25 gets you into an ICU. So we looked at all heat

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1 illness and all admissions to an ICU, and about
2 270,000 Marine Corps recruits. We wanted to compare
3 rates of fatal or life-threatening cardiovascular
4 events between those who did and didn't have heat
5 illness. Next slide.

6 (Slide)

7 Now, we sought cases of exertional heat
8 stroke, rhabdomyolysis, or isolated renal failure as
9 risk factors, but in this study we only found serious
10 cases of heat stroke, and I think that's because the
11 management of heat illness is so quick at Parris
12 Island, which is a very small base -- they practically
13 get most of their cases into the clinic within 5-10
14 minutes, and it's practical to begin hydration in the
15 field, which they do. So, the cases were restricted
16 to heat stroke because that's how it turned out to be.

17 We also sought distributive shock, which
18 is typical of exertional heat stroke, by which I mean
19 shock in which there has been a dilatation of the
20 vessels (inaudible). Life-threatening arrhythmias and
21 ischemia/infarction as outcomes that might cause a
22 life-threatening or fatal illness. And actually most
23 of the cases presented as shock, although two of our
24 cases had poorly documented arrhythmias prior to
25 shock. Next slide.

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1 (Slide)

2 This shows our results. In the left-hand
3 column, we see a group of people who have been
4 diagnosed as exertional heat stroke, and the right-
5 hand column are controls of people who presented
6 without heat illness. Cardiovascular events, 7
7 events, 2 of which were deaths in the heat stroke
8 group, and 4 events, all of which were sudden deaths
9 in the non-heat stroke group. And the population at
10 risk here was 137 episodes of heat stroke versus
11 267,000 people without heat illness. The case rate
12 was 5.1 percent versus .0015 percent of 3,400 for
13 relative risk. So this group of people who did not
14 have sickle trait -- the risk of life-threatening
15 event was very much higher if they had heat illness.
16 Actually, one of the cardiovascular events in the non-
17 heat illness group, that patient had a tunnel through
18 an artery which undoubtedly caused death, but there
19 also was severe clinical evidence of rhabdomyolysis
20 preceding stress, which probably was the nature of
21 stress that led to the heart failing and having an
22 infarction at that particular point in time. So there
23 might have been one episode of heat illness related
24 death in the control group. Next slide.

25 (Slide)

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1 The next thing we looked at is whether
2 heat stress exposure -- that means exposure to a high
3 temperature while exercising in basic training --
4 contributes to exercise-related sudden death. Over
5 here is 5.8 million military recruits during basic
6 training for the time period of '77 to '91. We
7 collected all exercise-related deaths, and we obtained
8 hourly WBGT values for the day before and the day of
9 the fatal event. We looked at percent of deaths with
10 a high WBGT exposure. We find very simply that 75
11 degrees either the day before or prior to collapse
12 during the exercise. Since at that point you have
13 about a 10-fold increase risk of exertional heat
14 illness. We compared them to control deaths in which
15 the death clearly was not related to exercise. Next
16 slide.

17 (Slide)

18 This is how we analyzed the data. The
19 slide shows the percent of exercise related recruit
20 deaths who had a substantial heat stress -- the green
21 bar on the X-axis is percentage from 0 to 100 percent.

22 We start at the bottom with the control, that's our
23 reference, 11 percent had a high heat exposure but had
24 a death unrelated to heat illness. If you look at the
25 next bar, those are the sudden cardiac death where

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1 there was pre-existing heart disease, 39 cases, and
2 the odds ratio of their exposure to about -- I think
3 the number is about 37 percent -- was 5-fold and
4 suggests that maybe 20 percent of those deaths are
5 associated with heat illness. The next bar is the
6 idiopathic sudden death where the autopsy was
7 negative, and their odds ratio was 9, the exposure was
8 around 54 percent, so maybe 44 percent of those cases
9 had significant association with a high volume and
10 unrecognized heat illness.

11 And then the SCT cases themselves, and
12 they run about 72 percent, 15 cases. And then lump
13 all the sickle trait deaths together, two of them were
14 defined as explained cardiac deaths, and the others
15 were either idiopathic death or EHI, and they had the
16 same heat exposure as EHI. Their odds ratio was 17,
17 and it was likely that nearly all of them were
18 actually unrecognized or recognized heat illness. So
19 this marker for heat illness suggests that
20 unrecognized heat illness play a major role in
21 exercise related deaths of these types. We don't know
22 for sure that they do because only 5 percent of the
23 sudden deaths are screened for the presence of heat
24 illness by measuring body temperature or chemistries
25 here. Next slide.

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1 (Slide)

2 I wanted to mention that I reviewed about
3 120 recruit deaths, 50 additional cases of fatal heat
4 illness with SCT outside of these studies, and I found
5 quite a number of patients who had hyperthermia or
6 typical chemical changes of rhabdo, and a substantial
7 pre-existing cardiac lesion. So we believe that
8 cardiac stress from exertional heat illness which
9 increases the cardiac output enormously can provoke
10 fatal complications to the pre-existing heart disease,
11 and such death might be preventable because if you
12 didn't get into a heat illness, maybe you will present
13 as angina and not as a fatal cardiac arrest. Next
14 slide, please.

15 (Slide)

16 The most important study we've done is to
17 see whether effective intervention to prevent
18 exertional heat illness will reduce exercise-related
19 deaths, especially for recruits with sickle trait.
20 The population used were w.1 million recruits who were
21 studied in '77 to '81, and then recruits in a ten-year
22 period from '82 to '91, 2.7 million participants and
23 1.1 million non-participants.

24 The data we collected was information on
25 exercise-related deaths that I showed you before

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1 during training, and used that data to determine
2 probable cause of death. And we wanted to compare the
3 exercise-related death rates and estimate the number
4 of lives saved in the intervention group versus the
5 nonintervention group, assuming that changes might be
6 related to the intervention. Next slide.

7 (Slide)

8 So our intervention was very simple-
9 minded, but based on the fact that right around in
10 1981 and what was going on in all the recruit centers,
11 I felt that people were not living up to the spirit of
12 the hot spot procedures. They frequently were not
13 recording the WBGT at the training site, but on top
14 of a hill, under a tree, a little nice place while the
15 recruits slog around in a swamp somewhere. And they
16 aren't measuring WBGT regularly. It specified at
17 least hourly, but Parris Island and some other bases
18 they measured it half-hourly. And then the drill
19 instructors would decrease exercise intensity and
20 increase rest cycles as the WBGT rose, to a minimal
21 effort at 90 degrees Fahrenheit, and I didn't alter
22 those specifications which the drill instructors had
23 and tended to adhere to if they know what WBGT is.

24 And knowing that water is really
25 unpalatable, they don't feel like drinking when they

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1 start to suffer not just the effects of exercise,
2 whether or not they really have heat illness, so I
3 said that the drill instructor ought to order an
4 increased water intake appropriate to that heat level,
5 and observe the water consumption, observe the recruit
6 actually drink the water. So that was our intent to
7 achieve that.

8 Later on, we added the concept of exercise
9 using light track clothing whenever possible in hot
10 weather, and being very wary of special events that
11 require heat-inclusive military gear. Using immediate
12 cooling, immediate identification of overheating in
13 the field by a recruit, slowing the exercise, taking
14 the temperature, starting to cool down and rehydrating
15 them, hopefully even providing fluids while in the
16 field, and opting for the long trip into the medical
17 center, maybe 40 minutes or more for the Army and some
18 of the larger centers.

19 Participating centers are shown there, and
20 the non-participating centers below. What happen was
21 the non-participating centers weren't really
22 interested in this intervention. It wasn't my choice
23 to have that. Next slide.

24 (Slide)

25 For the data collection for military

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1 recruit deaths, I talked to each PM officer each
2 season, and I tried to do that twice a season, and
3 visit each training center periodically, which meant
4 really probably about two and a half to three years,
5 obtain a list of all deaths which wasn't hard to do.
6 There are several overlapping sources, redundant
7 sources. And it's not hard to also get full autopsy
8 protocol and toxicology in 99 percent of the cases,
9 and then a little harder to obtain a review of
10 clinical and eyewitness accounts and lab data. The
11 first study, I got that for over 95 percent, and in
12 the current study I'm running about 60-70 percent, and
13 pathology subspecialty review, again, that's all --
14 the first study, we started with about a 60 percent
15 baseline, and we raised that to 95 percent by asking
16 for the records. In the current study, the baseline
17 is much lower. Some of the Army groups and the Navy
18 regularly do not send -- and the Air Force, actually -
19 - regularly don't send such cases to the Office of the
20 Armed Forces Medical Examiner.

21 WBGT is easily obtained from the local
22 airstrip records, and at the current time we have good
23 material on all the trait cases, and about 70 percent
24 of the other indications, we have satisfactory
25 material, 30 percent are up in the air. Next slide.

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1 (Slide)

2 This is our current level of analysis.
3 We've really just analyzed for the sickle cell trait
4 group at this point. What you see there in the left
5 column are the observed number of deaths, middle
6 column is predicted number of deaths, and the right
7 column is the difference, and presumably that's the
8 lives saved if it's a positive number, and lives lost
9 if it's a negative number, in comparison with the
10 rates that were persistent during '77 through '81. So
11 the top group are the participating group with the
12 trait. We predicted nearly 19 deaths and we found
13 none, so we may have saved 19 lives.

14 Those participating who do not have AS but
15 presumably are mainly AA hemoglobin, we observed 35
16 deaths, predicted 37, and saved only 2 lives. That
17 number is surprising. I'm hopeful that it will turn
18 out that we've done better in the EHI heart illness
19 group when we analyze that. We haven't analyzed it
20 yet. So, overall, from the participating group we
21 predicted nearly 56 deaths and we saw only 35, we may
22 have saved 21 lives, most of which with sickle trait.

23 I believe the figure was around 47,000 people with
24 sickle trait were training and there were no deaths,
25 and that includes a substantial number of the Army,

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1 over 25,000, who had no sickle trait screening. So
2 the screening for sickle trait was not necessary.
3 It's not necessary in the diagnosis of heat illness,
4 and it's not necessary in the management -- it doesn't
5 affect the management. So you don't have to know the
6 person has sickle trait in order to manage them and be
7 able to prevent disease, diagnose disease, or to treat
8 the disease.

9 In the nonparticipants with sickle trait,
10 we observed 4 deaths, we expected 7.1, the difference
11 was 3, so there was an improvement of some kind, which
12 made sense, because our first study was widely
13 publicized. And in the nonparticipating group there
14 were 20 deaths -- in the AA group, there were 20
15 deaths observed, whereas about 15 to 16 had been
16 predicted, so around 5 or 6 actual deaths occurred.
17 There's a mistake there. I guess that should be the
18 sickle trait number should have been a positive and
19 the AA number should have been a negative. So we
20 saved some lives in the sickle trait group, but lost
21 some lives in the non-trait group, and overall they
22 came out very close to what was predicted, 24 deaths
23 observed versus 23 predicted -- the 3 there is a
24 little too great -- must have gotten tired when I did
25 that slide. Sorry. Next slide, please. I'm almost

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1 done.

2 (Slide)

3 When you look at the heat illness measures
4 but you use the nonparticipant training centers, 3 of
5 the 4 cases with sickle trait occurred during the hot
6 season. The WBGT was not measured hourly for these
7 cases. An opportunity for water drinking was given,
8 but no one knew whether the victims had actually drunk
9 water. Even their recruit partners didn't know
10 whether they had drunk any water or not.

11 There was a fifth case which occurred in
12 AIT at Orlando, and that additional case showed at
13 that particular time the recruit training center
14 wasn't even using a WBGT, it was using a different
15 heat index and they were following it erratically.
16 There was a three-day period when it wasn't actually
17 done, that led up to the point when that person died
18 of a sudden death from heat illness. So, a high WBGT
19 period that was missed. The victim was not observed
20 drinking water again. So, we know that the measures
21 we wanted to have followed weren't being followed in
22 those deaths of the nonparticipants. Next slide.

23 (Slide)

24 So the major conclusions we can come to is
25 there is a significant association between high-risk

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1 hot weather for 24 hours before collapse, and
2 exercise-related sudden death, and this association is
3 greatest for people who have sickle cell trait.

4 Heat stroke increases the rate of
5 exercise-related threatened or actual sudden cardiac
6 death by 3,400-fold in populations that did not have
7 sickle trait, and this is probably because life-
8 threatening cardiovascular collapse is common. So,
9 it's probably the shock that's endured with this life-
10 threatening event.

11 The third thing is that intervention to
12 prevent exertional heat illness appears to eliminate
13 the excess risk of death for recruits with sickle cell
14 trait, and I don't think it eliminates it entirely,
15 but it can get back to very close to what it should
16 be. It seems to be a fairly effective way of handling
17 the problem.

18 Exertional heat illness is a major
19 preventable factor contributing to exercise-related
20 death of young adults. Next slide.

21 (Slide)

22 I have some advice I could give to
23 military members with sickle cell trait. There is a
24 greater risk of fatal heat illness for those with
25 sickle trait. This risk is high if one allows to

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1 develop that favor heat illness. So if you're poorly
2 conditioned for an event you're at higher risk, if you
3 enter the event dehydrated you're at higher risk, if
4 you're obese, you're sleep-deprived, you're the
5 exercise at altitude -- probably above 4,000 feet --
6 if there are conditions such as occlusive military
7 clothing that prevent you from losing body heat by
8 evaporation and, finally, maybe one of the most
9 important factors I really haven't touched yet is if
10 heroic effort is being made with disregard for effort-
11 related symptoms. Those are periods of danger. We
12 found in our Parris Island studies that a lot of
13 hospitalizations were clustered around special events
14 that required heroic attitude in which often people
15 are in full military gear and they are trying to do a
16 number of things at the limit of their ability. If
17 that happens in hot weather, you can be in trouble in
18 a lot of cases.

