

UNITED STATES DEPARTMENT OF DEFENSE

DEFENSE HEALTH BOARD

CORE BOARD MEETING

Arlington, Virginia

Monday, November 1, 2010

1 PARTICIPANTS:

2 Core Board Members:

3 WAYNE LEDNAR, M.D., Ph.D.

4 GREGORY POLAND, M.D.

5 CHRISTINE BADER

6 COLONEL (Ret.) ROBERT CERTAIN

7 JOHN CLEMENTS, Ph.D.

8 NANCY W. DICKEY, M.D.

9 FRANCIS A. ENNIS, M.D.

10 WILLIAM HALPERIN, M.D.

11 EDWARD KAPLAN, M.D.

12 JAMES LOCKEY, M.D.

13 RUSSELL LUEPKER, M.D.

14 THOMAS J. MASON, Ph.D.

15 GENERAL (Ret.) RICHARD MYERS

16 DENNIS O'LEARY, M.D.

17 JOSEPH E. PARISI, M.D.

18 MICHAEL PARKINSON, M.D.

19 ADIL E. SHAMOO, Ph.D.

20 JOSEPH SILVA, M.D.

21 DAVID WALKER, M.D.

22 HONORABLE TOGO WEST

1 PARTICIPANTS (CONT'D):

2 Task Force Members:

3 BRIGADIER GENERAL PHILIP VOLPE

4 COLONEL JOANNE McPHERSON

5 FLORABEL MULLICK, M.D., Sc.D.

6 RIDGELY RABOLD

7 KENNETH W. KIZER, M.D.

8 CHARLES FOGELMAN, Ph.D.

9 THOMAS W. UHDE, M.D.

10 FRANK K. BUTLER, JR., M.D.

11 Service Liaison Officers:

12 GROUP CAPTAIN ALAN COWAN

13 LIEUTENANT COLONEL PHILIP GOULD

14 COLONEL WAYNE HACHEY

15 COLONEL MICHAEL KRUKAR

16 COLONEL ROBERT MOTT

17 CAPTAIN NEAL NAITO

18 COMMANDER ERICA SCHWARTZ

19 Flag Staff Officers:

20 VICE ADMIRAL JOHN MATECZUN

21 MAJOR GENERAL DOUGLAS J. ROBB

22 BRIGADIER GENERAL PHILIP VOLPE

1 PARTICIPANTS (CONT'D):

2 CAPTAIN NOE MUNIZ

3 ASD Staff:

4 COLONEL NANCY DEZELL

5 ALLEN MIDDLETON

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7 General Mailing List:

8 LIEUTENANT COLONEL(P) STEVEN CERSOVSKY

9 COLONEL RENATA ENGLER

10 COLONEL JAMIE GRIMES

11 DR. GEORGE LUDWIG

12 CAPTAIN SHARON LUDWIG

13 DR. PERRY MALCOLM

14 DR. WILLIAM UMHAU

15 Additional Invitees:

16 JOHN ALLEN

17 A.J. AWAN

18 LAKIA BROCKENBERRY

19 CAPTAIN JOYCE CANTRELL

20 DR. LIMONE COLLINS

21 DENISE DAILY

22 STEVEN EBERLY

- 1 PARTICIPANTS (CONT'D):
- 2 DR. FIRPO-BETANCOURT
- 3 DEBORAH FUNK
- 4 ELDESIA GRANGER
- 5 JEFF HACKMAN
- 6 JOHN HACKMAN
- 7 DR. JOAN HALL
- 8 RYAN HEIST
- 9 COLONEL DONALD JENKINS
- 10 JOSEPH JORDAN
- 11 DR. STEVEN KAMINSKY
- 12 PHILIP KARASH
- 13 JOHN LUDWIG
- 14 GENE MILLER
- 15 LARRY NISENOFF
- 16 PAUL REPACI
- 17 ALMA RICO
- 18 STEPHEN SCANGO
- 19 COMMANDER CYNTHIA SIKORSKI
- 20 PORTIA SULLIVAN
- 21 PAUL WILSON
- 22

1 PARTICIPANTS (CONT'D):

2 DHB Staff:

3 CHRISTINE E. BADER  
Director and Designated Federal Official

4 COLONEL JOANNE McPHERSON  
5 Executive Secretary

6 CCSI Contractors:

7 MARIANNE COATES

8 JEN KLEVENOW

9 LISA JARRETT

10 OLIVERA JOVANIC

11 ELIZABETH MARTIN

12 HILLARY PEABODY

13 BRITTNEY SCHNESSLER

14 KAREN TRIPLETT

15 Presenters:

16 COLONEL THOMAS BAKER

17 WILLIAM HALPERIN, M.D.

18 DR. JAMES KELLY

19 CAPTAIN JEFF TIMBY

20 Court Reporter:

21 CHRISTINE ALLEN

22 \* \* \* \* \*

## 1 P R O C E E D I N G S

2 (9:02 a.m.)

3 DR. POLAND: Can we have folks take  
4 their seats, please, and we'll get started.

5 All right. I'd like to welcome  
6 everybody to this meeting of the Defense Health  
7 Board. We have a number of important and somewhat  
8 lengthy topics on our agenda. So, we'll get  
9 started.

10 Ms. Bader, would you call the meeting to  
11 order, please?

12 MS. BADER: Certainly. As the  
13 designated federal officer for the Defense Health  
14 Board, a federal advisory committee, and a  
15 continuing independent scientific advisory body to  
16 the Secretary of Defense via the assistant  
17 secretary of Defense for Health Affairs and the  
18 surgeons general of the military departments, I  
19 hereby call this meeting of the Defense Health  
20 Board to order.

21 DR. POLAND: Thank you, Ms. Bader. And  
22 carrying on the tradition of our board that I hope

1 will long outlast any of us individually, I'd like  
2 to ask the board to stand for a minute of silence  
3 to honor the men and women who serve our country.

4 (Minute of Silence)

5 DR. POLAND: Thank you very much. I  
6 don't think we realized when we first scheduled  
7 this meeting well over a year ago that this would  
8 be time to vote. So, I apologize that many of you  
9 had to get absentee ballots.

10 MS. BADER: Yes.

11 DR. POLAND: If you did that, you may  
12 have realized and speak up in your home state,  
13 they don't make absentee ballots very easy or  
14 user-friendly for the military, the very people  
15 who ensure a continuation of our democracy.

16 Since this is an open session, before we  
17 begin, I'd like to go around the table and have  
18 the board and distinguished guests introduce  
19 themselves, if we can. I'll start to my right,  
20 and we'll go around.

21 MR. WEST: Good morning. I'm Togo West,  
22 and I would add on the question on military votes

1 is new legislation that all the jurisdictions are  
2 being required to comply with. It should have a  
3 big input, the Move Act. So, we'll see.

4 GEN MYERS: Dick Myers, core board  
5 member, retired military.

6 DR. ROBB: Dr. Douglas Robb. I'm the  
7 new joint staff surgeon. The Pentagon replaced  
8 Admiral Smith.

9 DR. ENNIS: Dr. Frank Ennis. I'm a  
10 professor of medicine, molecular genetics, and  
11 microbiology at the University of Massachusetts  
12 Medical School.

13 DR. PARISI: I'm Dr. Joe Parisi, a  
14 professor of pathology at Mayo Clinic College of  
15 Medicine and a consultant in the Department of  
16 Pathology there. Also chair of the Subcommittee  
17 on Pathology and Laboratory Services for the  
18 Defense Health Board.

19 DR. WALKER: I'm David Walker, chair and  
20 professor at the Department of Pathology  
21 University of Texas medical branch. I'm still the  
22 director of the Center for Bio Defense and

1 Emerging Infectious Diseases.

2 DR. DICKEY: Nancy Dickey. I'm  
3 president of the Texas A&M Health Science Center  
4 and family physician by training.

5 DR. MASON: I'm Tom Mason, professor of  
6 Environmental and Occupational Health, University  
7 of South Florida, College of Public Health, Tampa.

8 DR. O'LEARY: Dennis O'Leary, president  
9 emeritus of the Joint Commission.

10 DR. LUEPKER: So, I'm Russell Luepker,  
11 and I'm professor of Epidemiology and Medicine at  
12 the University of Minnesota.

13 DR. KIZER: I'm Dr. Ken Kizer.

14 CPT COWAN: I'm Alan Cowan. I'm a U.K.  
15 liaison, so, I work in the Department of Defense  
16 Enforced Health Protection and also in the  
17 Department of Veterans' Affairs in the Office of  
18 Public Health and Environmental Hazards.

19 CDR SLAUNWHITE: Good morning. I'm  
20 Commander Cathy Slaunwhite, Canadian Forces  
21 medical officer, general practitioner by training,  
22 and I work in a liaison role at the embassy in

1 Washington, D.C.

2 CDR PADGETT: Good morning, Bill

3 Padgett, the Marine Corps liaison.

4 DR. HACKEY: Wayne Hackey, Health

5 Affairs liaison.

6 LTC GOULD: Phil Gould, Air Force

7 liaison.

8 CPT NAITO: Neal Naito, Navy liaison.

9 CDR SCHWARTZ: Erica Schwartz, Coast

10 Guard liaison.

11 COL KRUKAR: Good morning. Michael

12 Krukar, director of Military Vaccine Agency.

13 COL MOTT: Bob Mott. I'm the Army

14 liaison.