19 The risk for sickle cell trait people, the
20 actual risk, can be largely eliminated by intervention
21 to improve hydration, improve the ability to sweat,
22 limit exercise when occlusive clothing or high ambient
23 temperature increase the threat of excessive body
24 temperature.

25 And, finally, rapid treatment to correct

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1 early mild signs or symptoms of heat illness, such as
2 unusual muscle pain or muscle weakness, is important.

3 Each individual should try to learn and recognize and
4 act upon such symptoms, which unfortunately are
5 nonspecific and might mean many other things, but they
6 should, if they're trying to do demanding exercise,
7 reduce effort and seek medical advice. That's
8 obviously not always possible in the military
9 operations and training events. Next slide.

10 (Slide)

11 After entry training, the risk of
12 unexpected exercise-related death is much less, but
13 it's still significant. I know that's one of the
14 questions that was asked. I can't give you exact
15 figures. I do have case collection of all the sickle
16 trait related deaths that I know of, and for a time
17 period the mortality rates that John Gardner ran
18 lacked such information for military members, and Army
19 especially. So we can give you some ballpark figures
20 for that with some additional work.

21 As I mentioned, in our recruit study we
22 had 2 out of about 27 sickle cell deaths overall, and
23 there were 2 additional cases that occurred in AIT,
24 and AIT should be about the same number of people as
25 recruit training, which shows you how much lower that

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1 would be, 27 versus 2, so maybe that gives you some
2 idea of the level of risk that it reduces to after
3 entry training. We don't know whether this is because
4 you eliminate susceptible people, or whether people
5 are now better conditioned for what they are doing and
6 less likely to have to go through as much conditioning
7 trauma as an initial recruit does.

8 The same precautions should be taken to
9 avoid heroic effort, to remain conditioned for any
10 task, and to follow sensible procedures to minimize
11 risk of heat illness as much as possible. That would
12 be my advice to military members with sickle trait.

13 Next slide.

14 (Slide)

15 So I was going to touch briefly on the
16 utility of screening for sickle trait. The diagnosis
17 and management of heat illness and the prevention of
18 heat illness is identical for those with or without
19 sickle trait, so there isn't any burning urgency to
20 identify sickle trait for that purpose.

21 While knowledge that one has sickle trait
22 can motivate a person to better protect themselves
23 from heat illness, a beneficial effect on behavior or
24 medical outcome has not been demonstrated. Obviously,
25 there is a moral concern that it would be nice to let

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1 people know that they are at higher risk, and that
2 also motivates people. Sickle trait mortality has
3 varied widely irrespective of screening policy, and at
4 times the Army has done extremely well, including the
5 ten-year period when we were doing our intervention,
6 without needing any screening.

7 In our prospective study it was 35,000
8 Army recruits with sickle trait who completed basic
9 training without deaths in the absence of expensive
10 screening for trait. Next slide.

11 (Slide)

12 The main advantage of screening for trait,
13 I believe, would be the detection of recruits with
14 unrecognized sickle cell disease either because they
15 had a very mild case, and that's quite possible. As I
16 mentioned, about 15 percent or so, maybe even 20
17 percent, of sickle cell disease allowed a person to
18 have a normal life span. Many of those people have so
19 few events they don't recognize that they have sickle
20 cell disease. You can't identify it very well just by
21 physical exam. There either has to be a history where
22 a person is actually screened, but there are a fair
23 number of people who aren't appropriately screened,
24 but who don't have a necessary history to be able to
25 give you that information. So, the history and

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1 physical is not really sensitive enough to expect to
2 identify sickle cell disease.

3 I think people with sickle cell disease
4 are at high risk of developing serious or fatal events
5 because they get crisis episodes from mild heat
6 illness, it would be important to complete screening
7 prior to PT.

8 The cost of not screening for sickle cell
9 disease involves not only the loss of personnel but
10 the expense of investigation of hospitalizations and
11 training deaths. These may have major legal
12 implications which are expensive, and potential impact
13 on the military careers of the personnel who are
14 conducting the training. So that ought to be taken
15 into account. Next slide. Well, that's it.

16 DR. OSTROFF: Thank you very much for that
17 very comprehensive overview. Let me just ask the
18 Board if there are one or two questions before we take
19 a break because there will be more time for discussion
20 concerning this presentation and other presentations
21 that we heard. David.

22 DR. ATKINS: I was a little unclear on
23 your original study and subsequent studies. Are we
24 using prevalence of sickle cell trait in a population
25 to estimate the prevalence in the military, or do we

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1 actually have data on the prevalence of sickle cell
2 trait in the military?

3 DR. KARK: There are two major studies
4 which looked at around 19,000 to 25,000 recruits.
5 Those show us that the prevalence of hemoglobin S is
6 about 8 percent in the African American population and
7 about .08 in the non-African American population in
8 the military. And in my studies, I've used those
9 figures, which agree very well with civilian
10 estimates. I haven't actually measured the prevalence
11 of sickle cell trait, but I've used those figures to
12 calculate how many people were in the nonmeasured, but
13 the rates aren't quoted. I've identified the cases.

14 Now, you can identify -- even though
15 screening isn't done, if the histology is done
16 correctly, you can identify people who have sickle
17 trait post-mortem very well based on the fact that
18 everyone with sickle trait will show some sickle cells
19 especially in the spleen and bone marrow, and if they
20 have trait but not disease, the spleen will not
21 otherwise be abnormal. If they have sickle cell
22 disease, it will very reliably show scarring in the
23 spleen. They should be able to identify with good
24 histology post-mortem people who have sickle cell
25 trait and sickle cell disease. So, we've done that.

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1 For the cases we've looked at whatever
2 reports we have of electrophoresis and the histology.

3 The denominators I've calculated from known
4 prevalence rates based on primarily two large military
5 surveys that were done in Orlando, in the Navy.

6 DR. OSTROFF: Other questions?

7 (No response.)

8 If not, let's take a five-minute break. I
9 know that there are a number of us who need to check
10 out of our rooms, and come back and, again, I would
11 emphasize to the speakers in the next session to try
12 to keep on time because we do have a number of things
13 to discuss.

14 (Whereupon, a short recess was taken.)

15 DR. OSTROFF: Our next presenter is Col.
16 Margot Krauss, from Accession Medical Standards
17 Analysis and Research Activity at Walter Reed Army
18 Institute of Research. Col. Krauss.

19 COL. KRAUSS: Thank you for asking me
20 back. I've actually only been dealing with this for
21 the last couple of years, so I'm a relatively new to
22 the issue that's been going on for over 30 years, as
23 Col. Corcoran pointed out, and actually my interest in
24 sickle cell disease started in response to an Air
25 Force colonel who called me and asked me if AMSARA

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1 could get involved in the whole sickle cell trait
2 screening program, and he had called with a request
3 that the Air Force stopped doing it and stop
4 discharging people who are sickle cell trait positive.
5 And I said, "Well, sickle cell trait is not a medical
6 accession issue, AMSARA would never get involved in
7 this". I was wrong because sickle cell disease is a
8 medical accession issue, and so I'm approaching that
9 today from sickle cell disease and, as I understand
10 the question being posed to the Board today, and not
11 sickle cell trait, but they are linked.

12 I looked at this -- I've been revising my
13 presentation numerous times to try to make this as
14 clear as I'm going to be giving my presentation a
15 little bit different than the handouts that hopefully
16 you received. I even thought this morning maybe I
17 should retitile my presentation in light of the recent
18 media coverage of "what do we know and when did we
19 know it".

20 (Laughter.)

21 COL. KRAUSS: I wanted to find what is
22 sickle cell disease. We float around these
23 terminologies very cavalierly, and oftentimes we're
24 confusing not only ourselves, but others in the
25 process.

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1 (Slide)

2 Sickle cell disease is actually a group of
3 diseases, and really it's only characterized by the
4 production of hemoglobin S, and this is resulting from
5 the inheritance of a beta S gene from one parent and a
6 gene for other abnormal hemoglobin which polymerizes
7 with hemoglobin S, and that's the bottom line, unless
8 polymerized in order for the sickling. And as you
9 heard in Dr. Kark's presentation, the sickling is
10 actually what causes the sickle crisis.

11 Now, hemoglobin S molecules polymerize
12 most effectively with other hemoglobin S molecules and SS
13 individuals would have the most severe disease. But
14 then they polymerize with other abnormal
15 hemoglobinopathies and hemoglobin in decreasing order,
16 so hemoglobin C is the next most severe form of
17 disease. Hemoglobin D actually is often asymptomatic,
18 as is O, and you see hemoglobin A which is normal
19 hemoglobin really doesn't polymerize well with
20 hemoglobin S, and that's when we get sickle cell
21 trait, and then there's other abnormal hemoglobins
22 such as J and F. Persistent fetal hemoglobin can
23 exist in conjunction with someone who has 70 percent
24 hemoglobin S. These individuals do not have clinical
25 disease, but for our terminology today we refer to it

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1 as sickle cell disease, but they would never be
2 anemic, they would not present clinically, and you see
3 by the electrophoresis result they would look
4 concerning, if you only looked at that hemoglobin S
5 fraction.

6 (Slide)

7 So what is sickle cell disease? Well, in
8 my mind, sickle cell disease really is something that
9 is clinically significant, not just abnormal
10 hemoglobin, which we can identify all types of
11 abnormal hemoglobins that do not result in clinical
12 disease, but certainly the top three I have listed
13 there do result in disease. Homozygous SS, this
14 usually refers to sickle cell anemia; homozygous SC,
15 meaning an S gene from one parent, C gene from the
16 other, results in sickle -C disease, and then you have
17 the beta-thalasseмииs, and there's two types of that.

18 As I mentioned, many other abnormal hemoglobins, many
19 do not cause disease. You heard Dr. Kark say that
20 maybe 20 percent would be asymptomatic or clinically
21 not significant. I couldn't find exact percentage
22 because, frankly, people don't look at these other
23 abnormal hemoglobins. I know that excessive D is
24 clinically insignificant. The D does result in a mild
25 sickle cell anemia type picture. E, G and O are all

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1 clinically insignificant according to the literature.

2 (Slide)

3 So, sickle cell anemia, again, homozygous
4 sickle cell, these individuals have permanently
5 sickled cells, anywhere from 5 to 50 percent of the
6 red blood cells run around being sickled all the time.
7 They are anemic anywhere from moderate to severe. The
8 average hemoglobin you'll see in these individuals is
9 8. It can range from 6 to 10. If you did a
10 reticulocyte count, which Dr. Kark alluded to, they
11 would all have an elevated retic count. The actual
12 sickly crisis, when we see them with their abdominal
13 pain or their bone pain, is not associated with
14 increased anemia. These individuals are always
15 anemic. If we actually did a CBC, we might see they
16 had a low MCV and elevated MCHC.

17 (Slide)

18 Now we know newborn screening first
19 started in 1975. It is currently in process in over
20 40 states in the United States. I could not find
21 anywhere where it's published which states are not
22 doing it. It's probably logical to think that most
23 states are doing it now, and the only states that
24 probably wouldn't would be ones with no African
25 Americans or a very low prevalence of African

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1 Americans in their population. But screening has been
2 going on for over 20 years. The majority of Africans
3 in the military should have been screened as newborns
4 and appropriately identified as having sickle cell
5 disease.

6 Now, most of the emphasis is on those
7 individuals with homozygous SS with sickle cell anemia
8 because at the turn of the century none of these
9 individuals would survive to reproductive age. Now
10 with increased protection and penicillin prophylaxis
11 for those who are homozygous, or who have the more
12 severe form of S beta-thalassemia, many of these
13 individuals are surviving. In fact, even though they
14 still have an increased mortality rate over those who
15 do not have SS disease, 85 percent are surviving to 20
16 years of age and could be applying for military
17 service.

18 (Slide)

19 Dr. Kark also alluded to alpha-
20 thalassemia. If an individual does have alpha-
21 thalassemia and homozygous SS, they actually will have
22 a less severe clinical presentation. They still are
23 increased of dying, but an decreased mortality when
24 compared to just SS without alpha-thalassemia. Alpha-
25 thalassemia is a little more complicated, 30 percent

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1 of black Americans actually have a single alpha gene
2 deletion. This is considered clinically silent, but
3 if you have two of these genes deleted, you actually
4 have clinical disease, and approximately 2 percent of
5 American blacks have this disorder.

6 (Slide)

7 Sickle SC disease, these individuals are
8 also usually anemic, mild to moderate. Twenty percent
9 do not have anemia, though, and maybe asymptomatic,
10 according to all the literature I could find.
11 Individuals with this particular disorder often are
12 noted to have crystals in their smear, and they are
13 viewed in the military as being indicative of someone
14 have SC disease.

15 These individuals who have clinical
16 disease, again, looking like sickle cell anemia, often
17 called sickle cell anemia, but it's usually much
18 milder disease. I think I'll not look at the unusual
19 aspects, but they do have other clinical
20 manifestations which are really unusual.

21 (Slide)

22 The sickle beta-thalassemia do have the
23 type or no beta globin is synthesized, and this is
24 virtually indistinguishable from homozygous SS
25 disease, unless you have a good electrophoresis where

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1 you have the A2 fraction that's elevated, and that
2 means over 3 percent. Oftentimes, I don't have the
3 electrophoresis, so it's difficult to really know if I
4 could determine if these individuals have this
5 particular disorder.