15 CPT TIMBY:: Captain Jeff Timby, I'm the

16 second Marine expeditionary force forward surgeon.

17 DR. BUTLER: Dr. Frank Butler from the

18 Committee on TCCC.

19 DR. LEWIS: Frank Lewis, I'm the

20 executive director of the American Board of

21 Surgery.

22 DR. KAPLAN: Ed Kaplan, professor of

1 Pediatrics, University of Minnesota Medical  
2 School.

3 DR. SHAMOO: Adil Shamoo, professor,  
4 University of Maryland School of Medicine, member  
5 of the board, and chair of the Medical Ethics  
6 Subcommittee.

7 DR. CLEMENTS: John Clements, I'm the  
8 chair of Microbiology and Immunology and director  
9 the Tulane University Center for Infectious  
10 Diseases in New Orleans.

11 DR. LOCKEY: Jim Lockey, professor of  
12 Pulmonary Medicine and Environmental Health at the  
13 University of Cincinnati.

14 DR. HALPERIN: Bill Halperin, chair of  
15 Preventive Medicine, New Jersey Medical School in  
16 Newark, New Jersey, and core board member.

17 REV CERTAIN: Robert Certain, core board  
18 member, Episcopal priest, retired Air Force  
19 chaplain.

20 COL McPHERSON: I'm Joanne McPherson.  
21 I'm the executive secretary of the DoD Taskforce  
22 on the Prevention of Suicide by Members of the

1 Armed Forces, holding down the seat for General  
2 Volpe until he can arrive later today. Thank you.

3 MS. BADER: Christine Bader, director of  
4 Defense Health Board.

5 DR. LEDNAR: Wayne Lednar, global chief  
6 medical officer of the DuPont Company and co-vice  
7 president of the Defense Health Board.

8 DR. POLAND: And I'm Greg Poland,  
9 professor of Medicine and Infectious Diseases at  
10 the Mayo Clinic in Rochester, Minnesota, and one  
11 of the co-vice presidents.

12 Maybe we can also start over here and  
13 introduce all our guests.

14 DR. JENKINS: Don Jenkins, chief of  
15 Trauma at Mayo Clinic, retired Air Force, member  
16 of the Trauma and Injury Subcommittee.

17 DR. CHAMPION: Howard Champion,  
18 professor of Surgery and senior advisor on Trauma  
19 and Uniform Services University, and a member of  
20 the Injury and Trauma Subcommittee.

21 DR. UMHAU: William Umhau, Family  
22 Medicine, Travel Medicine at Occupational Health

1 and Safety Services, NSA, Fort Meade.

2 DCDR DANIEL: Good morning, Chris  
3 Daniel, deputy commander at the Army Medical  
4 Research and Materiel Command.

5 MS. DAILY: Good morning. I'm Denise  
6 Daily. I'm the executive director for the Defense  
7 Taskforce for Wounded Warriors. And what I have  
8 here is my staff, and we're kind of RECON-ing your  
9 event because we hope to have our first meeting  
10 here pretty soon. I'll really quickly run  
11 through. Ryan, Phil, Joseph, Lakia, Alan, Larry,  
12 and myself, Denise Daily. Thank you.

13 MAJ LEE: I'm Major Roger Lee. I'm on  
14 the Joint Staff, work for the Joint Staff surgeon  
15 and the J4 Health Service Support Division.

16 MR. CRON: Kevin Cron. I'm a preventive  
17 medicine resident with RARE.

18 MS. SIKORSKI: Good morning. I'm Cindy  
19 Sikorski, preventive medicine resident, USUHS.

20 MS. GRANGER: I'm Eldesia Granger, and  
21 I'm an internal medicine and pediatric resident  
22 from the University of North Carolina, Chapel

1 Hill.

2 MR. MILLER: Good morning. I'm Gene  
3 Miller from Battelle, retired Army and military.

4 MR. MALCOLM: I'm Perry Malcolm, a  
5 position with the OSD, DDRN&E.

6 MS. COATES: I'm Marianne Coates. I am  
7 a communications consultant to the Defense Health  
8 Board, contracted.

9 COL GRIMES: Good morning. I'm Jamie  
10 Grimes. I'm the national director of Defense and  
11 Veterans' Brain Injury Center.

12 LTC CERSOVSKY: Good morning. Steve  
13 Cersovsky. I'm the director of Epidemiology and  
14 Disease Surveillance at the U.S. Army Public  
15 Health Command.

16 MS. PEABODY: Good morning. I'm Hillary  
17 Peabody, and I'm an analyst with the Defense  
18 Health Board.

19 MS. MARTIN: I'm Elizabeth Martin, and  
20 I'm also an analyst with the Defense Health Board.

21 MS. JOVANIC: Good morning. I'm Olivera  
22 Jovanic. I'm a senior analyst at the Defense

1 Health Board and CCSI contractor.

2 MR. CRETEN: Jean-Paul Cretien. I'm  
3 the two Marine expeditionary force forward  
4 preventive medicine officer.

5 MS. JARRETT: Lisa Jarrett, Defense  
6 Health Board staff.

7 MS. KLEVENOW: Jen Klevenow, DHB support  
8 staff.

9 MS. SCHNESSLER: Brittany Schnessler,  
10 DHB support staff and events assistant.

11 MR. SILVIA: Joe Silva, professor of  
12 Medicine and Infectious Diseases, University of  
13 California, Davis School of Medicine, and dean  
14 emeritus.

15 DR. POLAND: Mike, we missed you, too.  
16 Or you missed us. (Laughter)

17 DR. PARKINSON: I'm sorry. Mike  
18 Parkinson, past president of the American College  
19 of Preventive Medicine, now a principal in P3  
20 health, working with employers and hospitals  
21 around performance.

22 DR. POLAND: All right. Thank you. Ms.

1 Bader has some administrative remarks, and then  
2 we'll begin.

3 MS. BADER: Sure. Good morning again  
4 and welcome. I'd like to thank the Key Bridge  
5 Marriott for helping with the arrangements for  
6 this meeting, and, of course, all of the speakers  
7 who have worked hard to prepare their briefings  
8 for the board. As well, I'd like to thank the  
9 Defense Health Board staff, Jen Klevenow, Lisa  
10 Jarrett, Elizabeth Graham, Olivera, and Gene Ward,  
11 as well as welcome our new staff, Elizabeth,  
12 Hillary, and Brittany, who have joined us here  
13 today.

14 I'd like to ask everyone to please sign  
15 the general attendance roster on the table outside  
16 of the room if you have not already done so. And  
17 for those who are not seated here at the U-shaped  
18 table, there are handouts that are provided also  
19 outside where you should sign in to the meeting.

20 Because this is an open session, it is  
21 being transcribed, and please be sure that you  
22 state your name before you speak and use the

1 microphone so that our transcriber can accurately  
2 record your comments.

3           We will have a catered working lunch  
4 here for board members, ex-officio members,  
5 service liaisons, and DHB staff. Lunch will also  
6 be provided for speakers and distinguished guests.  
7 For those looking for lunch options, the hotel  
8 restaurant is open for lunch, as well there are  
9 several dining options within walking distance,  
10 such as McDonald's, Chipotle, Starbucks, et  
11 cetera. And if you need further information, you  
12 can ask the concierges down in the lobby.

13           There is a group dinner tonight, which  
14 is scheduled for 6:30 p.m. at Restaurant 3,  
15 located at 2950 Clarendon Boulevard in Arlington.  
16 The restaurant is only approximately 1.5 miles  
17 from the hotel, and the Defense Health Board will  
18 be providing shuttle service. The shuttle will  
19 leave the hotel at 6:00 p.m. promptly from the  
20 hotel lobby, and there will also be a return  
21 shuttle service to the hotel. The cost for dinner  
22 is \$36. Please provide \$36 in cash to Jen

1 Klevenow.

2           Finally, Mr. Middleton is scheduled to  
3 make remarks on our agenda for this morning.  
4 Unfortunately, commitments at the Pentagon have  
5 prevented him from being here today. He wanted me  
6 to send to you his regrets and to thank the board  
7 for their hard work in working to promote health  
8 and wellbeing for our armed forces and their  
9 beneficiaries.

10           So, with that, I would like to turn the  
11 meeting back over to Dr. Poland.

12           DR. POLAND: I might say, too, Dr. Mike  
13 Oxman couldn't be with us today. He is in Italy  
14 with his wife on their -- I forgot now -- is it 40  
15 or 45th anniversary or something? We know her as  
16 Saint Marcy. (Laughter) And you know Mike well  
17 enough, you know what I mean.

18           Okay, two things. One, we're ahead of  
19 time on our agenda because the reason Ms. Bader  
20 just mentioned, and one of my goals is to keep us  
21 that way. The second is we're going to talk first  
22 thing this morning on the proposed revisions to

1 fluid resuscitation and tactical evacuation.

2 Let me just tee this up a little bit and  
3 say that we divided the question previously,  
4 hypothermia and fluid resuscitation at our last  
5 meeting and postponed a vote on this. We asked a  
6 lot of questions regarding fluid resuscitation.  
7 We asked that there be epidemiologic rating of the  
8 evidence, and I can tell you because of the two  
9 co-vice presidents, I've been the one to help  
10 manage or shepherd that question through. How  
11 impressed I've been at the amount of time, effort,  
12 and resources that have been put into this.  
13 They've done exactly as we've asked them to do,  
14 and I think you'll see that this morning. My goal  
15 is to move through the presentation, give plenty  
16 of time for comments and discussion among the  
17 board, and then bring this to a vote and  
18 resolution.

19 I also recognize, because many of around  
20 the table are internists, and I know our love for  
21 data. The reason that this is epidemiologic, we  
22 graded, is so that we can see where the data are

1 high-quality and where they are of lesser quality,  
2 but the data are the data, and that's what we have  
3 to work with. I know in certain instances you may  
4 feel like you'd like to have more, but we simply  
5 don't, and I think as we recognize in all of  
6 medicine, that data changes over time and these  
7 guidelines will change over time as more studies  
8 become available.

9 Dr. Butler did send me a lot of the  
10 papers that were used in this and other  
11 professional societies' guidelines. I spent about  
12 a day going through them. It's been a long time  
13 since I've looked at material like that, and I  
14 just have to say how impressed I am with the work  
15 of this group.

16 So, with that, I'm going to introduce  
17 Captain Jeff Timby. He's currently stationed as a  
18 surgeon with the Joint Taskforce Civil Support at  
19 Fort Monroe in Virginia. His previous duties  
20 included head of Pulmonary Division for Pulmonary  
21 Diseases and Critical Care at the Naval Medical  
22 Center in Portsmouth; senior medical officer,

1 Shock Trauma Platoon, Combat Service Support  
2 Battalion 22; officer in charge of the Detention  
3 Center with the Joint Taskforce Guantanamo; and  
4 command surgeon with the Naval Special Warfare  
5 Development Group in Dam Neck, Virginia. Captain  
6 Timby is an assistant professor of Medicine at  
7 USUHS, a position he's held since October of 2002,  
8 and a recipient of numerous awards and  
9 recognitions, including the Navy Defense Medal,  
10 Outstanding Military Volunteer Medal, Navy Marine  
11 Corps Commendation Medal, Defense Meritorious  
12 Service Medal, July 2001 and June 2004 Bronze Star  
13 in the Iraqi Campaign Medal with Marine Combat  
14 Unit Insignia. He'll be presented the proposed  
15 revisions to fluid resuscitation and tactical  
16 evaluation, after which we'll have discussion,  
17 and, as I mentioned, a vote.

18 So, Captain Timby? And his presentation  
19 is under Tab 2 in your folder.

20 CPT TIMBY:: Good morning. Dr. Poland,  
21 thank you for that warm introduction.

22 Let me make a couple of amendments to

1 that. I'm no longer with the Joint Task Force  
2 Civil Support at Fort Monroe. I'm now the second  
3 Marine expeditionary force forward, operative word  
4 being "forward," surgeon, ready to deploy to  
5 Afghanistan in March. So, again, trying to get  
6 our ducks in a row to get the leadership or take  
7 the leadership role with my commanding general at  
8 RC Southwest down in Helmand Province.

9 So, with that, I'm not sure why I feel  
10 nervous now. I guess I should be feeling nervous  
11 then. (Laughter)

12 Anyway, a couple of caveats. Last time  
13 I was with the Marines, I came home, and my son  
14 said -- that time he was in eighth grade. He  
15 said, I like when you're with the Marines, dad.  
16 And I think wow, that must be because of my cool  
17 hairdo, my buff physique. No, dad, you curse a  
18 lot more, is what he said. (Laughter) And so, if  
19 I let anything rip, it's only by my environment,  
20 and I apologize upfront. I'll try to keep it  
21 clean.

22 Slide, please. The discussion today is

1 on pre-fluid management of combat injuries. The  
2 talk will be broken into three parts basically,  
3 and one is how did the guidelines get to where  
4 they currently are; then the proposed guideline  
5 change and the reasoning for that, and then,  
6 thirdly then is a response to a teleconference  
7 that we had on October 21 to then address the  
8 issues and questions that were raised during that  
9 time and, again, to give kind of the feedback  
10 information to the board to help to answer those  
11 questions that were raised at that time.

12 There will be a break about two-thirds  
13 of the way into it to ask questions. Again, I  
14 turn to the board members if we can just get  
15 through some of the background information. Then  
16 I'll leave a moment before we get into the  
17 teleconference issues for any comments that folks  
18 want to make.

19 The initiative began actually back in  
20 1993 as part of a pre-hospital fluid resuscitation  
21 discussion as part of the biomedical R&D project  
22 listed below. At the time, the ATLS

1 recommendation was aggressive fluid resuscitation,  
2 two liters of fluid in route to the hospital.  
3 Usually, those transport times were brief. And,  
4 again, I'm guilty of this myself. What some of my  
5 residents would actually have referred to as  
6 saltwater drowning, we provided a lot of saline, a  
7 lot of crystalloid solutions in support of blood  
8 pressure, adding pressors and whatnot to the  
9 management.

10 Slide, please. The key premise was that  
11 we're not going to ask our corpsman or medics to  
12 do anything that we can't provide solid evidence  
13 in the literature or at least field experience to  
14 say that this is actually prudent and a good thing  
15 to do, and we'll save lives on the battlefield.  
16 The picture to the bottom right shows our current  
17 war-fighter. The medic looks similar to that.  
18 They carry about 100 pounds of really light stuff  
19 throughout their battle space.

20 In general, space and cube weight is a  
21 critical factor whenever we're talking about  
22 adding something to them; you really almost at

1       this point have to take something away for them to  
2       be able to carry it into the field. Again, much  
3       of the care that our folks are providing and care  
4       under fire, as well as in the tactical field care.  
5       It's exactly what is carried on that member's  
6       back. They may have a vehicle that may be pinned  
7       down in a different position.

8                So, the majority of the work is done  
9       with what this man has carried in on his back.

10       So, again, to ask him to carry more fluid, more  
11       materials, more equipment, again, you have to take  
12       something away for him to be able to do that.

13               Slide, please. In the initial research  
14       and looking at the R&D project, 17 references  
15       state that despite the widespread use, there was  
16       little evidence to really support it. And, again,  
17       12 references look at aggressive fluid  
18       resuscitation in the setting of an unrepaired  
19       vascular injury may actually promote further  
20       bleeding and higher mortality.

21               Slide, please. Again, the beneficial  
22       effect of that in the animal studies was largely

1 done in a controlled hemorrhage type of a model.  
2 And so, again, the beneficial effects in that  
3 model will differ from those that would be in a  
4 uncontrolled hemorrhage.

5 Slide, please. If you look at combat  
6 information, feedback from as far back as World  
7 War I, again, aggressive fluid resuscitation prior  
8 to the member getting to the operative suite where  
9 a hemorrhage can be controlled was generally found  
10 to be an unfavorable intervention.

11 Slide, please. In Kaweski study for  
12 1990, 6,855 patients looking at hypotension as a  
13 major predictor for adverse outcomes showed that  
14 pre-hospital fluid resuscitation did not  
15 necessarily change these numbers when you look at  
16 that cohort of patients.

17 Slide, please. Crawford study of  
18 patients with ruptured abdominal aortic aneurisms  
19 showed that those patients who had received  
20 aggressive fluid resuscitation prior to the  
21 operative suite had a survival of about 30  
22 percent. Slide, please. Whereas those who had a

1 less- aggressive fluid approach had a higher  
2 survival rate at 46 percent, provided their blood  
3 pressure was maintained somewhere between 50 to 70  
4 mmHG in the ride in. Again, favoring a  
5 hypotensive resuscitation approach to management.  
6 And so, again, the recommendation in this paper  
7 was to withhold aggressive fluid administration  
8 prior to the arrival to the operative suite.

9 Slide, please. The study by Bickell  
10 through I think it was University of Houston's  
11 Medical Center looked at a cohort of 598 patients.  
12 Half received aggressive fluid resuscitation, half  
13 received less aggressive fluid resuscitation.

14 Slide, please. In the folks that  
15 received the aggressive fluid resuscitation, there  
16 was 62 percent survival, and in that group that  
17 received the less- aggressive approach, their  
18 survival was actually higher. A lot of things  
19 that you could poke in the eye about this  
20 particular study, and I've heard a number of folks  
21 do that, but, again, the literature in this study  
22 seems to suggest that an aggressive fluid

1 management program may not be the most prudent  
2 approach to fluid management. Again, keep in mind  
3 that these were patients coming in from a civilian  
4 trauma environment transport time is measured in  
5 minutes.

6 If you look at the Battle of Mogadishu,  
7 you could take that time in minutes, multiply that  
8 into hours, and that's what the actual  
9 resuscitation interval pre-hospital intervention  
10 that those folks -- and so, this then asks the  
11 question, this is common in a lot of the civilian  
12 literature: Is this the right answer to the wrong  
13 question? Again, is this not necessarily  
14 applicable to what our war-fighters, our medics,  
15 corps men are experiencing out there in the  
16 battlefield?

17 Slide, please. Animal studies looking  
18 at uncontrolled hemorrhage, again, support the  
19 aggressive fluid resuscitation is not the way to  
20 go, but, again, withholding fluid resuscitation  
21 may have a greater benefit, and nine references  
22 are cited there.