6 The hemoglobin S beta+ thalassemia means
7 that some beta globin is produced, but it is reduced
8 from the normal individual. These individuals will
9 also have mild to moderate anemia. It's considered
10 somewhat milder than SC disease. The key here is that
11 there is hemoglobin A, anywhere from 5 to 30 percent
12 of the hemoglobin identified will be normal
13 hemoglobin. You need to look for the A2 fraction, it
14 is elevated over 3 percent is abnormal. The reason I
15 want to point this out is the many individuals in the
16 record review that I will be presenting later were
17 classified SCT when, in fact, they had hemoglobin S
18 beta thalassemia. I think there's a great probability
19 of this classification between trait and disease.

20 (Slide)

21 So I looked for estimates of sickle cell
22 disease in our population. I got these numbers
23 actually from a 1993 publication, Guidelines for
24 Sickle Cell Disease: Screening, Diagnosis, and these
25 numbers have been relatively constant over years. I'm

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1 not sure if any further studies have been done, we
2 just keep quoting the old numbers, but these are the
3 numbers. One in every 375 black American or African-
4 American is suspected to have sickle cell disease.
5 Native Americans, 1 in 3,000; Hispanic, much rarer,
6 and white, extremely rare, although it can happen.
7 Next.

8 (Slide)

9 But the majority of cases we see are in
10 black Americans, so I want to concentrate on this
11 particular group. I got these data, these estimates
12 from Interpretation of Diagnostic Tests. These
13 numbers also have not changed over the last four
14 editions of this particular book. So, you have to
15 take that into consideration. Since more people are
16 living with these disorders, the incidence could be
17 going up.

18 Sickle cell anemia is considered to occur
19 once out of every 625 live births among black
20 Americans. Sickle C disease, there was a range I
21 found anywhere from 1 in 835 live births to 1,100 live
22 births, and S-beta thalassemia is much rarer. Sickle
23 D disease I put up there just to give you an estimate
24 of how much rarer this disorder is, even though it
25 usually does not result in disease, it is usually

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1 asymptomatic. Same rate with persistently high fetal
2 hemoglobin. These individuals could be expected to
3 have no clinical disease.

4 (Slide)

5 All told, there are 644 hemoglobin
6 variants that have been identified, so it's a very
7 confusing field and I'm not a hematologist, and I
8 spent a lot of time trying to come to grips with the
9 data that I was reviewing. You can see here that
10 clinically significant alpha-thalassemia, which is
11 referred to alpha-thalassemia minor, is occurring 57 -
12 - and these are prevalence numbers now -- 57 for every
13 1,000 black Americans. You can see for all homozygous
14 S conditions which are referred to as sickle cell
15 disease whether they cause clinical disease or not,
16 occurs about in 4 people for every 1,000 black
17 Americans, and sickle cell anemia now you see a
18 prevalence number of 1 in 1,000. This is why the
19 reflected increased mortality of these individuals
20 still have today. So this is probably the best number
21 or estimate of prevalence in our population. Next.

22 (Slide)

23 Now we finally get to the DODI. What is
24 actually disqualifying from military service -- Col.
25 Corcoran has gone over that already -- it really is

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1 anemia that has not been permanently corrected with
2 therapy. Next.

3 (Slide)

4 So I wanted to look at individuals who
5 were discharged due to anemia. EPTS means prior
6 service. These are discharges that occur within the
7 first six months on active duty. Now, the coding for
8 these discharges or for anemia can fall under
9 hereditary hemolytic anemia, or 282, and you see under
10 that classification the sickle beta-thalasseмии, the
11 sickle cell anemia whether it's SS or SC, other
12 hemoglobinopathies, and sickle cell trait is actually
13 included under this ICD9 code, but it is not
14 disqualifying. I just point that out because as we
15 have EPTS individuals for sickle cell trait, they fall
16 under this category.

17 The other category where sickle cell
18 disease might be found is in this other unspecified
19 category. Next slide.

20 (Slide)

21 I just want to remind you again,
22 hemoglobin S conditions are not disqualifying. There
23 are certainly a lot of asymptomatic forms of
24 hemoglobinopathies, approximately 20 percent SC
25 disease and sickle cell trait is not disqualifying.

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1 Next.

2 (Slide)

3 So what is our experience in 1998 to 2000?

4 I reviewed the EPTS records. These are actually
5 paper records. I looked at -- I actually found over
6 50 percent were due to hereditary hemolytic anemia
7 coded as 282. The rest were really Other or
8 Unspecified. There was only one aplastic anemia and 1
9 acquired anemia, so all told we could document over 43
10 percent of the anemia that resulted in discharge or
11 premature discharge from the military was really
12 sickle cell disease.

13 Now, I went back and looked at
14 distribution of discharge by the Army. The Army does
15 not have a sufficient program, and the other services
16 do. I wanted to see where our sickle cell disease may
17 be being coded or being discharged. You see that the
18 Army represents 36 percent of all accessions, but as I
19 reviewed sickle cell disorders in the military, I
20 found 94 actually that had sickle cell disorders, and
21 only 23 of those were from the Army. So Army is
22 underrepresented, as you'd expect without a screening
23 program, in identifying people with sickle cell
24 disease. However, if you look at individuals who were
25 discharged for other anemia, the Army was

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1 overrepresented, and my interpretation of that is the
2 Army may well be discharging people with sickle cell
3 disease that we just never identified as having sickle
4 cell disease, they just happened to be anemic and they
5 needed to be discharged under that criterion. Next.

6 (Slide)

7 So, what I did next was I wanted to look
8 in-depth at the paper records for anyone that was
9 coded 282 meaning hereditary hemolytic anemia. I
10 restricted my look at only enlisted accessions from
11 1998 to 2000. The reason I restricted to enlisted is
12 we've had no officers leave the service because of
13 sickle cell disease. We've had no hospitalizations
14 from the officers with sickle cell disease, and we can
15 discuss why that is later. I also focused my look at
16 only active duty. The reason for that is the
17 denominator data for Reserves and National Guard are
18 not accurate. We're just really guessing with numbers,
19 and when I do that, the rates just go crazy. So, I
20 wanted to give the most conservative rates as I
21 submitted this data today. Also, with the Reserves
22 and National Guard, I can't follow them up for
23 additional training, so if they get hospitalized later
24 with sickle cell disease, I'll not know that.

25 I actually confirmed sickle cell disease

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1 cases in my review, and I'll go over how I did it for
2 each service, and then I compared the services for
3 EPTS discharges. I did look at hospitalizations, and
4 disability for the Air Force and the Army. Next.

5 (Slide)

6 So, how did I determine what was what?
7 Sickle cell anemia, if I had someone who had no
8 hemoglobin A, the A2 was normal, it was predominantly
9 hemoglobin S, they were sickle cell anemia by my
10 criteria.

11 I really don't think I was able to
12 determine sickle beta 0 thalassemia unless I had
13 hemoglobin S and a high A2 fraction over 3 percent.
14 If I found that, then I have labeled them as beta
15 thalassemia.

16 The majority of individuals I labeled as S
17 beta+ thalassemia, and this is because I had high
18 Hemoglobin S and the A2 fraction was high, that was
19 the major determining factor in my classification, and
20 most of these were 4 percent or higher. I put the SCD
21 in there if I talked to pathologists prior to the
22 presentation. He said you certainly would never want
23 to make a diagnosis of sickle beta-thalassemia without
24 a CBC. We don't have CBCs. We don't have the SCD.
25 If it was less than 78, that would be a clear

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1 indicator, that's just not done. Next.

2 (Slide)

3 So, other diagnosis I was grappling with
4 was sickle cell trait, and the hematology textbooks
5 tell me that hemoglobin A is always greater than
6 hemoglobin S. So, if it was not that way, I would not
7 classify it as trait in my review. Persistent
8 hemoglobin F. I had a couple that did have a very
9 high fetal hemoglobin. This was considered
10 nonclinically significant of sickle cell disease, and
11 hemoglobin SG is also clinically silent. We know we
12 had at least one of those. Next.

13 (Slide)

14 So the Army policy is we don't screen, and
15 we identify people by clinical presentation. Next.

16 (Slide)

17 So over this three-year time period, I
18 identified 40 EPTS that were coded hereditary anemia
19 under the 282 ICD9 coding. And I'd just take this
20 moment to say there are people who are there because
21 included in our databases -- this might be the best
22 database we have, but there are problems even here.
23 ICD9 coding do not answer all your questions because
24 certainly when it gets down to the clinical question,
25 we have to go beyond the ICD9 coding which means

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1 looking at the records, which is what I did. Eighteen
2 of these records I could confirm as sickle cell
3 disease in active duty personnel. I excluded 5 that
4 definitely had sickle cell disease that were
5 considered Reserve and National Guard component,
6 again, because I wanted to get the best estimate or
7 the best rates for this presentation.

8 The other anemias identified were mostly
9 alpha-thalassemia minor. Next.

10 (Slide)

11 Of those that were active duty personnel
12 identified with sickle cell disease, over 67 percent
13 were hospitalized for sickle cell disease. I cross-
14 referenced these with our hospitalization records. I
15 referred specifically to PASBA, that's the Patient
16 Administration Statistical Activity in San Antonio,
17 Texas, and I'll just take a moment to explain a little
18 bit about this data.

19 Prior to the Tri-Service Center data, the
20 standard inpatient data record, the Navy, the Air
21 Force, the Army all collected their own
22 hospitalization databases and discharge diagnosis
23 which were coded in ICD9. And actually the services
24 are continuing to do that, and then they forward all
25 the data to PASBA. PASBA then creates a standardized

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1 record. From that point, the hospitalization database
2 goes to a contractor. I'm not quite sure what they do
3 with the data, and I've never really figured it out,
4 and that's why I go to PASBA. From there, it goes to
5 other locations.

6 So, you'll see in the military a lot of
7 people using inpatient data. It comes from different
8 locations, and you will get different results
9 depending on which data source you go to. And, in
10 fact, I've done other studies going directly to the
11 Navy and the Air Force, to find data that they have
12 that was not in PASBA, although technically they all
13 go to the same place.

14 The reason I say this is that even though
15 all my paper copying of EPTS, it's clearly there is a
16 discharge diagnosis that is an inpatient record of
17 what happened to this person. Six of them I could not
18 find in PASBA, there was no record of their
19 hospitalization. So, 50 percent I could not verify by
20 our administrative databases.

21 That aside, the 6 that were hospitalized
22 and had discharge diagnosis of crisis, which is what
23 that 262.62 means, sickle cell crisis, this is
24 actually confirmed by the EPTS record review. I
25 couldn't look at their whole hospital reports, they

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1 certainly were in crisis, they certainly had sickle
2 cell disease.

3 Most of these individuals presented in the
4 normal fashion -- abdominal pain, back pain,
5 rhabdomyolosis, most minor was severe anemia. Next.

6 (Slide)

7 How do we diagnose it or what was included
8 at least on the EPTS records was quite variable. I
9 had 5 that were only diagnosed on a positive
10 sickledex. And then they gave me the type of sickle
11 cell disease based on history provided by the recruit,
12 or the smear. If it had hemoglobin crystals, they
13 decided it was SC disease.

14 Electrophoresis, usually the full results
15 were not recorded. This is my best guess, the
16 distribution that I figured out. Certainly there were
17 4 individuals clearly that had homozygous SS disease,
18 that had come into the military and went into sickle
19 cell crisis. Only 7 of these 18 had any hemoglobin
20 and hematocrit recorded. Only 1 had what I considered
21 a near-normal hemoglobin level. The majority had
22 hemoglobins of 10 and, as I mentioned before, crisis
23 does not lower your hemoglobin, so they were anemic at
24 the time they came into the military. Next.

25 (Slide)

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1 There's no documented denial of disease in
2 these records and, in fact, 16 clearly gave a history
3 of sickle cell trait or sickle cell disease that they
4 did not divulge at the prescreening at MEPS. Thirteen
5 gave a positive history of sickle cell disease in
6 crisis prior to coming into the military, one to two
7 crises a year, hospitalizations, no mention at all
8 during the MEPS physical.

9 Three did report that they had sickle cell
10 trait and in reality they had homozygous SC disease,
11 and they probably were truly mistaken about what they
12 had.

13 It's safe to assume that we don't identify
14 anyone with sickle cell disease in the Army since we
15 don't screen. They may well be under the other anemia
16 code, as I mentioned, since we don't routinely do
17 hemoglobin electrophoresis, and we all recognize that
18 some hemoglobin S conditions are asymptomatic and
19 would never come to our attention.

20 (Slide)

21 So I thought what happens long-term if
22 we're letting people in with sickle cell disease in
23 the Army, maybe they're getting in trouble later, and
24 they don't get EPTS discharge, but they get
25 hospitalized for the disease. And, certainly, looking

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1 at the hospitalization records, there are more people
2 in the Army getting hospitalized, maybe discharged
3 with a discharge diagnosis code consistent with sickle
4 cell disease. The numbers are not that impressive,
5 and you see the Navy, Air Force, Marines also have a
6 few that appear to be hospitalized with sickle cell
7 disease after six months, which in theory shouldn't
8 happen with a screening program.

9 So I then looked at the length of service
10 and said, well, when did this happen. It certainly
11 must have happened during INT and that doesn't appear
12 to be the case either. We had some people who were
13 being hospitalized at 7 months, 7 months means 7
14 months of active duty, up to 9 years or 18 years on
15 active duty. Well, then I'm thinking, well, is this
16 really sickle cell disease? It's hard to know. Again,
17 there's a problem with discharge diagnosis and coding.

18 When you're dealing with such small numbers, being
19 wrong in one or two cases disinflates your rates
20 tremendously, you've got to be very careful. So I
21 thought, well, if I look at loss, maybe those who are
22 lost are more likely to have sickle cell disease.
23 Well, it looked like maybe half were lost, so maybe
24 half had sickle cell disease, I couldn't tell. And I
25 certainly couldn't get all these records. Next slide.

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1 (Slide)

2 So I asked four of my friends, colleagues
3 in different locations, to pull some records for me
4 and tell me were these people who had sickle cell
5 disease or not. I had 10 records for patients where I
6 think people would tell me, and I asked them to look
7 up the records. There were 3 actually had discharge
8 diagnosis of sickle cell with crisis, and you see the
9 ICD9 code in parentheses, 2 of these I could confirm.

10 One clearly had SC disease and the other one the
11 record just said electrophoresis consistent with
12 hemoglobin SS, so they didn't even give the
13 electrophoresis in that record, but the fact that they
14 actually did a hemoglobin electrophoresis and they
15 said it was SS, I had to believe them. The 1 death
16 they actually had electrophoresis which was consistent
17 with trait. I'm not sure how the record got in, it
18 actually was a recruit death, and so I got the autopsy
19 record and I was quite surprised when I read the
20 record. This was a 17-year-old young black person who
21 in his first week of training had run a mile in 9
22 minutes. I can't say that's too strenuous, even I can
23 run a mile in 9 minutes, and I'm way past 17.

24 (Laughter.)

25 And it was not a hot day. None of the

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1 other risk factors were there. Dropped dead. The
2 pathologist at AFIB and, oh, by the way, he had sickle
3 cell trait. No mention in the autopsy record of any
4 sickling, any target cells, nothing in the autopsy
5 report, just the fact that he had sickle cell trait,
6 there could be an association. So, I was surprised by
7 that one.

8 The one that was put at SC was confirmed
9 sickle cell disease, two of these were confirmed, one
10 had SC one had S-thalassemia, one was clearly trait,
11 and two only had sickledex positive. No hemoglobin
12 electrophoresis was ordered. In my opinion, this is
13 truly sickle cell trait because these were both
14 pregnant black women, and there's a lot of people when
15 they deliver become a positive sickledex, and these
16 individuals did not leave military service.

17 And the other one under other
18 hemoglobinopathy actually was also SC. Next.

19 (Slide)

20 So, in my very small very review, I was
21 able to confirm 60 percent of the hospitalizations
22 actually having sickle cell disease in the Army, and
23 actually, just coincidentally, this is consistent with
24 the 60 percent loss that I saw after hospitalizations
25 in the Army. I can't really connect these since I

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1 didn't look at all the records. But we might think
2 that at least 60 percent of these hospitalizations may
3 really be linked or related to some form of sickle
4 cell disease. Next.

5 (Slide)

6 I switched to the Air Force which screens
7 for sickle cell trait thereby would also recognize
8 disease. They do a hemoglobin electrophoresis,
9 although I don't know what type, and that actually is
10 important in making a diagnosis.

11 In the Air Force there was sickle cell
12 trait can leave under an admin separation and, as I
13 mentioned, the medical side of Air Force was not very
14 happy with this policy and the fact that they're
15 losing quite a few people because of policy. Since
16 it's coded under their admin separation, I cannot tell
17 you the absolute number. By his estimate, it was over
18 60 a year are leaving because of their sickle cell
19 trait, not a medical discharge.

20 Certainly, those with sickle cell disease
21 would receive EPTS discharge. Next.

22 (Slide)

23 I identified 18 individuals who had EPTS
24 records, 17 were identified by screen and 1 was
25 symptomatic. That 1 that was symptomatic actually was

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1 in a sickle cell trait positive person. Next.

2 (Slide)

3 The history, I think, was information in
4 the Air Force. Over 50 percent -- well, 50 percent
5 actually gave a clear negative history of ever having
6 any problem in the past. Typically, at presentation
7 is when you're going to hear people or people are
8 going to tell you the truth. These individuals all
9 had SC disease or S-thalassemia and, as I mentioned
10 before, it's very possible that these people were
11 truly asymptomatic. One individual of note was from
12 West Africa. He had successfully fought in several
13 wars in his country. He desperately wanted to be in
14 our military. He applied for a waiver and they said,
15 no, you have sickle cell disease, you have to be
16 kicked out.

17 There were 5 that clearly gave a history
18 of having sickle cell disease and crisis when they
19 presented that they did not divulge on prescreening at
20 MEPS. One had homozygous SS and the other 4 had SC
21 disease. And these individuals all had 1 to 2 pain
22 crisis a year, they were hospitalized. There was no
23 doubt in their mind that they had sickle cell disease.
24 The mildest that I could find reported was a young
25 lady who had arthritic pains every time she ran, and

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1 on her MEPS physical she did not report having any
2 joint pain, that's clearly a questions asked. She
3 decided not to divulge that. Next.

4 (Slide)

5 So, all this to say I'm going to try to
6 give you some estimate of how much sickle cell disease
7 is out there that's not disclosed at MEPS, and this is
8 quite a difficult thing to try to do. So I tried to
9 use a much higher prevalence of sickle cell disease
10 that we have seen in an unscreened population that I
11 think is probably real, so a very high expected rate.

12 I based my expected for most of this on
13 the incidence of disease at birth and, as you know,
14 the incidence of disease at birth would be much higher
15 than the prevalence in our population because some of
16 these individuals would have died. Also, as you look
17 at all the incidence at birth, the subtypes, the SS,
18 SC and S-thals, and add them all together, I'm going
19 to overestimate the prevalence, so I'll point that out
20 in my slide.

21 For the observed, I only used the
22 confirmed sickle cell disease cases. That means I
23 excluded data that wasn't clear. I excluded the Navy,
24 Reserve and National Guard. So, with this approach
25 I'm going to overestimate the ability of the MEPS exam

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1 to deny entry to those with sickle cell disease, since
2 that was the first question posed to the Board, how
3 good is the MEPS exam.

4 (Slide)

5 Let me run through this table here. On
6 the left, I only looked at black population, so all
7 the cases were among blacks. You see the incidence
8 rate that I'm using for each of the subtypes and
9 sickle cell disease, and I calculated expected, and
10 then what we actually observed. It does seem that
11 homozygous SS is not seen often, there is 1 in the Air
12 Force, so this is statistically lower than we would
13 have expected if we didn't screen at all. Those with
14 SC disease is not statistically different, finding 11
15 in this population, small numbers and whatnot, it's
16 not really different from 16 or even 21 that we might
17 have expected.

18 At the very bottom you see my total sickle
19 cell disease expected, and I put together all
20 incidence rates which you really shouldn't do, but I
21 did it anyway, so it gives you concept of how really
22 overinflated my numbers really are. We might expect 1
23 in every 05 black Americans to have some form of
24 sickle cell disease, and as you remember this is much
25 higher, or is higher than the published prevalence

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1 numbers of 1 in 375. So, my expected is clearly high,
2 my observed is probably correct -- well, it may be
3 correct for the Air Force. Next.

4 (Slide)

5 And I move on to the Navy. It also
6 screens. I know they do each year a hemoglobin
7 electrophoresis. Alpha-thal electrophoresis fall by
8 an active electrophoresis which is very good in
9 identifying exactly what kind of abnormal hemoglobin
10 you have. Those with sickle cell disease are
11 discharged. Those with trait remain on active duty
12 unless their hemoglobin S is over 45 percent, which is
13 Navy policy. Next.

14 (Slide)

15 I found 69 EPTS records that were coded
16 282. You see the top bullet, just the other kind of
17 anemias that I found, or disorders actually. Eighteen
18 were actually coded as sickle cell trait, but 67
19 percent or 23 of these actually had sickle cell
20 disease. There were 6 that had sickle cell trait, so
21 we have a large miscoding here, very rare.

22 So, all told, I'd say this confirmed 47
23 individuals with EPTS for sickle cell disease. All
24 these cases except the 1 Native American were in
25 blacks.

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1 Now, I had 5 records that I couldn't find,
2 these are hard copy records that we file at AMSARA, I
3 don't know where they were, probably misfiled. But I
4 couldn't review them, I felt they mostly like were
5 sickle cell disease based on the diagnosis that was
6 assigned to them, and having reviewed these other
7 records for the Navy. And I'll address how that
8 affects my rates later. And there was also another
9 potential additional case that I found among
10 hospitalizations in the Navy -- I'm sorry, this is
11 complicated data. I mean, this has been discussed for
12 30 years, so I want to make sure I'm clear on this,
13 okay?

14 (Slide)

15 In the Navy, they did not talk about the
16 history or whether the individual knew about this
17 sickle cell disease. Next.

18 (Slide)

19 So here's my observed versus expected in
20 the Navy, again, a high estimate for expected, a low
21 estimate on observed. My calculation of how much that
22 MEPS did not detect is 51 percent, with 95 percent
23 confidence interval, anywhere from 36 to 72 percent.
24 Next.

25 (Slide)

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1 But a little more accurate estimation, how
2 much sickle cell disease there is, really should be
3 based on the prevalence number, the 1 in 375, where we
4 would have expected 75 individuals with sickle cell
5 disease coming into the military, if we did no
6 screening whatsoever.

7 I was able to confirm 47. I think truly
8 there are 6 more. So, using the very bottom line, 53
9 individuals with sickle cell disease out of the 75
10 expected means the MEPS physical was not detecting at
11 least 71 percent. Looking at the 95 percent
12 confidence interval, at least half were not detected,
13 and maybe all. Next.

14 (Slide)

15 This is just a comparison of the four
16 services with black populations for those two years
17 enumerated at the top, the prevalence used, sickle
18 cell disease expected, the sickle cell disease that I
19 would be able to absolutely confirm in the next line,
20 and then the approximate number not identified at MEPS
21 across-the-board. The Navy has the best data, the
22 Navy has the highest percentage that are not
23 identified at MEPS as really a reflection of the
24 verified data, the screening, and the fact that I was
25 able to go through all their records and recode sickle

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1 cell trait as disease, as it should have been. Next.

2 (Slide)

3 So, again, why does Navy have more than
4 the Air Force since they both screen? My contention
5 is that individuals with sickle cell trait can be
6 discharged administratively, they may certainly have
7 disease. I base that on the fact that I was able to
8 show 67 percent of those coded as trait in the Navy
9 actually had sickle cell disease. There's a lot of
10 confusion between trait and disease and what is
11 clinically significant and what is not. Next.

12 (Slide)

13 So I got the latest -- well, the 2001 data
14 directly from LtCdr. MacNamara at Great Lakes Navy
15 Hospital to see what are we really finding. These
16 numbers are not easy to get to, most of is just an
17 estimate based on 8 percent of blacks in the U.S.
18 population who have sickle cell trait, it actually
19 could be as high as 14 percent depending on where the
20 blacks are from originally, and it could be 25-30
21 percent. So, since our population is changing
22 dramatically in the United States, it's difficult to
23 really know what is the magnitude of the problem.

24 (Slide)

25 So you see up there over 50,000 recruit

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1 screening tests were accomplished, 6,000 specifically
2 among the Reserves, for a total of 57,000 screening
3 tests. This was not based on race, so you see a much
4 lower prevalence of sickle cell trait, 1.6 percent of
5 all individuals screened were detected or had a
6 positive sickledex. Actually, they don't use
7 sickledex, so positive solubility test at Great
8 Lakes. From there, you look at the positive sickle
9 cell disease, and you see that 17 had sickle cell
10 disease, which happens to be almost exactly what I
11 found in my EPTS review. The Navy has 17 being
12 discharged every year for sickle cell disease. What I
13 thought most telling is that CBCs are not done. Only
14 2 of those identified with sickle cell disease had
15 hematocrit drawn, both of them were severely anemic.

16 (Slide)

17 So, my observation is the Navy data is
18 actually the most accurate for sickle cell disease and
19 actually also for trait. The initial coding is not
20 accurate, we just went with our evidence found in
21 databases. We have the wrong answer at this point,
22 but given that the electrophoresis is usually fully
23 described on their EPTS records, I felt I was able to
24 get a pretty accurate determination of what the
25 hemoglobinopathy was. Unfortunately, it never gave

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1 the history of sickle cell disease or prior problems,
2 and they also did not document anemia, which is the
3 real reason for EPTS. Air Force and Army data gave me
4 some insight into the history of sickle cell disease
5 prior to service. Next.

6 (Slide)

7 So, what is the total impact to the DOD?
8 All together, we lose about 33 people EPTS for sickle
9 cell disease every year. The reason I leave it as
10 sickle cell disease is that anemia has not been
11 documented in the majority of these individuals,
12 although that is the part of the DODI they are putting
13 EPTS under.

14 There's probably another 4 additional
15 losses for sickle cell disease after 6 months on
16 active duty in the Army. Since the Army does not
17 screen, people who do come in with sickle cell
18 disease, end up in crisis and end up in the hospital.
19 Next.

20 (Slide)

21 I don't know if you're interested in the
22 cost. I had actually tried to gloss over this because
23 I was looking at only active duty. Col. Lee's numbers
24 are probably better in that they actually do about
25 400,000 physicals every year, but the 240,000 are for

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1 the active duty component. The estimates on cost
2 vary, Great Lakes thinks it's only \$1.25 to screen,
3 CHPPM thought it was around \$4 to screen, but testing
4 alone would cost approximately \$1 million. The other
5 costs that need to be considered are the loss of those
6 who have sickle cell trait-positive, who might
7 misunderstand the significance of the test and choose
8 not to come into the service. Individuals who actually
9 still had disease might be told they have trait.
10 There's a lot of confusion. Next.