1           Slide, please. And if you look at it  
2 from just what is our perspective in terms of  
3 giving fluids out in the field and then you have a  
4 hour later, if it's a crystalloid solution, 1000  
5 CCs of your lactated ringers is quickly  
6 redistributed into the interstitial space really  
7 even before the Medevac has even arrived. So,  
8 again, this is a short-lived intervention in the  
9 environment here.

10           Slide, please. In the typical transport  
11 time ranging in 15 to 30 minutes in the civilian  
12 environment, again, infusion of a crystalloid  
13 solution is probably an acceptable approach to  
14 things because 15 minutes later, the fluid will  
15 still be where you had put it, and as the member  
16 or as the person arrives to the emergency  
17 department or the operative suite, then blood  
18 products and other fluid interventions can be  
19 done. It can then offer a more definitive  
20 management, including the surgery.

21           Slide, please. The first publication of  
22 the tactical combat casualty care guidelines was

1 in 1996, as a supplement to the Military Medicine  
2 publication. Slide, please. And in those  
3 guidelines published then, IV fluid resuscitation,  
4 IVs in general were delayed until the tactical  
5 field care. Again, we are not recommending that  
6 in a hail of bullets that anybody would be out  
7 there on the firing line in the kill zone putting  
8 in IVs and delaying the transport of the patient  
9 away from the hail of bullets, as well as  
10 yourself, but in tactical field care, again, no IV  
11 fluids were recommended, and patients were not in  
12 shock. In fact, we recommended or Captain Butler  
13 recommended that fluids be administered orally in  
14 that subgroup. In casualties that had  
15 uncontrolled hemorrhage, and that was largely  
16 torso or maybe within the groin or in the axilla  
17 where options for controlling the hemorrhage were  
18 somewhat more limited. No IV fluids were  
19 recommended in that setting, as well, of  
20 uncontrolled hemorrhage.

21 IV fluids in the form of Hespan, a  
22 colloid agent that had a starch, was recommended

1 initially for casualties who were in shock as a  
2 result of hemorrhage, but that hemorrhage has  
3 since then been controlled, i.e., extremity  
4 hemorrhage that has then be tourniquetted. And  
5 so, again, that was the limited use for IV fluids,  
6 was in the shocky patient with controlled  
7 hemorrhage, and that fluid intervention was  
8 limited to 1,500 CCs.

9 Slide, please. This was my first lesson  
10 in the trapdoor, spider techniques of Captain  
11 Frank Butler. I happened to be walking in the  
12 hallway out in front of his office as I overheard  
13 Frank, oh, I'm really disappointed you won't be  
14 able to make the meeting, but I think I may have  
15 an alternative. Jeff, come here. And I come  
16 walking in, and that's when I got invited to be  
17 the leadoff speaker for this, or not leadoff, but  
18 I ended up with the discussion of casualty number  
19 one in this symposium. But the Special Operations  
20 Medical Association meeting in 1999 outlined  
21 casualties or clusters of casualties that occurred  
22 during the Battle of Mogadishu, and then asked the

1 question: Applying the care under fire tactical  
2 field care and evacuation care, tactical  
3 evacuation phases of care, what intervention would  
4 you recommend and what literature supports that?

5 Slide, please. And then fluid  
6 resuscitation, there was a clear consensus among  
7 the panel members that if a casualty even with an  
8 uncontrolled hemorrhage situation was hemorrhaging  
9 to the point or had developed a shock state  
10 significant enough that they then had an altered  
11 mental status, that that person should be fluid  
12 resuscitated, trying to maintain them long enough  
13 to be able to get them into surgical hands. And,  
14 again, the emphasis was not on trying to  
15 aggressively administer fluids, but to administer  
16 just enough fluids to achieve a hypotensive  
17 resuscitation with systolic pressures in the 80 to  
18 90 range and not trying to achieve normal blood  
19 pressure, where, again, a pressure had, especially  
20 in the phase of coagulopathy, hyperthermia, may  
21 actually pop the clot off of the vascular injury  
22 and result in extensive further bleeding.

1                   Slide, please. The Joint MRMC-ONR Fluid  
2 Resuscitation Conference held in 2001, 2002,  
3 co-chaired by Dr. John Holcomb and Dr. Howard  
4 Champion, revealed or produced a fluid  
5 resuscitation strategy that has since been largely  
6 employed into the current guidelines. And with  
7 that, the assessment for hemorrhagic shock being  
8 altered mental status in the absence of a head  
9 injury and a weak or absent peripheral pulse being  
10 the best indicators for shock in the field. And  
11 that, again, if you go down through, no fluids are  
12 necessary if the member is not in shock, and,  
13 again, permissible to deliver PO fluids, even in  
14 the face of an abdominal wound, provided the  
15 member is able to take it without pain or further  
16 nausea or vomiting.

17                   Slide, please. Fluid resuscitation in  
18 those in shock, Hextend was now recommended  
19 because of the lesser coagulopathic affect of  
20 Hextend versus Hespan, again, 500 CC initial bolus  
21 to be repeated after 30 minutes of still in shock,  
22 and then the Hextend, 1,000 CCs of Hextend was the

1 recommended peak.

2 Slide, please. This was carried into  
3 the PHTLS Manual and the chapters on tactical  
4 combat casualty care, and then ultimately the  
5 sixth edition with the green edition, it is  
6 largely the training manual that we use in the  
7 Department of Defense currently. The PHTLS  
8 recommendations are endorsed by the American  
9 College of Surgeons' Committee on Trauma, as well  
10 as the NAEMT, which is the certifying organization  
11 for all paramedics going out into the field. And,  
12 again, it's widely used and is really the document  
13 of educational use for the Department of Defense  
14 for pre-hospital resuscitation.

15 Slide, please. The current fluid  
16 resuscitation guidelines are as you see them now,  
17 and they largely effect what we just went through  
18 in terms of the discussion. And this, again, note  
19 is in the tactical field care portion of the  
20 guidelines. And with this, we assess for  
21 hemorrhagic shock using altered mental status,  
22 weak or absent peripheral pulse are the best

1 indicators for shock in the field. The same  
2 caveats for if the member is not in shock. If the  
3 member is in shock, again, the same as had been  
4 developed in the 2003 conference.

5 This letter C, subheading C is very  
6 important. When you're in a tactical field  
7 environment, again, the resources that are  
8 available for the medic or corpsman to deliver to  
9 his casualty or limited by that which he carries  
10 on his back or is spread-loaded across the force  
11 continued efforts to resuscitate any one  
12 individual really needs to be weighed against the  
13 logistical and tactical considerations of further  
14 casualties. Is this a one of one casualty? Does  
15 he have more casualties? Are you still under  
16 fire? Are they likely to come under more fire  
17 prior to the evacuation of this particular  
18 casualty, as well as the unit in general?

19 So, that the corpsman and medic are not  
20 only making medical decisions, they're also making  
21 these life and death decisions of do I use  
22 everything that I've got in my pack on this one

1 man or am I likely not going to benefit another  
2 one of my service members who may have a better  
3 chance of surviving? And so, this decision-making  
4 capacity or decision-making responsibility for our  
5 corpsmen and medics is really an onerous one, too,  
6 then, and a lot of the medics and corpsmen have  
7 come back to me saying boy, that was not an easy  
8 decision to make. Why did you do it that way?  
9 Well, it seemed like it was the right thing to do  
10 was usually about the best answer they can come  
11 back with.

12 Now, way down here, buried at the bottom  
13 is the discussion well, what if the member does  
14 have a head injury, what do we use then? And in  
15 this, it is if a casualty with TBI is unconscious  
16 and has no peripheral pulse, resuscitate to  
17 restore the radial pulse, which should bring us to  
18 a blood pressure at least in the 85, maybe 90 mmHg  
19 range.

20 Slide, please. Now we're in the  
21 tactical evacuation care. Again, these are the  
22 guidelines as they are currently published. We

1 are now reassessing for hemorrhagic shock using  
2 the same methods as before. No change in the  
3 no-shock subgroup. If in shock, again, not really  
4 a change from the tactical field care side. Here,  
5 because the member is now in the evacuation phase  
6 of care, the resources available are usually more  
7 robust.

8 Now, this may be an evacuation on back  
9 of a fast boat, this may be an evacuation in the  
10 back of a truck, this may be an evacuation in a  
11 place where resources are not that readily  
12 available, but, again, in a large part of the  
13 evacuations as folks are leaving the battlefield,  
14 it's either in an ambulance or in a helicopter  
15 that is equipped to be able to provide medical  
16 resources. And, again, if those resources are  
17 available, they continue resuscitation. And,  
18 again, if blood products are available, to use  
19 those first, Hextend, Lactated Ringers, whatever  
20 is needed, again, to support the member or support  
21 the casualty until they arrive back at a treatment  
22 facility. And, again, no real difference in the

1 traumatic brain-injured patient relative to the  
2 guidelines for tactical field care.

3 Slide, please. As we entered into the  
4 discussion for changing the current guidelines,  
5 these were some of the deceived deficiencies, is  
6 that the guidelines, as they stand now, don't  
7 necessarily call for the use of blood pressure or  
8 to give a target for that blood pressure if a  
9 sphygmomanometer or some other device, monitor of  
10 some device is available to be able to provide  
11 that. And, again, we want to give the transport  
12 medic and corpsman the opportunity to know what  
13 their target blood pressure range is.

14 Also, though we did mention Packed Red  
15 Blood Cell administration in the casualty  
16 evacuation phase, it does not reflect the current  
17 one-to-one ratio of plasma to blood in the  
18 guideline as it speaks now.

19 It calls for Hextend to be used  
20 initially instead of plasma and packed red blood  
21 cells when packed red cells and plasma may be  
22 available.

1                   And then, lastly, the decision for fluid  
2    resuscitation for the traumatic brain-injured  
3    patient, you use both mental status as well as  
4    absent or diminished radial pulse as a measure.  
5    And, again, the full spectrum of mental status  
6    alterations may be present for those members with  
7    traumatic brain injury, and I felt that it needed  
8    to be removed as a measure by which fluid  
9    resuscitation guidance should be offered.

10                  Slide, please. And so, in red are the  
11    guideline revision proposals. One that if blood  
12    pressure monitoring is available on your tactical  
13    evacuation, again, this is in tactical evacuation  
14    phase, if blood pressure monitoring is available  
15    to use the target between the 80 and 90 mmHg,  
16    again, using that hypotensive resuscitation  
17    philosophy.

18                  No change in the patient without shock.  
19    If in shock and blood products are not available.  
20    So, again, what we tried to do here is try to  
21    break out if blood products are available or blood  
22    products are not available. So, in this

1 situation, blood products are not available.  
2 Again, used Hextend as our primary fluid  
3 administration agent, repeat in 30 minutes if the  
4 patient is still in shock, assuming that this is  
5 still the measure by which they will be using it,  
6 and to continue resuscitation with Hextend  
7 crystalloid or crystalloid solution as needed to  
8 maintain the target blood pressure or the clinical  
9 improvement in the mental status.

10 Again, if you note, we did not continue  
11 with the recommendation to limit the fluid volume  
12 of resuscitation of Hextend because in the review  
13 of the literature that we had available to review,  
14 the 1,500 or 1,000 CCs of hetastarch really was  
15 not supported by the literature that we had  
16 available to us to review. So, we removed that  
17 limitation.

18 Slide, please. And then the caveat now  
19 is the blood products now are available, and,  
20 again, it is under an approved command or theatre  
21 protocol, and so, that takes a lot of the weight  
22 of having to add a lot of burden of other

1 guideline requirements because those will be under  
2 that super heading, if you will, for any use of  
3 blood products in a evacuation platform. And that  
4 we recommended that the resuscitation begin with  
5 two units of plasma, followed by packed red blood  
6 cells, again, using the one- to-one ratio. If  
7 blood component therapy is not available, fresh  
8 whole blood would be recommended if it is  
9 available where blood component therapy was not  
10 available, and then to continue the resuscitation  
11 as needed to maintain the target blood pressure or  
12 clinical improvement.

13 And then, lastly, from the traumatic  
14 brain-injured casualties, we took out the altered  
15 mental status determinant and carried over the  
16 weaker absent peripheral pulse, and then if blood  
17 pressure monitoring is available, those folks,  
18 again, looking at the Brain Trauma Institute  
19 guidelines, they recommend at least a blood  
20 pressure of 90 or better as their guidelines, and  
21 we went along with their recommendation on that.

22 Slide, please. The only change to the

1 tactical field care fluid resuscitation was to  
2 have the altered mental status in the face of  
3 traumatic brain injury, make that reflect the same  
4 as in the tactical evacuation care, but we did not  
5 address any of the components of the fluid  
6 resuscitation strategy in the other subheadings.  
7 Slide, please. The proposed change was approved  
8 unanimously by the board on August 3, 2010, and  
9 then subsequently approved unanimously by the  
10 Trauma and Injury Subcommittee of the Defense  
11 Health Board on August 3, 2010.

12 And slide, please. I think that should  
13 bring us to the questions.

14 So, again, Dr. Poland, I open it to  
15 discussion before we enter into the --

16 DR. POLAND: Okay, questions from  
17 members of the board?

18 Dr. Kaplan?

19 DR. KAPLAN: Kaplan. Is this meant  
20 across all services or is this just the Navy and  
21 Marines?

22 CPT TIMBY:: This would be across all

1 services, sir.

2 DR. KAPLAN: Thank you.

3 DR. POLAND: Russ?

4 DR. LUEPKER: Luepker. A couple of  
5 years ago, we had a subcommittee looking at the  
6 transfusion of fresh whole blood from service  
7 members out in the field. We were unenthusiastic  
8 about that. It seems as I look at your fourth  
9 from the last slide, that fresh blood is the  
10 option without much discussion or debate.

11 Am I missing something here?

12 CPT TIMBY:: No, sir. There was  
13 actually quite a bit of discussion and debate.  
14 Frank, correct me if I'm wrong. I believe it was  
15 November of 2009, we had a separate meeting. This  
16 was, again, one of our scheduled Committee on  
17 Tactical Combat Casualty Care meetings where blood  
18 use in theatre was more broadly discussed, and the  
19 discussion was rather lengthy.

20 Frank, if you would expand on that.

21 DR. BUTLER: Yes, sir. We've tried our  
22 best to dissuade our forces from the concept of

1 doing buddy transfusions on the battlefield  
2 because you know what? They're still on the  
3 battlefield, and the guy who's not shot next to me  
4 now may be shot 30 seconds later. In addition to  
5 which the tactical field care environment doesn't  
6 really lend itself to the level of attention to  
7 the medical procedures at hand that you want to  
8 have to do blood transfusions.

9 So, this recommendation is confined one,  
10 to the tactical environment or the tactical  
11 evacuation care, where you can have potentially a  
12 physician, a nurse, a paramedic supervising care  
13 and be only in those circumstances when blood  
14 components are not available and that is in  
15 accordance with the March 2010 memo on fresh whole  
16 blood out of ASD Health Affairs.

17 CPT TIMBY:: And, Frank, if I can expand  
18 on that, it also was in that aspect of the  
19 guideline proposal; we fell in line with what was  
20 the clinical practice guideline for the CENTCOM  
21 AO, Area of Operations. So, again, I didn't just  
22 write that as just in case, it was actually in

1 compliance or in keeping with the current  
2 guidelines that were already there in theatre, and  
3 that's why it all falls under the heading of an  
4 approved command or theatre protocol.

5 DR. LUEPKER: Let me make sure I  
6 understand this. So, the Ultra Fresh Blood  
7 Protocol is under the evacuation circumstances and  
8 still not recommended in the acute circumstance?

9 DR. BUTLER: Yes, sir.

10 DR. LUEPKER: Okay, thank you.

11 DR. POLAND: Dr. Parkinson?

12 DR. PARKINSON: Mike Parkinson. Thank  
13 you, Captain Timby, and, of course, Frank, for  
14 your excellent work here.

15 I personally come down -- all the hard  
16 work has been done -- and endorse the guidelines,  
17 but I kind of stand back a minute again and say  
18 what can bringing this to the Defense Health Board  
19 be of value beyond the guidelines? And the  
20 documents that you've presented and the work that  
21 has been done back to the board I think has been  
22 most valuable, at least to this member, because,

1 first of all, again, what it shows is whether or  
2 not the level of evidence and the recommendation  
3 parallels or not that used in internal medicine or  
4 preventive services, and it's actually an ACC and  
5 AHA, if I've got this correct, it's the flip in  
6 terms of the level of evidence and the  
7 recommendations that come from those.

8 But as I go through the whitepaper  
9 document here, as a non-surgeon, it begs the  
10 question: What can the Defense Health Board bring  
11 to the process of an evidence-based maturation for  
12 trauma and surgery care? That sounds a little  
13 global, and it's not meant to sound negative, but  
14 again and again, august bodies of stellar names in  
15 the field that are cited with C-level evidence,  
16 which is largely we got together, we produced a  
17 report, it was based on a case study, and it went  
18 forward, it seems to me that there might be some  
19 other way of national, international use that the  
20 DHB could put a little brain cells to this.

21 Is there ever the role for an  
22 ethically-sound RCT in an area of trauma or war

1 care or something beyond what we've done? That's  
2 just a thought. I do think though that the work  
3 is just absolutely superb, but beyond saying  
4 absolutely, we agree with every other body that's  
5 had expert experience in trauma casualty care and  
6 more, and OR theatre, most of the board members,  
7 what can we add to the process is what I'm asking?

8           And this document has been most helpful  
9 to me to illuminate a little bit of a framework  
10 that would be traditionally used for any other  
11 medical intervention from preventive to a  
12 therapeutic intervention, whether it's a  
13 prescription drug or immunizations? And yet, it  
14 you look at whether or not one implant works  
15 better than another in non-traumatic situations,  
16 the whole field of surgery in general, which is  
17 why it's such a topic at CMS and other areas and  
18 why it's absolutely cost-wise going through the  
19 roof, it doesn't seem to apply to the same level  
20 of evidence standards that we traditionally pursue  
21 in other areas. Not meant to be negative, just  
22 meant to be how can we add a little light so that

1 a year from now or two or three years from now, we  
2 can talk about some methodologies that, perhaps,  
3 aren't there yet. Just a thought.

4 DR. POLAND: Dr. Lewis and then Dr.  
5 Shamoo.

6 DR. LEWIS: Dr. Poland, did you want to  
7 discuss the pros and cons of the specific issues  
8 or was Captain Timby going to present more  
9 material? I know there's a good deal more  
10 material.