11 (Slide)

12 There it is -- confusion is common.
13 Incorrect EPTS code, 67 percent were told they had
14 trait actually had disease. At least three recruits
15 in the Army thought they had trait and they also had
16 disease. And hospital discharge diagnosis, I could
17 confirm 60 percent. There's a lot of confusion either
18 way.

19 (Slide)

20 And, again, all sickle cell disease is not
21 clinically significant. Fifty percent of those
22 identified in the Air Force gave no history of having
23 problems, whereas 80 percent in the Army clearly gave
24 a positive history. We do have some individuals with
25 sickle cell SC disease on active duty up to 18 years.

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1 At least two of these that were hospitalized went to
2 a PEB and found fit for duty and returned to active
3 duty.

4 (Slide)

5 So, I guess, in conclusion, it's a very
6 rare disorder currently identified in the Air Force,
7 Marines and Navy by screening at basic training and
8 clinical presentation in the Army. The current
9 screening at MEPS clearly does not identify at least
10 50 percent of those with sickle cell disease, and
11 perhaps more.

12 I think screening is very expensive and it
13 is certainly not a disqualifying position to be sickle
14 cell trait, and uncorrectable anemia is really a true
15 disqualifying condition for military service.

16 Any questions?

17 DR. OSTROFF: Thank you very much. I
18 think we're going to have to move on to the next
19 presentation. Again, I would urge the presenters to
20 try to keep to their allotted time. I hate to try to
21 cut off the presentations, but the Board really does
22 need time to have discussions.

23 We'll do this presentation and then we're
24 going to break for lunch, and we'll have Col. Gardner
25 briefly give his presentation after lunch.

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1 MAJ. NEUHAUSER: Good morning. I'm Maj.
2 Neuhauser, I'm at Brooks Air Force Base. I work on
3 recruits in collaboration with Lackland Air Force
4 Base. I've been doing this for the last several
5 years. And I'd like to share with you some of my
6 data. Next slide, please.

7 (Slide)

8 I'll do a brief review of sickle cell
9 trait screening. I will show you some mortality data
10 that I've collected, as well as sickle cell trait data
11 from Lackland. Next slide.

12 (Slide)

13 This is a review. You've heard this from
14 several different briefings now. In the Air Force we
15 screen all recruits upon entry into basic training.
16 For U.S. Air Force recruits, basic training lasts six
17 weeks. They are screened within the first week of
18 arrival, first with sickle prep, followed by
19 hemoglobin electrophoresis.

20 Those that are identified with sickle cell
21 disease are discharged, that is existed prior to
22 service. And then the rest, those that are sickle
23 cell trait positive, receive a preventive medicine
24 screening. And, basically, during that preventive
25 medicine briefing, they are told about different

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1 complications and risk that they have, and then they
2 are given the option to get out. The exit option for
3 the Air Force began in 1999. Next slide, please.

4 (Slide)

5 Now I'm going to shift gears and show you
6 some of my mortality data. I did a retrospective
7 review of all recruit deaths since 1956, and I chose
8 1956 basically because before that time there was
9 basic training in the Air Force that were done at
10 other sites. So, from 1956 forward all basic training
11 was occurring at Lackland Air Force Base.

12 I went through all of the autopsy records
13 and I pulled those individuals that were recruits at
14 the time of their deaths, and what this slide is
15 showing you is the count of deaths over the years
16 since 1956. There have been anywhere from 0 to 5
17 deaths in any given year, with an average of 1.8
18 deaths per year over the 45-year time span. The last
19 two deaths that you see actually occurred after I
20 completed my study in 1996.

21 The stars that you see are individuals
22 that were identified in the autopsy record as being
23 sickle cell trait positive. And over this 45 year
24 period, there were 7 deaths that we believe were
25 sickle cell trait positive. The Exit Out policy,

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1 again, began in 1996. Next slide, please.

2 (Slide)

3 This slide summarizes the causes of death
4 in the 87 recruits that died in this 45-year period.
5 Most, as you expect, were natural and those that were
6 natural were either cardiac or infectious disease
7 related.

8 There were only 36 individuals that I knew
9 the date of training at the time of their demise, and
10 25 of those, or roughly 70 percent, died within the
11 first three weeks of basic training. Next slide,
12 please.

13 (Slide)

14 There were 7 recruits that were identified
15 in the autopsy record as having a positive sickle cell
16 trait. All of these individuals were black males
17 between the ages of 18 and 22 years of age. Two of
18 these individuals died from unrelated causes to sickle
19 cell trait. One had meningococemia and the other
20 died actually by suicide, so I took those out. Next
21 slide, please.

22 (Slide)

23 Of the remaining 5 individuals, all of
24 them died and their deaths were temporally related to
25 exercise, and most of those occurred during the

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1 warmest time of the year, and in San Antonio it gets
2 really hot.

3 You heard various lectures about the
4 relative risk for individuals that are sickle cell
5 trait positive. In the literature, there has been
6 reported 28-40 times higher risk for individuals with
7 sickle cell trait dying versus those that are not.

8 In my study, even though it was a
9 retrospective review, I wanted to see if I could
10 calculate a relative risk as well, so what I did was I
11 used numbers that were published in the literature, so
12 I assumed the 8 percent of blacks are positive versus
13 sickle cell trait in .08 percent with caucasian, and
14 then I calculated a relative risk, and I got a risk
15 that was similar to that that was published in the
16 literature, and I calculated that for a 24 times
17 higher risk. Next slide, please.

18 (Slide)

19 Now I'm going to shift gears and I'm going
20 to share with you some data that we've collected at
21 Lackland. I mentioned that we started the Exit Out
22 policy in 1996. What this slide is showing is the
23 number of individuals that are sickle cell trait
24 positive or have sickle cell disease, the rate per
25 thousand since October of 2001. The data prior to that

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1 wasn't very good, so I did not include it.

2 Basically, the average rate, there's been
3 every week they identified 3 positive individuals for
4 every 1,000 tested, and over this same time period
5 from October 2001 to April 2002, 3 individuals had
6 sickle cell disease so they were discharged and not
7 given the Exit Out option. Next slide, please.

8 (Slide)

9 Then I wanted to look at retention of
10 individuals after the preventive medicine counseling,
11 and basically of those individuals that were S
12 positive, 90 percent of them decided to remain on
13 active duty. So, there have been since 1996 when the
14 Exit Out policy began, there have been zero deaths in
15 basic training due to sickle cell trait. Next slide,
16 please.

17 (Slide)

18 And now I'll just basically make a few
19 concluding remarks. There have been very few active
20 duty deaths in the Air Force in any given year. Of
21 those that I know the date of their demise during
22 training, most of those deaths occurred during the
23 first three weeks of training.

24 There have been very few sickle cell trait
25 related deaths, 7 out of the 87 deaths over the 45-

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1 year period were identified as sickle cell trait
2 positive. And of those individuals, all of the deaths
3 were temporarily related to -- 5, not including the 2
4 that were not related -- were related to exercise, and
5 the relative risks were high.

6 At Lackland again, basically 3 positive
7 for sickle cell trait individuals for every 1,000
8 tested, and most of those decided to remain on active
9 duty. And that concludes my presentation. I'll take
10 any questions.

11 DR. OSTROFF: Thank you. You get the
12 award for the most concise presentation.

13 (Laughter and applause.)

14 We have time for one or two questions
15 before we break for lunch, if anyone on the Board has
16 any questions. Dr. Haywood?

17 DR. HAYWOOD: Were any of the deaths
18 related to flight status?

19 MAJ. NEUHAUSER: None of the recruits are
20 on flight status.

21 DR. PIERCE GARDNER: I wonder about
22 splenomeglia (phonetic). In SC disease and
23 S.thalassemia, splenomeglia is fairly common. Can you
24 proceed through an accession process and go to camp
25 with splenomeglia, and I wondered if any of the

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1 problem is emerging in camp with splenic rupture or
2 difficulties during the strenuous process.

3 MAJ. NEUHAUSER: I believe individuals
4 that have splenomeglia are disqualified at MEP.

5 LtCOL. GIBSON: Just a couple of
6 questions. When are the recruits told of their
7 hemoglobin S status during basic training, what day of
8 training? And then what definition are you using for
9 sickle cell disease to disqualify those individuals
10 who are diagnosed as such?

11 MAJ. NEUHAUSER: They are told of their
12 status within the first week of basic training. The
13 second part of the question actually I'm not really
14 sure what is the definition that is used for sickle
15 cell disease.

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

17 QUESTION: Do recruits go through a
18 physical fitness test thrown at them the first day
19 like they do in the other services?

20 MAJ. NEUHAUSER: Yes, they do, because
21 that was used to determine -- in the Air Force basic
22 training, what they do is they do a fitness test, and
23 then individuals train with individuals that are
24 similar in fitness, to help reduce injuries.

25 QUESTION: The fitness is running a mile,

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1 or --

2 MAJ. NEUHAUSER: A mile and a half.

3 QUESTION: Before they get the results of
4 the test?

5 MAJ. NEUHAUSER: No. Actually -- well,
6 they occur basically concurrently. This is all
7 happening during their first week of training.

8 DR. OSTROFF: It's a stressful week.
9 Okay. Let's break for lunch. I think Rick has some
10 comments about lunch.

11 LtCOL. RIDDLE: What we're going to do,
12 we're going to have a working lunch for the Board
13 members, the Preventive Medicine Consultants, and the
14 speakers this morning, and Dr. Peterson and Dr.
15 Gardner for this afternoon, so that we can discuss the
16 topics on the table. And so the lunch is going to be
17 outside on the patio, and just go right outside the
18 door right next to the Reservation Desk, and then
19 right outside on the patio, and it's a buffet lunch,
20 and we'll show up here again at 1:00 o'clock.

21 (Whereupon, at 12:05 p.m., the luncheon
22 recess was taken.)

23

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

25 (1:05 p.m.)

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1 DR. OSTROFF: The next presenter is Col.
2 Gardner.

3 COL. GARDNER: Thank you. I first started
4 this stuff when I started working with Dr. Kark in
5 1998, and have been all over since. A lot of what I
6 wanted to go over has been adequately covered by Dr.
7 Kark and Dr. Corcoran, so we're going to move forward
8 quickly. In fact, the next slide is No. 11 in your
9 handout.

10 VOICE: Round of applause.

11 (Applause.)

12 (Slide)

13 COL. GARDNER: In 1996, the Deputy
14 Secretary of Defense put out a memo, the last policy
15 memo, which said that hemoglobin S screen for sickle
16 cell trait could not be mandated for military
17 accessions. And the services took that wording to
18 imply that that means they don't have to do it, but
19 they can if they want to, and as you can see on this
20 slide -- this is from Terry Lee -- four of the five
21 services do continue to screen for sickle cell trait.

22 They kind of ignored the last two
23 paragraphs, the second paragraph said we will continue
24 research, and as far as I know there's been no
25 research funds allocated. And the third paragraph

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1 said hemoglobin S testing for sickle cell trait shall
2 not be contacted at accession. Let's go to the next
3 slide, and this is where the new material starts.

4 (Slide)

5 The first four columns are similar to what
6 Dr. Kark showed you, and these are the total number of
7 sickle cell trait deaths in recruits in all military
8 services, all DOD military services, and we've since
9 then refined that a couple of those deaths as being
10 sickle cell disease, and it was during advanced
11 training instead of basic training. And the only
12 reason we have these data is because we're free again,
13 we've been able to get a doctoral student, Stephanie
14 Scoville, to agree to do her dissertation on recruit
15 deaths for the past 25 years in the military, and
16 these data come from her.

17 There are about 10 -- here we have 26
18 sickle cell trait deaths in 25 years in service, so we
19 only have an average of 1 a year, but half of those
20 occurred in the first five years, so we've done a lot
21 better since then. The first 5 years is the data
22 which established the 30-fold excess risk.

23 The next ten years are the data which Dr.
24 Kark described as the intervention time period, and
25 you see the Army, Air Force and Marine Corps have no

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1 deaths during that period, even though the Air Force,
2 Marine Corps and the Navy continued to screen. The
3 Navy continued to have sickle cell trait deaths. And
4 then since 1991, all services have had deaths due to
5 sickle cell trait. The Marine Corps death was last
6 month, and they are still trying to confirm the sickle
7 cell trait status of that individual. Our sense of
8 looking at that is that what's changed is that the
9 services have put more and more emphasis on running
10 and physical conditioning during basic training, and
11 the big furor that began in 1995 with the 3 Air Force
12 recruit deaths with sickle cell trait, after they'd
13 gone more than ten years with none, suddenly they had
14 3 in two years, and that led to lots of things you
15 heard this morning.

16 As I reviewed what they did, it turns out
17 the year before that the Air Force changed their basic
18 training. Prior to that period, they were running
19 people a total of 10-15 miles in six weeks, and after
20 that period they were running them 60-80 miles in six
21 weeks, and it very simply said now they're pushing
22 people hard enough to generate enough heat and
23 exercise stress to create a situation where you will
24 get deaths. Those 26 deaths, there were 2 sickle cell
25 disease deaths in recruits, in addition to those.

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1 Next slide.