11 DR. POLAND: Yes, there's another about  
12 third or so of the presentation to go.

13 DR. LEWIS: Right.

14 CPT TIMBY:: Yes, the topics that we  
15 discussed during the teleconference, we have  
16 further information to expand on those topics that  
17 we discussed.

18 DR. LEWIS: I'll wait.

19 DR. POLAND: You want to wait? Okay.  
20 Then maybe we'll proceed on then to the next part  
21 of the presentation.

22 CPT TIMBY:: Slide, please. Okay, these

1 are supplemental slides. The ones you saw before  
2 were the main body of slides that we had forwarded  
3 prior to the teleconference, and these are now  
4 supplemental slides to address those issues that  
5 were raised during the teleconference to help to  
6 address that information. Slide, please. The  
7 teleconference was conducted on October 21. Dr.  
8 Lewis, thank you for your participation. That  
9 really helped to kind of bring some of the issues  
10 to the forefront that we needed to address. And  
11 then additional information was requested out of  
12 that.

13 And if you will, slide, please. Dr.  
14 Poland has asked for a copy of the results from  
15 the USAISR, that's the U.S. Army Institute of  
16 Surgical Research, Fluid Resuscitation Conference,  
17 which was just conducted in January of 2010.  
18 We'll look at the membership for that conference  
19 and the outcome of it in just a second.

20 And then, also, just in general, the  
21 Committee on Tactical Combat Casualty Care  
22 membership, who makes up the committee, how do we

1 go about our decision-making process, which is  
2 kind of an interesting thing for those on the  
3 board, and then the information distribution as  
4 guideline approvals are made or as guideline  
5 recommendations are approved, then how do we then  
6 distribute out to the branches and implement them  
7 into use?

8 Dr. Lewis had questions more on the  
9 basic science side of the house. Using Hextend,  
10 is that the right fluid? Offering issues relating  
11 to coagulopathy or other agents of equal or  
12 similar benefit: Lactated ringers, dextrans,  
13 hypertonic saline with dextran, albumin. And,  
14 also, we discussed for some length the  
15 intravascular dwell time effect of Hextend and the  
16 pharmacodynamics of that. And then ending on the  
17 not all hetastarches are equivalent and what are  
18 the differences, and is there a different product  
19 that would be more beneficial? And then,  
20 secondly, was then the use of mental status and  
21 radial pulse character as indicators of shock in  
22 the field.

1                   Slide, please. The committee members,  
2                   Committee on Tactical Combat Casualty Care, here's  
3                   kind of a list of the general categories of folks  
4                   that are on the committee. I won't read those to  
5                   you. A couple of highlights though. Two command  
6                   surgeons, U.S. Special Operations commands,  
7                   there's trauma directors from level one trauma  
8                   centers. We have actually a member who was on the  
9                   committee and then was approved for the White  
10                  House Medical Office, and so, he actually is  
11                  working up there then.

12                  I'll tell you the real power block and  
13                  real strength of, I think, the committee comes  
14                  down lower in the slide. Now, my name seems to  
15                  have fallen off the bottom of the slide. I  
16                  apologize for that. No, but these guys down here,  
17                  these senior enlisted medical advisors and the  
18                  Army Ranger Command surgeons and really these  
19                  senior medics, because there's a lot of times  
20                  where we eggheads on the group oh, yes, I think  
21                  it'd be a great idea to do X, those guys sit there  
22                  and shake their heads and say doc, that dog

1 doesn't hunt, and the Ranger guys, they'll form a  
2 voting block and block out anything that just  
3 doesn't make sense to them. But, again, they're  
4 also very appropriate in coming forward with  
5 recommendations, and I would say probably at least  
6 50 if not two-thirds of the change proposals come  
7 out of their experience in the field. And so,  
8 they are very welcome participants in the  
9 committee membership.

10           The other thing that's very important,  
11 none of this, we don't wear any uniforms in the  
12 meetings, which is nice in terms of the bag that I  
13 have to carry to drag all that stuff with me, but,  
14 more importantly, I don't want the number of  
15 stripes on somebody's sleeve to make the  
16 difference between who has the right idea, and  
17 that is very, very firmly adhered to, that anybody  
18 on the committee carries the same weight of  
19 recommendation as any other.

20           Slide, please. The committee gets input  
21 from all kinds of direction, but listed here are  
22 just some of the major ones. Again, published

1 pre-hospital trauma literature, which Frank is  
2 probably the bird dog on hunting down most of that  
3 stuff. The Joint Theatre Trauma System, weekly  
4 trauma teleconferences is another good source of  
5 information where current issues are brought to  
6 the forefront. Direct input from our combat  
7 medical personnel, again, with the senior medics  
8 representing 6, 8, 10 deployments into Iraq and  
9 Afghanistan, they've come back with a host of good  
10 ideas.

11 Research facilities, we have really a  
12 good amount of information coming in independently  
13 from a variety of military and otherwise research  
14 facilities, just new technology that may come to  
15 the forefront, and then service medical lesson  
16 learned centers, again, make up kind of the main  
17 part of our information source of issues to be  
18 brought to the committee.

19 Slide, please. How does that  
20 information as a guideline get approved, how does  
21 that then get disseminated out into the services  
22 and then approved? I can tell you firsthand down

1 at the Camp Lejeune at the Second Marine  
2 Expeditionary Force Surgeon's Office, this guy,  
3 his chief, bird dogs this probably on a monthly  
4 basis just to see has anything changed? So, I  
5 would say if there's anything that we do  
6 differently in terms of disseminating information,  
7 just to make it easier for them to pick out the  
8 things that have change, whether that's a red  
9 font, whether that's a highlight, whether that's  
10 whatever, that it makes it just easier for them to  
11 go holy cow, wait a minute, that's a difference,  
12 and they incorporate that immediately into their  
13 training, and they'll oftentimes come to me, at  
14 least in the last couple of months, they'll come  
15 to me and say hey, doc, what does this mean? What  
16 was the intent behind that? How do we train that?  
17 How does this change what we're doing?

18 But if you look at the Navy letter here  
19 from the surgeon general, again, out to the major  
20 components, the proposed changes to TCCC  
21 guidelines are reviewed by Trauma Injury  
22 Subcommittee, Defense Health Board, and Corps

1 Board of the Defense Health Board, and then once  
2 approved, that curriculum changes and then posted  
3 on the MHS website, all Navy medicine training  
4 sites are then authorized to incorporate the  
5 changes as soon as possible. So, there's not  
6 another layer of decision-making between the  
7 Defense Health Board core decision and then the  
8 implementation by the services.

9 Slide, please. And just by way of  
10 showing the Air Force has a similar philosophy in  
11 terms of pushing that information forward. I  
12 can't speak to the Army.

13 Frank, do you know? Is there a letter  
14 of similarity to that?

15 DR. BUTLER: The Army is well  
16 represented enough on TCCC Committee and with the  
17 participation from the Army Institute of Surgical  
18 Research that they've typically implemented the  
19 changes about three months before the rest of the  
20 services.

21 CPT TIMBY:: And, again, the important  
22 point is down here, effective immediately all

1 changes are then pushed forward or are recommended  
2 to be implemented into those current training  
3 programs.

4 Slide, please. This is from the U.S.  
5 Army Institute of Surgical Research Fluid  
6 Resuscitation conference. This was January 2010,  
7 held in Dallas-Fort Worth. Scheduled for  
8 publication Journal of Trauma, March 2011. The  
9 final draft was submitted to Dr. Poland for his  
10 review. Again, just to see the substance of that  
11 information that will be published.

12 Slide, please. These are the members  
13 who the report was prepared by and participated in  
14 the conference, among others who were much more  
15 robust representation.

16 Slide, please. Excerpts from the  
17 conclusions sections is most important, is the  
18 restricted use of crystalloids for the  
19 resuscitation to prevent fluid overload and  
20 particularly Compartment Syndrome, as it may  
21 effect the abdomen, lungs, head, et cetera. Early  
22 hemorrhage control. Hextend, though it has not

1       been found to improve survival over and above  
2       other agents that were out there, it has also not  
3       been found to produce coagulopathy or other  
4       significant negative effects. And then, lastly,  
5       in combat and at times when cube weight ratios are  
6       important, this is found to be the correct  
7       solution for its use.

8               Slide, please. Here, the TCCC  
9       guidelines as they are currently published, and as  
10      I previously showed, that those guidelines were  
11      supported unchanged. Now we then turned around  
12      and started changing them. But we did not change  
13      them in substance; it was more in clarity of how  
14      those guidelines were written.

15             Slide, please. In terms of Hextend use,  
16      to get into the basic sciences issues. Slide,  
17      please. Looking at Dr. Holcomb's publication from  
18      Journal of Trauma in 2003, and this was at one of  
19      the fluid resuscitation conferences, absolutely  
20      clear logistic benefits for the military medics to  
21      carry the smallest volume and weight of  
22      resuscitation fluid consistent with effective

1 practice.

2 Hypertonic saline with dextran was not  
3 at that time and is not now FDA-approved, so, not  
4 available for use. Thus, Hextend represented the  
5 next logical choice. If you look at other agents,  
6 albumin needs refrigeration, can't carry it  
7 forward. If you look at the dextrans, problems  
8 with anaphylactic response to that has limited its  
9 clinical use.

10 Slide, please. If you look a study by  
11 Mortelmans in the European Journal of Anesthesia  
12 in 1995, looking at the dwell time of Hextend or  
13 actually hetastarches, 8 healthy volunteers,  
14 limited fluid intake, limited food intake were  
15 then bled 500 CCs of blood volume and replaced  
16 1-to-1 volume with 6 percent hetastarch, and with  
17 that, looked at then the systolic blood pressures,  
18 intravascular dwell time, et cetera, and, again,  
19 the intravascular volume was found to be  
20 isovolemic for an 8-hour period. In the current  
21 war effort, the evacuation times certainly fall  
22 easily -- well, I wouldn't say "easily." We fall

1 within that eight-hour guideline at this time. We  
2 tried to adhere to the Golden Hour Philosophy,  
3 more of a stop the hemorrhage philosophy than the  
4 Golden Hour Philosophy. We are probably having  
5 the vast majority, I would argue. I don't have  
6 the data to say, but we have a good proportion of  
7 our folks are back in surgical hands within a  
8 90-minute if not a 2-hour period.

9 Slide, please. If you look at the  
10 Marino Handbook published in 2007, the ICU Book,  
11 the hetastarches equivalent, this is his  
12 statement, "5 percent albumin as a plasma  
13 expander." Major difference between the two  
14 fluids, cost. The hetastarch is cheaper, and then  
15 the risk of altered hemostatis, which is greater  
16 in the hetastarches.

17 Slide, please. If you look at a recent  
18 publication, Journal on Cardiothoracic Vascular  
19 Anesthesia 2010, Murphy and Greenberg stated the  
20 FDA has stated that Hespan use is not recommended  
21 during cardiopulmonary bypass because of an  
22 increased risk of coagulation, abnormalities, and

1     bleeding, and it's similar FDA warnings have not  
2     been extended to the administration of Hextend or  
3     Voluven, which is a smaller molecular  
4     weight-averaged product this is FDA- approved, at  
5     least in those folks with cardiac surgical  
6     patients.

7             Slide, please.  If you look at the  
8     graphs to the right, these are different  
9     hetastarch products.  Again, if it is a 6 percent  
10    hetastarch, it is isovolemic to plasma.  The other  
11    numbers here, the 450 versus Hextend, which is a  
12    670, is the average molecular weight of the  
13    product, but, again, as the term that they use,  
14    it's a polydiverse, meaning this is just the  
15    average molecular weight of the product.  There  
16    are molecules within each solution that are higher  
17    or lower, and it's kind of a bell curve  
18    distribution.  If you look at the molecular weight  
19    as opposed to what is the molar substitution, each  
20    glucose molecule has opportunities for  
21    hydroxyethyl esteration and blah, blah, a lot of  
22    pharmaco, pharmacology, biochemical type stuff,

1 but the bottom line, this tells you the number of  
2 molecules for every 10 glucose, how many of them  
3 are actually substituted. The higher the  
4 substitution, the less likely it is to be  
5 metabolized by plasma amylase, and, thus, its  
6 dwell time is expected to be longer. Hextend has  
7 a alpha half-life, alpha meaning immediate  
8 elimination from the plasma of about 6.3 hours.  
9 So, again, that kind of falls into about the  
10 timeline of the dwell time that we saw with that.

11 Now, when you talk about the plasma  
12 half-life, you have to be a little bit careful  
13 because the hetastarches, again, because this is  
14 an average, if you go down to the smaller  
15 molecular weight average products, some of those  
16 will fall below the 45 to 60 kilodalton size that  
17 are rapidly cleared by the kidney. Those that are  
18 larger remain within the circulation, but, again,  
19 if you have a smaller molecular weight at the  
20 beginning on average, then more of the product  
21 will be eliminated more quickly, and then if you  
22 have a lesser molar substitution, that also then

1 portends a faster metabolic rate. And so, again,  
2 it would be more quickly cleared from the  
3 circulation.

4 So, again, agree with Dr. Lewis'  
5 assertion that not all hetastarches are the same.  
6 They are not. They are actually 10 percent  
7 solutions which are hyperosmotic. There are 3  
8 percent solutions that are hypotonic, relatively  
9 speaking. The ones usually commercially available  
10 in use in the U.S. are the 6 percent hetastarches.

11 When you go to Murphy's Journal of  
12 Cardiothoracic and Vascular Anesthesia, although  
13 dextrans may attenuate the inflammatory response  
14 and have other features that make them good for  
15 use, in pulmonary bypass, there are rarely used  
16 clinically because of the risk of life-threatening  
17 anaphylactic reactions. And then if you look at  
18 the colloid effect of the third generation  
19 hetastarches, which are the ones that are the  
20 smaller molecular weight and lower molar  
21 substitutions, they are as a colloid effect  
22 equivalent to Hextend, but the elimination

1 half-life tissue deposition and side effects,  
2 coagulopathic effect, those features of the  
3 products are different. But, notably, the volumes  
4 of hetastarches required were not significantly  
5 different in cardiac surgery, in orthopedic  
6 surgery, and clinical outcomes in all groups were  
7 comparable. And that's a Westphal anesthesiology  
8 article from 2009.

9 Slide, please. The Ryder Study,  
10 published in the Journal of American College of  
11 Surgeons 2010 looked at 1,714 trauma patients  
12 arriving at the Ryder Trauma Center in Miami.  
13 They were resuscitated with either standard of  
14 care or standard of care with Hextend. In the  
15 non- randomized format that they used, so, again,  
16 it's kind of a level C data, that was largely  
17 because of Florida law prohibiting pre-hospital  
18 use of informed consent, blah, blah, so, they  
19 couldn't do it until they reached the hospital  
20 despite that, and either members or any of the  
21 patients that were treated with the hetastarch  
22 Hextend in this particular case was associated

1 with a reduced initial mortality and no obvious  
2 coagulopathies, and they had folks who received  
3 well above the 1,000 CCs that we recommend.

4 Slide, please. This comes out of the  
5 excerpts of the point paper that I had submitted  
6 to the board prior to the meeting, again, looking  
7 at the level of evidence supporting and not  
8 supporting the use of Hextend. Again, if you look  
9 at colloids better than crystalloids, again, the  
10 literature is pretty much un-supporting in terms  
11 of saying colloids are better than crystalloids.  
12 However, three major fluid resuscitation  
13 conferences, one by the Institute of Medicine,  
14 1999, where they actually recommended the use of  
15 7.5 percent saline. However, most of the  
16 supporting literature that they used in that was  
17 actually 7.5 percent saline with dextran.  
18 Nonetheless, their recommendation was actually for  
19 use of the hypertonic saline. The Combat Fluid  
20 Resuscitation Conference of 2001, conference  
21 recommended by a fairly narrow margin Hextend or  
22 hetastarches for the use, and then the

1 pre-hospital fluid conference from Dallas, 2010,  
2 also favored Hextend largely because there is no  
3 literature to support anything being of greater  
4 benefit. If you look at the Cochran Database  
5 Systematic Review 2008, again supports the use of  
6 hetastarch as the fluid of choice.

7           The NIH News, this referenced the two  
8 large, randomized, multicenter, yadda, yadda, all  
9 the good stuff that you want in research studies.  
10 Looking at 7.5 percent saline in trauma patients  
11 and then a second study looking at the traumatic  
12 brain-injured casualties, both of those studies  
13 were stopped prematurely about halfway into the  
14 study design because of failure to demonstrate  
15 efficacy. Again, you can poke it in the eye about  
16 the decision to stop a study midstream, but the  
17 bottom line that the end term analysis, there was  
18 no benefit of the hypertonic saline versus  
19 conventional therapy. And so, again, that is  
20 probably the best level B data that we have to say  
21 that not so much that Hextend is the right choice,  
22 but that hypertonic saline is not the right

1 choice. So, again, I use that as supporting  
2 evidence. And then a variety of papers published,  
3 again, supporting expert opinion across the board  
4 stating that the hetastarches as the product of  
5 choice.

6 And is Hextend the best? Again, some  
7 support, some don't support. Again, I don't think  
8 that there's really great evidence to support that  
9 absolutely it is the agent of choice, but there's  
10 certainly not evidence of anything else pushing it  
11 off the table either. And then, again, lots of  
12 studies down here below. I use just a handful of  
13 them that I selected to show the safety and  
14 efficacy of the agent of choice.

15 Slide, please. Indicators of shock in  
16 the field slide, please.

17 If you look at the electronic blood  
18 pressure monitoring, our combat medics do not  
19 currently carry any kind of electronic device or  
20 even just a manual device into the field, and when  
21 I ask them if you had that option available to  
22 you, would you want it? And they all do the east

1 west. No, I don't want it. Reliance on  
2 electronic blood pressure monitoring is,  
3 therefore, not part of the care under fire or the  
4 tactical field care. Slide, please. But it is  
5 actually one of the recommended change proposals  
6 for using that as a measure within the tactical  
7 evacuation phase. And, again, we advocate that,  
8 using the target 80 to 90 mmHg and those with  
9 uncontrolled hemorrhage, and 90 or better in those  
10 with Traumatic Brain Injury and Shock.