2 (Slide)

3 Of those 26 deaths, we got the hemoglobin
4 S concentration of all 7, and they all came between 36
5 and 42 percent hemoglobin. We got the distribution of
6 training duration. They occurred mostly in the first
7 week and the third week, and the fifth week -- third
8 and fourth week, and so they actually were split quite
9 evenly between the three two-week periods across basic
10 training. Of course, the number of recruits beyond
11 six weeks is lower because the Air Force program is
12 six weeks and the Army and Navy are eight weeks, and
13 the Marine program is 12 weeks. Next slide.

14 (Slide)

15 I tried from the DOD Medical Mortality
16 Registry to identify other deaths related to sickle
17 cell trait, and, again, we're dealing with extremely
18 inadequate data. We just searched for sickle cell
19 through the database since 1980 deaths about how much
20 is a year's average, and we found 37 deaths from 1984
21 where it listed sickle cell in there, which 4 or 5 of
22 those were sickle cell disease and the rest were
23 sickle cell trait, as far as we could tell. Eleven of
24 them were recruits that we've already counted, but
25 there's actually 20 that we've already counted, and

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1 the other 9 were in the database but they weren't in
2 the database in such a way that we could identify them
3 as having sickle cell trait.

4 Of the 26 nonrecruits, 11 were definitely
5 exercise related, and the rest had a pretty random
6 distribution of cause, and you notice that there are
7 only 2 traumatic deaths, 1 suicide and 1 fall, which
8 was in the alcohol related category. And we know that
9 75 percent of the military deaths are trauma, and so
10 that simply tells you that our database is not picking
11 up those people with traumatic death that have sickle
12 cell trait. Next slide.

13 (Slide)

14 Again, with free labor, we tried to --
15 using students, we tried to get a better handle on
16 exercise related deaths in the military, and we got --
17 tried to collect four years worth of exercise related
18 deaths. It's extremely difficult to do because
19 there's no ICD code for exercise, and the causes vary
20 all over the place, but the Army at least, since 1966,
21 started an extra code in the office, trying to
22 mention whether it's PT related, but their cause is
23 not due to PT. So, anyway, we think we have pretty
24 good data from the Army in terms of identifying all
25 exercise related deaths, especially during 1988 and

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1 1999. And we got as many as we could find from the
2 other services, including searching the Air Force
3 Mortality Registry, and so we came up with 215. Next
4 slide.

5 (Slide)

6 And what this side shows is the
7 distribution of the type of exercise leading to death,
8 at least led to the fatal event, and you see that the
9 majority of these are related to runs, all of the PFT,
10 Physical Fitness Test deaths, were during the run
11 phase, and all the red ones are due to PT which is
12 almost always running. And, in fact, the Army has 7
13 or 8 deaths per year during the PT test, and then
14 another 25 or so a year other PT related deaths. Next
15 slide.

16 (Slide)

17 I'm going to skip that.

18 (Slide)

19 Here you look at the cause, the medical
20 cause of death in those under 35, and you see that the
21 blue is the Other/Coronary heart disease, which is
22 those with pre-existing heart disease -- that is
23 anomalous coronary arteries or atherotropic
24 cardiomyopathy or so on. And then the ISD is the
25 idiopathic sudden deaths, those are presumably cardiac

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1 arrhythmias and sudden death where there's no anatomic
2 or historical findings. So nearly half would be
3 recruits. And still even under 35 -- in fact, we have
4 them as low as 22 with coronary artery disease,
5 atherosclerotic coronary artery disease. At 30, it
6 really picks up, the coronary artery disease really
7 picks up and skyrockets above 35 as you'll see in the
8 next slide.

9 (Slide)

10 In that case, the atherosclerotic coronary
11 disease, and the red is the idiopathic sudden death
12 which, in this case, are primarily coronary heart
13 disease whereas with the younger cases they are
14 primarily presumably noncoronary artery disease
15 related. So the picture of exercise related death is
16 dramatically different in the under-30 versus the
17 over-35 range whereas the over-30 or over-35 group are
18 mostly coronary heart disease. Next slide.

19 (Slide)

20 We really felt comfortable calculating
21 rates -- I'm sorry you can't see that well, it's in
22 your handouts, though, on the top of page 4, which is
23 the last page. In fact, that might even be the last
24 slide. The rate of 66 per 100,000 people in total
25 deaths is very low compared to the civilian rates in

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1 corresponding age groups. The rate in exertion-
2 related deaths of 4.3 is probably high compared to the
3 civilian age groups, although it's difficult to find
4 good data to compare to. Dr. Kark pointed out the
5 Rhode Island study, which is in older people. The
6 rates there I think were 7 -- or 2.5, and we've got 4
7 and here we're still primarily a young population. So
8 being in the military at least during these times is
9 less risky in terms of death than not being in the
10 military in the United States with respect to total
11 deaths, but not with respect to exercise related
12 deaths.

13 I'm going to end. I have other comments
14 related to why we should or shouldn't screen for
15 sickle cell trait. I guess my summary is in the last
16 slide, which is not there. It basically is that it
17 appears that the excess exercise related death risk in
18 sickle cell trait is primarily limited to those who
19 are severely overexercised contrary to sensible
20 training guidelines. And that depends on the context
21 of both the medical and physical condition of the
22 individual and the environmental and other
23 circumstances.

24 And those deaths can be prevented by
25 appropriately related exercise to the circumstances of

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1 both the individual and the environment. And the
2 treatment is the same. How you deal with it is the
3 same. And the Safety Centers want us to screen
4 everyone, so I see that as a way for them to call this
5 a medical problem instead of a training problem. So
6 I'll end there and take your questions.

7 DR. OSTROFF: Thank you very much. We
8 have one more presentation, and that is from Dr.
9 Peterson. Dr. Peterson is from NIH, from the National
10 Heart, Lung and Blood Institute, and he is also the
11 Executive Secretary for the NIH Sickle Cell Disease
12 Advisory Committee, and we certainly appreciate your
13 taking the time to speak with us.

14 DR. PETERSON: My pleasure. It's good to
15 be here. I'm the Director of the Division of Blood
16 Diseases and Resources at the National Heart, Lung and
17 Blood Institute. Next slide. It actually is the 30th
18 anniversary since blood was added to the Heart, Lung
19 and Blood Institute. In 1972, which is a familiar
20 date now after all these presentations, there was
21 quite a problem with sickle cell disease. In fact,
22 legislation was passed empowering the National Heart,
23 Lung and Blood Institute to charge research into what
24 the blood supplies and problems with the blood and
25 some other issues, and sickle cell disease, and there

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1 was also a great deal of turmoil in the area of today
2 screening at that time, and sickle cell disease, of
3 course, was the index disease of the '70s. You can
4 see that the more things change, the more they stay
5 the same, in a sense. Next slide, please.

6 (Slide)

7 I'll try and keep it very simple here.
8 The Sickle Cell Disease Advisory Committee was formed
9 about that time, and as one of two Advisory Committees
10 to the National Heart, Lung and Blood Institute. It
11 is difficult to get advisory committees approved and
12 put together, and NHLBI has two and this is one of
13 them. It is comprised of individuals with expertise
14 in the areas of sickle cell disease more from the
15 basic and clinical levels, but also it includes
16 representatives of public interest organizations,
17 community programs, for example, the Sickle Cell
18 Disease Association of America is represented, and
19 members of the patient community. So, it's a fairly
20 broad-based advisory forum.

21 We also have agencies represented that
22 involve health care delivery, including the CDC, HRSA
23 FDA, VA, and most recently the Department of the Army.

24 Next slide.

25 (Slide)

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1 We meet normally two times a year, and
2 other times as needed. The meetings generally include
3 a couple of scientific presentations, a program
4 review, and program management efforts, but also issue
5 of public interest. Next slide.

6 (Slide)

7 I just thought I'd get into two quick
8 definitions. In the quick guide to sickle issues,
9 sickle cell disease or sickle cell anemia generally
10 involves greater than 50 percent hemoglobin S,
11 includes hemoglobin S/S and many S/beta thals. And
12 then sickle cell trait includes one alpha and one beta
13 globin gene, so usually you're dealing with less than
14 40 percent hemoglobin S in these things. Now, where
15 this gets muddled, the hematologists who are really
16 sitting here telling you you're scholars and you want
17 to obsess about these things, is that there are really
18 multiple hypostatic or modifier genes that impact the
19 phenotype of the hemoglobin S gene at times. And this
20 has been one of the major conundrums in people
21 basically predicting who is going to get sick, and I
22 think this is part of your problem here, is that you
23 can have people with hemoglobin SS who live quite
24 well, and you could have people with varying amounts
25 of hemoglobin SA who, because of other modifier genes,

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1 can be quite ill and, although they are rare, they are
2 enough to provide that limitability to whatever policy
3 decision you decide to take.

4 The other issue, of course, is amongst
5 hematologists, if you get two of them together, they'd
6 probably give three definitions of anemia, and we can
7 get into that in the discussion if you'd like. Next
8 slide.

9 (Slide)

10 Now we were asked actually by some of the
11 members of the public interest organizations to look
12 into the issue of sickle cell trait and the military
13 in 1999, in part because of the history that you've
14 heard about today. So we had a presentation by John
15 Kark who is one of the members of the committee. We
16 contacted the Army Surgeon General regarding input in
17 to the committee, and that was obligated and accepted
18 by Robert Sheffler from the Department of the Army.
19 Next slide.

20 (Slide)

21 To make a long story short, after several
22 meetings and a number of satellite meetings as well,
23 the following motion was approved. I'll just read it.

24 "Measures to prevent exertional heat illness
25 eliminate the disparity in sudden death during

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1 military basic training between persons with sickle
2 cell trait and persons without sickle cell trait and
3 reduce the risk of death in both groups." Next slide.

4 (Slide)

5 So, all military services should
6 systematically implement measures to prevent
7 exertional heat illness and monitor compliance with
8 such measures. Well, it's kind of a no-brainer. That
9 was the easy part of it. Next slide.

10 (Slide)

11 This group came up with a resounding
12 recommendation that routine screening of recruits for
13 sickle cell trait is unnecessary, potentially
14 stigmatizing and discriminatory, and should be
15 discontinued. Next slide.

16 (Slide)

17 Now, here's the Air Force -- we're going
18 to make suspension valid. Screening for sickle cell
19 trait may -- may -- be appropriate prior to
20 participation in selected activities that involve
21 predictable exposure to environmental hypoxia. In
22 such circumstances, screening should be universal and
23 education and counseling should be provided to persons
24 identified as hemoglobinopathy carriers, which once
25 you open that bag, you really have to follow it up.

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1 Next slide.

2 Well, that's a quick summary of what took
3 several years in the delivery, and I think you can
4 understand our committee was somewhat restricted with
5 information as well, but as we tried to sort this
6 through and make recommendations that were consistent
7 with the scientific evidence and put into practice,
8 this is what it came up with.

9 DR. OSTROFF: Thank you very much. Let me
10 ask the Board if there are questions for Dr. Gardner
11 or Dr. Peterson.

12 DR. SHANAHAN: Dennis Shanahan. The
13 question that's always been in my mind is essentially
14 the last one that was brought up, and that has to do
15 with incidence of problems in operational settings.
16 Training, at least in theory, we have some reasonable
17 control over, but for the groups that involve
18 aviation, diving, and to a large extent, special
19 operations, they are frequently subjected to hypoxic
20 conditions and less frequently to dehydrating
21 circumstances. Afghanistan is a good case in point,
22 where operations were carried out for extended periods
23 above 10,000 feet.

24 I wonder if anybody has any data,
25 anecdotally or otherwise, of problems that could be

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1 related to sickle cell trait in any of those settings,
2 operationally, not in training.

3 DR. PETERSON: There are some studies that
4 have been done. There were a set of them, exercise
5 studies that were done -- and I'm blacking out a name,
6 but it's a lady, a physician in Texas, at El Paso, in
7 which she studied people who were very well hydrated
8 and in a very good state of health, and exercised them
9 on bicycles with arm weights and legs. That simulated
10 altitudes that were very high. At one point in her
11 experiment, people had 12 percent sickling. And she
12 did not encounter any deaths (inaudible) whereas to
13 see a sickle trait death, you're usually talking about
14 looking at 3,000 to 8,000 people. And there was no
15 environmental heat stress or dehydration involved.

16 We did studies that aren't fully
17 published, we published some articles. We did some
18 studies at Walter Reed on people who were candidates
19 for the helicopter pilots and therefore might spend a
20 lot of time at altitude without pressurization. And
21 we simulated a test they go through at 25,000 to
22 40,000 foot exposure, and we also had a longer
23 exposure at I think at something like 18,000 feet for
24 30 minutes which I consider a worst exposure. We
25 measured a lot of climbers who were unable to show any

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1 measurable hemolysis (inaudible) didn't show any
2 change in dissolution during exposure. We did find
3 some sickling taking place in venous blood samples
4 that we drew.

5 DR. SHANAHAN: That was with trait?

6 DR. PETERSON: Yes. And the most
7 interesting findings were that if you underwent a lung
8 scan, tissue scan, where the dye is administered while
9 they are in the chamber, and about 50 percent -- I
10 think my memory is there were 14 people and 7 of them
11 showed very uneven multiprofusion scans afterward.
12 Also, you could see in -- and those were primarily the
13 same people, you could see a large increment in levels
14 that was not detectable when they left the chamber, or
15 it bounced up and down after they left the chamber,
16 but it was very reliable when they were in the
17 chamber. And what I thought was going on was that
18 with deoxygenation, there was some impact of rigid
19 cells in small vessels of the pulmonary circulation,
20 and that was leading to irritation and causing
21 (inaudible). The abnormal scans persisted. It looked
22 like they persisted for a few days and were gone by a
23 week, so that all the scans (inaudible). You couldn't
24 measure any (inaudible) unless you planned for it, so
25 they're clinically not significant. You could see

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1 some subclinical changes occurring in the lungs during
2 exposures, and we didn't find any renal problems or
3 hematuria or splenic problems, or any kind of other
4 connectable changes. And that, to my knowledge, is
5 the most comprehensive study of short-term altitude
6 exposure.

7 No one's done a survey that I know of, of
8 a lot of people at high altitudes. Perhaps the most
9 interesting studies there are there have been studies
10 of some runners in Cameroon, who do sort of a marathon
11 where they go up quite high altitude, maybe 12,000
12 feet, and something like hundreds of people do that,
13 and they haven't had any episodes of symptomatic
14 splenic infarct, or bleeding in the kidney with that.

15 We do get sporadic cases of splenic
16 infarction with either altitude or exercise in the
17 military. That's fairly unusual, but there are
18 occasional cases. I haven't heard of any occurring in
19 military operations, I've only heard of them occurring
20 in training events involving heavy exercise or in
21 flight, unpressurized or partly pressurized.

22 DR. SHANAHAN: That AFIP study, was that
23 the one published in Aerospace Medicine?

24 DR. PETERSON: Part of it was published in
25 that, part of it is unpublished.

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1 DR. OSTROFF: Other questions?

2 DR. ATKINS: I have to confess I'm having
3 trouble keeping all the data that's been presented
4 straight in my head. I guess what I took away from it
5 is that there had been a lot of progress done in
6 preventing exercise related deaths, and specifically
7 those related to sickle cell trait, and that had been
8 across all services, whether screening or not
9 screening, and then all of a sudden we got these 4
10 deaths in the Army. And it probably was presented,
11 but I've forgotten it, what happened there, and if we
12 propose that we can continue to focus on general
13 measures to reduce exercise related deaths without
14 screening. How can we reassure people that we're not
15 going to have another death -- more deaths?

16 COL. GARDNER: Well, since 1991 they had
17 the 3 deaths in two years in the Air Force, which
18 followed their implementation of a pretty extensive
19 running program. And then the Navy also continued to
20 have a few deaths. And then the Army -- in the last
21 five years, for some reason, only the Army has had the
22 deaths.

23 My approach to this is that these should
24 be considered sentinel events, like the canary in the
25 mine, that when you get a sickle cell trait death,

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1 then you need to go back and look at how you are
2 conducting training and re-evaluate how hard are we
3 pushing people and how appropriately are we managing
4 people.

5 Now, for some of the Special Forces and
6 other situations where they really do push you to your
7 limit and beyond, sickle cell trait might seriously be
8 a big issue, but for routine basic training, I don't
9 think that it should be a big issue.

10 DR. ATKINS: But for those 4 deaths, were
11 they -- I mean, if you went back and looked at them,
12 were they sort of violations of a protocol for
13 reducing exercise related deaths, or do they look like
14 unpredictable?

15 COL. GARDNER: They were all during runs.

16 VOICE: Of course, there were actually
17 more than 4 deaths, as has been pointed by Mr. Lee in
18 his earlier stuff. All people who died were not
19 exactly overly stressed. Yes, some of them were
20 recruits, 2 of them were sergeants, 1 was a captain,
21 all of them were going out and doing routine PT tests.
22 Anybody wearing a green suit in here should be able
23 to go out and do a PT test any day, so they should not
24 have had a problem. None of them were on profile.
25 All of them who died had not run or done anything very

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1 extremely physical for any great distance or length of
2 time at the time they died. So, when these
3 individuals have died, it hasn't been a result of
4 massive exercise, in these cases.

5 COL. DeFRAITES: This is Bob DeFraités.
6 I'm with the Army Surgeon General's Office. The
7 perspective of the Surgeon General's Office on this
8 issue has been basically the clustering of these cases
9 sort of brought this issue back on the table for as
10 far as Army policy is concerned because, as we've said
11 here, the policy of the Army is not to screen. That's
12 the Army's perception to basic training. And these
13 cases in the Summer of 2000 sort of brought this issue
14 back up. I guess I'm getting a little confused about
15 whether you're talking about sickle cell disease
16 screening or sickle cell trait, or both. I'm even a
17 little confused myself, but in terms of the sickle
18 cell trait, the approach that the Army Surgeon
19 General's Office in sickle cell trait is we've been
20 looking at the policy. The issue from the Surgeon
21 General's perspective is based on studies that show
22 that there is an absolute and a relative increased
23 risk of death to recruits based on a strictly
24 military-specific requirement to do basic training,
25 there's an initiative we haven't talked about here.

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1 What is the duty of the Army to warn people that they
2 might be at increased risk?

3 In terms of the situations under which
4 these deaths occurred, it's hard to say what the
5 individual circumstances were. In each case, they were
6 fairly supervised -- now, you know, you not only look
7 at details of how long did it take for suscitation to
8 start, what conditions were existing at the time of
9 the death. We certainly have been looking at the
10 Army's heat intervention program across-the-board,
11 there's a lot of variability from place to place and
12 situation to situation. Certainly, these performance
13 runs, like a 12-mile road march or a performance run
14 under time event, high performance event like a 12-
15 mile road march under time, and other timed runs are
16 very stressful, and that seems to be at least where
17 the heat injuries and heat illnesses seem to be
18 clustered. What relationship those have to the sickle
19 cell disease deaths is unclear to me. Is it Col.
20 Nobak?

21 LtCOL. NOBAK: Yes, sir, it is.

22 COL. DeFRAITES: I know you by name, but
23 not by face. He's the Safety Center --

24 LtCOL. NOBAK: Guilty as charged.

25 COL. DeFRAITES: You should have

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1 introduced yourself, but I will.

2 LtCOL. NOBAK: I did, but I think I was
3 muffled.

4 COL. DeFRAITES: I'm from the Surgeon
5 General's Office, but he's the Army Safety Center.
6 So, the Safety Chiefs' concern about this has been
7 that the discrepancies in service policies and which,
8 if any, of these make sense in terms of protecting the
9 health of the individuals. So that's where the Army
10 Surgeon is right now, he's not committed to a
11 particular policy, but he's leaning toward -- he's
12 concerned about the duty to warn somebody about some
13 condition that may pre-expose you to death, that's one
14 we need to warn. Now, if he knows, I think we all
15 understand that just screening alone does not save
16 anybody's life, it's what you do with that information
17 and what else we need to do to protect -- there's a
18 lot of issues here that are not clear that we're
19 separating them out, at least -- they're all kind of
20 getting mixed up together, but at least from the Army
21 Surgeon General's perspective, that's kind of where
22 we're approaching this issue. Now, see, Col. Urbauer
23 from the Army Secretariat, they have their own
24 opinion, too.

25 COL. URBAUER: I'm Col. Urbauer. I'm in

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1 the Office of the Assistant Secretary of the Army for
2 Manpower and Reserve Affairs. And I'm going to give
3 you an anecdote. This is not from me. About a year
4 and a half, this subject was brought to the Army
5 Secretariat for discussion, and our Sergeant Major, an
6 Infantry of some renown, asked a question at that time
7 -- "Why are we talking about this? When I was a drill
8 instructor, we didn't have deaths." He says, Have we
9 forgotten how to prevent deaths in the training
10 environment?" And we know that in the military people
11 move, and I believe Dr. Kark sensitized the entire
12 Department of Defense during the time that he was
13 conducting his experiment and visited all the training
14 bases. Those folks, that cadre, moved through. It
15 was a new group of people. They don't remember the
16 lessons. And not to put too fine a melodramatic point
17 on it, I can tell you that that Sergeant Major died in
18 the Pentagon on September 11th. That may have been
19 his final contribution.

20 DR. OSTROFF: Thank you. I think there
21 was --

22 DR. NESS: I just have a question for the
23 Air Force. When individuals are identified as having
24 sickle cell trait in the Air Force currently, what is
25 the intervention at that point? What then happens to,

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1 in fact, prevent those individuals from suffering the
2 adverse consequences of training?

3 MAJ. NEUHAUSER: Could you repeat the
4 question, I couldn't hear very well.

5 DR. NESS: Simply when individuals are
6 identified in the Air Force with sickle cell trait and
7 decide to stay within the training environment, how do
8 you at that point intervene to prevent adverse
9 consequences from occurring?

10 MAJ. NEUHAUSER: Well, back when I
11 initiated my study, there were several policy changes
12 that occurred at Lackland in an attempt to improve any
13 recruit during basic training. And things that
14 happened, for one thing, called the "Buddy System",
15 where recruits watch each other and TIs watch each
16 other. The other thing that happened was that
17 recruits were required to carry two canteens filled
18 with water all the time. During mealtime, especially
19 during hot weather, they're required to drink 3 drinks
20 of noncarbonated beverages, and all of those new
21 policies that they instituted are for all the
22 recruits, not just those that are sickle cell trait
23 positive. Specifically, for those that are sickle
24 cell trait positive, intervention basically has been a
25 warning to the recruit that they are at higher risk

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1 and they really do need to watch their hydration, and
2 get into them liquids if they can. Does that answer
3 your question?

4 DR. NESS: Yes.

5 CAPT. SMITH: Jack Smith, from Health
6 Affairs. Just one comment that definitely comes on
7 the anecdotal side of the ledger. In a previous life,
8 I was out in Japan where climbing Mt. Fuji qualified
9 as recreational activity. And in looking back over
10 about a five-year period, we discovered that we had on
11 average 1 episode of sickle trait related problems
12 that came to our attention in the health care system,
13 several splenic infarctions, and a couple of crises in
14 people with sickle trait. And that's not heat
15 related, but would be probably dehydration and
16 altitude related. It's 12,365 feet, give or take.

17 DR. SHANAHAN; The reason I ask the
18 question is because I've heard of a number of these
19 anecdotal incidents, too, but I've never seen anything
20 documented. I think one thing that was just kind of
21 embellish this point, I think that what Dr. Kark
22 pointed out was very interesting, and that was that we
23 tend to think of dehydration as a very short, temporal
24 issue, you know, that you're fine and hen you do your
25 exercise and get dehydrated during the day, over a

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1 period of hours, several hours, and then you have
2 problems. But I think your data was very interesting
3 in showing that it might be cumulative, and that could
4 be a very key point in terms of what goes on under
5 these situations, is that we may have several days'
6 worth of cumulative dehydration, and particularly the
7 early morning run. Most of us who have been in the
8 military know you get up and you go out on that run.
9 There's very little opportunity to hydrate, even under
10 today's circumstances. So, it may very well be that
11 we're looking at a much more insidious situation than
12 immediately meets the eye. So, I just thought I'd
13 throw that in and let Dr. Kark comment on that, too.

14 DR. KARK: We noticed that a lot of the
15 hospitalizations for heat illness at Parris Island
16 clustered around major events that were more demanding
17 than other things, and we decided that maybe one way
18 to make those safer was to look for dehydration the
19 morning of the event, and came up with the idea of
20 looking at the urine color. It seemed to complicated
21 to measure during specific gravity, so we made up a
22 crude color chart and some estimate of how much water
23 to give people. And the drill sergeant just used a
24 clear cup so he could see the color, and he had all
25 the recruits pass in the head and showed them their

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1 urine. And anyone whose urine was darker, they drank
2 some extra water. And that seemed to have -- we had
3 lower rates of heat illness from the event, and that
4 may have been one of the contributing factors. So,
5 that's a simple-minded approach that can help. I
6 think that a lot of times if you think about what kind
7 of training they're doing, the more heroic demanding
8 events that are competitive are the times, especially
9 if they fall in hot weather, where you're going to get
10 in trouble. And you can do some extra things like
11 looking at urine color, or some other measure of
12 hydration.

13 DR. KARK: In that particular event, we
14 didn't just do the one urine color that would check,
15 it was also changing the clothing, no helmets. It was
16 making it a timed run at a reasonable pace instead of
17 a competitive run where they're doing their best
18 effort, take off their blouse, their jacket, changes
19 of clothing, changed at a place where they had water,
20 had them walk through the showers. They set up showers
21 so they would walk through the showers half-way
22 through the run, and all the other things that they
23 did and, in fact, reduced the hospitalizations from
24 heat illness in that particular event. And in that
25 situation, the Marines decided they were going to do

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1 something about and they went all out and did
2 everything they could think of, and it worked, and I
3 think that's where the real payoff is.

4 DR. OSTROFF: Dr. Malmud, and then we have
5 two in the back.

6 DR. MALMUD: As someone whose expertise is
7 not in this area, I listened the way a layman would
8 listen. I've heard the anecdote from the Sergeant
9 Major indicating that something has changed, that in
10 his day this didn't occur.

11 We've heard the data that the exercise
12 program has increased from limited marches to longer
13 marches or runs. Now, as someone in his 60s who is
14 very sensitive to bladder emptying, I remember full
15 well when I was in my 20s, and even then I would not
16 drink a large quantity of water if I knew I was going
17 on a long trip. Similarly, I wouldn't drink a large
18 amount of water if I was going on a run because the
19 water that I would have consumed early in the morning
20 would be in my bladder and not in my intravascular
21 volume by the time I was running. So, it may be that
22 these young me are smart enough to know not to drink
23 too much before a prolonged run whereas in the old
24 days they would drink because they knew that the run
25 would be over in a finite period of time and they

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1 could empty their bladders. It's considered a sign of
2 weakness to have to empty your bladder too soon when
3 you're young. It's considered a matter of pride when
4 you're older.

5 (Laughter.)

6 So, it may be that we are applying an
7 enormous amount of scientific expertise to a problem
8 which has been suggested to us by one of the
9 commenters that may, in fact, be that the exercise
10 period is too long and these young men are wisely,
11 from their perspective, not overloading themselves
12 with water, and dehydrating themselves unintentionally
13 and creating crises that would not otherwise occur.

14 Is our armed forces better prepared now by
15 virtue of these longer runs than it was for World War
16 II or Korea? Has that question ever been asked or
17 answered? Has the change in the exercise program had
18 any beneficial effects? We now see that it may have
19 had an unintended consequence, but has it really
20 produced any positive effects other than the pride of
21 the individual who is driving these men for longer and
22 longer periods of exercise?

23 LtCOL. NOBAK: As Dr. Shanahan pointed
24 out, it's not just a question of training, but you've
25 got to look at the operational situation, too. And I

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1 am all for doing anything you can to prevent heat
2 injuries and anything to increase hydration, but in
3 reality it doesn't often happen. A lot of times
4 you'll go someplace, people won't drink the water
5 because they think there's too much chlorine.

6 In Bosnia, we had a situation where people
7 didn't drink the water because they thought it was
8 diuretic, which, of course, it is, but it isn't
9 really. So, getting a soldier who is actually
10 deployed and doing actually much harder work than
11 during a PT test is where the situation might get
12 interesting. For example, you can have a troop, the
13 101st, as was mentioned, in the hills of Afghanistan
14 with an 80-pound pack and whatever water he's got on
15 him. Nobody is going to bring him more water. He's
16 got what he's got. And that's the reality we have to
17 deal with, not just the training issue.

18 So, even though these deaths have showed
19 up in training, we don't know it's going to happen in
20 the operational setting as well.

21 DR. MALMUD: The answer to my question is
22 there is no evidence in the database to indicate that
23 our troops are stronger, more resilient, are better
24 able to deal with prolonged stress as a result of
25 longer runs than they were in the days of the drill

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1 sergeant of the Second World War and the Korean War.
2 It may be that they are, but there's no evidence that
3 they are, is that a valid assumption on my part?

4 COL. GARDNER: Well, in fact, there are a
5 number of studies that have looked at basic training
6 and the amount of running during basic training, and
7 they've shown fairly uniformly that running 2 miles
8 three days a week will give you just a good a score as
9 on the PT test at the end as running 10-15 miles a
10 week. And the injury rates are half. Rather than 40-
11 50 percent of people injured, you're down to 20-30
12 percent of people injured.

13 COL. DeFRAITES: We've looked at the same
14 question from the injury prevention perspective. One
15 thing seems to be clear is that the Army are better
16 runners than they used to be. Whether that's
17 translated into any physiologic event for combat is
18 hard to demonstrate. I don't think we have any data
19 to show that.

20 I will tell you, though, that trying to
21 effect a culture -- running, especially the formation
22 runs and the unit runs and the running itself as a
23 performance, means a lot more to the soldiers than I
24 think we can measure in terms of injury rates, overuse
25 injuries or heat injuries. There's a lot more to it

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1 in terms of the culture and having a soldier, person,
2 push themselves to do things that they didn't think
3 they were able to do and then successfully do it, I
4 think -- I'm guessing because I don't do this kind of
5 work -- but looking at it from an outside perspective,
6 I'm getting from the line that that's what they --
7 there are other things that they look for in this type
8 of endeavor. And that's why I think the Army is going
9 to have a hard time giving up the run just because
10 there's a lot more to it for them than we can
11 determine medically.

12 I want to actually answer an earlier
13 question, it was a question about the Air Force.
14 Speaking for the Army, we've been looking at the other
15 services' policies pretty closely, and we looked at
16 the procedures that Lackland does, and actually they
17 have a fairly well developed information packet both
18 for the training cadre, the administrative unit, when
19 they come into the reception station and get the
20 counseling, that there's actually a lot of material
21 that they give to the medical folks that actually have
22 to counsel these troops about their sickle cell
23 status. And then they actually have to go through a
24 procedure whereby the Airmen themselves, the Airman
25 Recruit, has to make a decision whether he's going to

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1 stay in the Air Force or opt out based on the sickle
2 cell trait. And so there's forms that they have to
3 fill out. So, that seems to be the procedure. Now,
4 once they do that, there's no more indication that
5 that Airman has any other problem different.

6 It's interesting to look at the policy and
7 the practices at Great Lakes Naval Training Station
8 for the Navy and then the Marine Corps, who also do
9 screening. At Great Lakes, I think it's still a
10 procedure that every Navy recruit is screened. Those
11 who are sickle cell trait positive are not given the
12 option to opt out in the Navy. If you have sickle
13 cell disease and there's a hemoglobin S cutoff that
14 determines who's got disease and who's got trait. If
15 you've got trait, you wear a red dogtag like a Medic
16 Alert dogtag, plus when you do your physical training
17 you wear a red flag like a flag football type of thing
18 when you're running. I understand that sickle cell
19 screening -- D6PD training, also if you're D6PD, you
20 also get one of those. What that has to do with
21 exercise, I don't know, but they give them one, too.
22 So that everybody knows that these guys are ones who
23 have sickle cell trait. That's my understanding, and
24 I'd be happy if somebody could correct what we're able
25 to learn. This is a lot of work that Terry Lee did in

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1 helping us research policies of the Army.

2 Marine Corps at Parris Island, after they
3 do their screening, there's no more indication
4 anywhere that this was done, and they don't indicate
5 anything. Out at San Diego, the Marines give a little
6 red dogtag, but they don't have any other external
7 indication that the Marine has a problem. That's my
8 understanding of what's done in each of these
9 situations.

10 DR. OSTROFF: Thank you. Let's take one
11 more.

12 CAPT. FRASER: Jim Fraser, Naval Safety
13 Center Surgeon, Naval Safety Center. Just to confuse
14 the situation a little bit further, I know from my
15 four years at the Naval Safety Center, of 2 deaths in
16 sickle cell trait positive individuals that did not
17 show up on John's data. I don't know how many sickle
18 cell trait positive Navy and Marine Corps really died
19 because we have such a terrible database. I know from
20 personal casualty reports that there are a number of
21 black males have died who have been in a training
22 environment and outside the training environment, and
23 because of the way our instruction is written whereby
24 you don't have to do an investigation if pre-existing
25 medical causes are found, I cannot tell you how many

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1 of these folks were sickle cell trait positive. But I
2 would just offer up based on the two investigations
3 I've had a part in and knowing that the database at
4 the Naval Safety Center is so woefully inadequate that
5 we may not know of all the sickle cell trait deaths
6 that really have occurred, who have been in training
7 environment and outside it.

8 DR. OSTROFF: Thank you. Dr. Engler?

9 COL. ENGLER: I just wanted to throw out
10 in terms of the timing of these events that about
11 three or four years ago that herbal supplements and
12 alternative medicine hit the main street of your
13 supermarkets and your traditional pharmacy. In
14 allergy, we now make a great effort to warn patients
15 who are exercising heavily in regards to allergy over-
16 the-counter medications that may interfere or have
17 some diuretic properties or enhance arrhythmia
18 potential, but we're struck -- and I don't have data -
19 - but at Walter Reed we've started to screen for the
20 people coming into the clinics who is using, and at
21 least 10-15 percent and a little bit more among those
22 who are the most fit because there are these drinks,
23 and some of them have in them herbals that have
24 activity that could be diuretic in property, and
25 because of the timing, I was wondering if when you do

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1 these death investigations and you're not going to
2 find it in a pharmacy database, you're not going to
3 find it, but maybe talking to people who know that
4 person, are they using supplements that are touted to
5 enhance their physical performance, but that may
6 interfere with their fluid balance and actually have
7 diuretic properties or mineral corticoid properties.

8 LtCOL. NOBAK: In the deaths that we
9 looked at at the Army Safety Center, there was only
10 one that we were able to confirm had been taking
11 ephedra (phonetic) prior. From toxicology reports on
12 the other ones, the information we do have, all the
13 toxicology was negative, and the AFIP --

14 COL. ENGLER: The herbals are incredibly
15 complex, and you may not be able to screen for some of
16 them.

17 LtCOL. NOBAK: When the AFIP does their
18 tox screens, they get way down in the weeds and can
19 find pretty much anything. I have great faith in
20 them.

21 COL. GARDNER: We've seen a lot of ephedra
22 problems with these cases in recent years.

23 DR. KARK: There was an officer candidate
24 death in the past few months. With (inaudible) seems
25 to be a popular thing with people who have to do

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1 difficult training events, they feel it's going to
2 help them. And it contains ephedrine and caffeine
3 seem to be the main active principals in it. They're
4 hard to keep away from the recruits because they are
5 actually sold at the PXes, so they are available on
6 base, and they are just a small capsule, so it's easy
7 for them to have them and take them just before they
8 do a run. There was an officer candidate death about
9 six months ago, if I remember correctly.

10 DR. OSTROFF: I hate to cut off
11 discussion, but this discussion will continue into the
12 Health Promotion Subcommittee meeting. I must
13 confess this is not my area of expertise, but just
14 when I listen to the presentations and I look at the
15 way the policies have zigzagged all over the place
16 over the last 20 years, I must confess I'm a little
17 bit confused as to why all of the recommendations
18 certainly from the Board and from other committees
19 such as the Sickle Cell Advisory Committee have been
20 not to do this type of screening for trait, and yet
21 three of the four services seem to be doing it, and I
22 can't quite figure out why that's the case and why the
23 policy has gone in the other direction. And I'm
24 trying to figure out -- I mean, can any of the
25 Preventive Medicine representatives from the services

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1 tell me why they've gone in that direction?

2 CDR. LUDWIG: I can comment on it from a
3 Coast Guard perspective. We also do screen in the
4 Coast Guard, and I discussed this when the memorandum
5 came through from the Safety Center. It turns out
6 that the Coast Guard is the only service where the
7 Safety Center Chief is the same person as the Medical
8 Department Chief, or the Surgeon General, if you will.

9 And so it came to our attention, my attention first,
10 I think, out of anybody in the office, and I had some
11 long discussions and looked at a lot of the
12 epidemiology and the research that was already
13 available. And I took it to my boss and I said,
14 "We're screening right now, but it looks like we're
15 going against the recommendations that have been made,
16 and it's quite conceivable that we could stop the
17 screening". And the answer was that we must continue
18 the screening because we have an obligation to tell
19 the people that they have this trait and to counsel
20 them accordingly.

21 DR. PETERSON: I just wanted to comment
22 from the perspective of the Sickle Cell Disease
23 Advisory Committee. The flip side of that is the
24 discriminatory/stigmatizing issue, which was felt very
25 strongly by the committee to be present when you're in

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1 the presence of screening for what is potentially a
2 nondisease in an underrepresented community. So I
3 think that -- and this was emphasized, I think,
4 especially with the red dogtag, red flag, et cetera.

5 The other issue that struck the committee
6 that might be food for thought is that here you have a
7 maximizing of this. Most services mandate if you have
8 anemia, you should be at least deferred, and yet you
9 have no screening policy for anemia. You don't do
10 tests. So, it's kind of an interesting dichotomy
11 where you're very aggressive about looking for what is
12 probably a nondisease whereas you have probably a 5
13 percent prevalence rate of anemia and yet you don't
14 look for it.

15 DR. OSTROFF: To that, I say "amen". It
16 struck me as being inconsistent as well, when, as I
17 think has been stated repetitively, that what you are
18 trying to screen for is disease, and you're not
19 particularly doing that, and whether or not the
20 screening is designed to detect disease, it's probably
21 not the best way to do it, but I'll leave this to the
22 subcommittee to further deliberate on and hopefully
23 come out with some suggestions about how to respond to
24 these very provocative questions that have been raised
25 to the Board.

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1 What we will do now is the official
2 portion of the meeting is completed, and let me just
3 thank all of the presenters for taking the time and
4 effort to give a series of outstanding presentations.

5 I do want to emphasize that I'm usually fairly
6 tyrannical about trying to keep on schedule, and
7 hopefully we can make the presenters better aware of
8 the fact that if they're slotted for a 20-minute
9 presentation, that it's not going to be consistent
10 with 40 slides. So, in the future, if the presenters
11 can get us their presentations prior to the actual
12 meeting, that will help in terms of us being able to
13 recognize presentations that need to be truncated, to
14 put it a better way.

15 What we are going to do -- and I'll let
16 Rick tell you how this is going to work -- is that we
17 actually, for several meetings, haven't had breakout
18 sessions for the subcommittees, but each of the
19 subcommittees does have a series of questions to
20 address and discussions to be held. And the way that
21 we usually do this is to break apart and have the
22 various subcommittees meet for a relatively brief
23 period of time, at least discuss a plan to address the
24 questions that are before them, and then we all come
25 back together again and give brief updates on the

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1 deliberations of the subcommittees. And so I think
2 based on the time frame that we have available to us,
3 I'd like to ask each of the subcommittees to try to
4 get together for about an hour, and then we'll come
5 together and have brief presentations from each of the
6 subcommittees, and then bring the meeting to a close.

7 For the breakout sessions, the Board is
8 considered to be meeting in Executive Session, and
9 sometimes we do have individuals that are directly
10 related to some of the questions that do attend the
11 breakout groups, and so I'd ask those individuals to
12 feel free to attend, but otherwise the public part of
13 the meeting is concluded.

14 (Whereupon, at 2:10 p.m., the public
15 session was concluded.)

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