11 Slide, please. If you look McManus'  
12 paper from 2005 in pre-hospital emergency care,  
13 looking at mental status and radial pulse  
14 characters, the analysis showed that mortality was  
15 29 percent in the patients with a weak radial  
16 pulse compared with the mortality of 3 percent in  
17 patients with a normal radial pulse character.

18 Slide, please. This is further  
19 supported by a study by Holcomb, et al., and in  
20 their cohort, they looked at mental status and  
21 radial pulse characters, indicators of shock in  
22 the field and looked at the multivariate addition

1 of certain procedures to say how much more does  
2 having blood pressure, systolic blood pressure,  
3 mental status, et cetera, how does that support  
4 the decision to do a lifesaving intervention?

5 And, again, I hate to quote numbers because I can  
6 never remember them, but they're in the high 80s.  
7 I believe it was 85 the addition of systolic blood  
8 pressure measurement over radial pulse character  
9 or presence. Took it from 85 to 88 percent in  
10 terms of predicting whether the member would  
11 receive a lifesaving intervention, and when you  
12 took the verbal portion of the Glasgow Coma Scale  
13 and added it to the pulse character or presence,  
14 it went into the low 90s to say that that was,  
15 again, a supporting piece of evidence.

16 So, if you look at radial pulse  
17 character, 85 to percent -- I forget what the  
18 number was -- were able to make the decision based  
19 on pulse character and presence. They got an  
20 additional 3 percent by being able to say that the  
21 guy's systolic blood pressure was 90, and they got  
22 into the low 90s by being able to say that the

1       guy's mental status was pretty good, was  
2       acceptable or not acceptable. So, again, looking  
3       at it, radial pulse and character offering the  
4       greatest selection or ability to differentiate  
5       those who needed a lifesaving intervention or not,  
6       and then the addition of systolic blood pressure  
7       and mental status then supported the greatest  
8       additional outcome measures.

9               Slide, please. So, if you look at the  
10       eastern -- Frank, help me with the east. What  
11       does that stand for?

12              DR. BUTLER: (inaudible)

13              CPT TIMBY:: Thank you. If you look at  
14       their guidelines, fluid should be withheld in the  
15       pre-hospital setting in patients who are alert and  
16       have the palpable radial pulse. So, within their  
17       own set of guidelines, they use palpable radial  
18       pulse. So, again, accepted by a large,  
19       pre-hospital care organization.

20              Slide. Okay. I think that brings us to  
21       the end.

22              DR. POLAND: Okay. Opportunity for the

1 board members to make comments.

2 Dr. Lewis?

3 DR. LEWIS: Let me comment, if I can,  
4 about three things about this. First, I'd like to  
5 address is the issue of resuscitation and Hextend  
6 and the value of that. The physiology of fluid  
7 resuscitation is quite well-defined. The science  
8 underpinning it is quite solid, and the way in  
9 which fluids exchange across body water  
10 compartments is quite well-defined. There's an  
11 intracellular compartment and interstitial  
12 compartment and intravascular compartment. The  
13 interstitial is about three times as large as the  
14 plasma volume. So, when you give a salt solution,  
15 which is isotonic with that, it redistributes into  
16 the interstitial space rapidly, and, therefore,  
17 the retained volume is only about 25 percent, but  
18 that's permanently retained.

19 When you're going to analyze the effect  
20 of any resuscitant fluid, there are only two  
21 characteristics that make any difference in that.  
22 One is the oncotic pressure, which is the pressure

1 due to the large molecules. The other is the  
2 osmotic pressure. That due to small molecules.  
3 Small molecules cause fluid transfer across the  
4 intracellular membrane. Large molecules cause  
5 fluid transfer into the vascular space across the  
6 capillary endothelial membrane.

7           When you're talking about Hextend,  
8 you're talking about oncotic pressure, and the  
9 only tendency to pull fluid into the circulation  
10 or to retain fluid is due to its oncotic pressure,  
11 and there's a significant error that's propagated  
12 through much of the information here. It's most  
13 apparent in the quotation from Marino that Captain  
14 Timby gave. It says, "Overall, hetastarch is  
15 equivalent to 5 percent albumin as a plasma volume  
16 expander." That's a totally false statement.

17 Okay, the oncotic pressure of any large molecule  
18 solution is equal to the physical weight which is  
19 present divided by the molecular weight, and  
20 what's absent from all these discussions is any  
21 discussion of the molecular weight, which is  
22 highly variably among the solutions. Hextend has

1 a molecular weight average of 660,000. Albumin is  
2 64,000. So, Hextend has one-tenth the oncotic  
3 pressure of albumin on an equivalent weight basis.  
4 Therefore, saying that it's "equivalent to 5  
5 percent albumin" is untrue. It's equivalent to  
6 one-tenth of 5 percent albumin. And that's what's  
7 missing from the discussions.

8 Giving 600,000 molecular weight Hextend  
9 is basically equivalent to giving saline. The  
10 only difference between Hextend and Hespan is that  
11 one's an imbalanced salt solution and the other's  
12 a saline solution. The molecular weight of Hespan  
13 is averaged about 330,000. Of Hextend, it's about  
14 660,000. So, Hextend has one half the oncotic  
15 pressure of Hespan, and Hextend has one-tenth the  
16 oncotic pressure of Dextran 70, for example, which  
17 is quite close to albumin.

18 So, what's missing from the discussions  
19 is any concern about the molecular weight of the  
20 large molecules which, in fact, makes all the  
21 difference in oncotic pressure. So, the studies,  
22 one has to be very, very careful when citing these

1 studies. Fluid balance studies are very hard to  
2 do.

3 As an example, I would cite for you in  
4 the 1980s, there were four prospective randomized  
5 studies done of crystalloid versus colloid in  
6 resuscitation. One study concluded that colloid  
7 was clearly better. One study concluded that  
8 crystalloid was clearly better. And two studies  
9 concluded that it made no difference. They were  
10 all class A studies. So, one has to have  
11 considerable skepticism about studies because  
12 they're very hard to do. There is no method for  
13 instantaneously measuring the volume of  
14 intracellular fluid. They are all indicator  
15 dilution techniques, they take time, and they are  
16 significant inaccuracies.

17 So, as Captain Timby has shown,  
18 virtually all of the studies that are cited are  
19 class C studies. Most of them suffer from lack of  
20 randomization and lack of clear endpoints. So,  
21 one has to be quite skeptical about them, and when  
22 the science of this is quite well-defined, one

1       should consider it.  So, the issue with Hextend is  
2       that it's a relatively ineffective resuscitant,  
3       basically the same as saline.  When one gives  
4       1,000 CCs of Hextend, it's like giving 900 CCs of  
5       saline plus 100 CCs of plasma equivalent, and  
6       that's going to have very little resuscitative  
7       effect.  So, the issue here is that the use of  
8       Hextend is probably not harmful, but it's probably  
9       not very helpful, and since it costs 24 times as  
10      much as saline, then it's probably not warranted  
11      to use it.  So, I would say that's my comments  
12      about resuscitation.

13                 The concern about cube weight is  
14      obviously a huge area for the medics.  If one  
15      really wanted to do anything about that, the only  
16      solution currently available that's safe is  
17      hypotonic saline dextran.  Two-hundred-fifty CCs  
18      of 7.5 percent saline gives you an intravascular  
19      volume equivalent to 2 liters, and so, that's an  
20      8-to-1 ratio.  So, in terms of cube weight  
21      effects, one gets the same effect for one-eighth  
22      of the weight, and that would be, in fact, a very

1 positive change. But there's no other solution  
2 around, which would have any advantage, and  
3 Hextend has no cube weight advantage over saline  
4 if you recognize that it has minimal oncotic  
5 effects.

6 My second comment is in regard to the  
7 recognition of shock. Recognition of shock on  
8 clinical grounds is extraordinarily difficult,  
9 even in the hospital setting, and mental status  
10 changes only occur at the most extreme levels,  
11 systolic pressures in the 40 to 50 range before  
12 patients sustain cardiac arrest. So, they are not  
13 erroneous; they're just quite late, and so, one  
14 has to be very careful about considering them as a  
15 useful indicator because I think it would be  
16 difficult to assess their accuracy. Radial pulse  
17 is most accurate if one has a blood pressure cuff  
18 and can inflate the cuff until the pulse  
19 disappears.

20 That's not what's present here, and what  
21 I've suggested is that the military should  
22 consider the fact that there are ambulatory blood

1 pressure monitors today of using ultrasound  
2 technology that are about the size of a pack of  
3 cigarettes, run on batteries, weight about six  
4 ounces. They are routinely used for ambulatory  
5 blood pressure monitoring. They're extremely  
6 accurate, and they might not be appropriate for  
7 the frontline field application, but they  
8 certainly would be applicable for the evacuation  
9 chain at some point when there's a little more  
10 stability, and basically what's needed is an  
11 accurate monitor of blood pressure, and the only  
12 way to do that is some sort of effective blood  
13 pressure measurement. All of these other  
14 indicators are quite erroneous. It's been shown  
15 that paramedic measurement of blood pressure is a  
16 little better than a rounded number in the field,  
17 for example.

18 So, one has to recognize that under  
19 conditions of the field, noise, movement,  
20 agitation, a whole bunch of things, it's a very  
21 difficult number to obtain accurately, and I  
22 really congratulate Captain Timby and all the

1 people who have done the work on hypotensive  
2 resuscitation over the last 15 years. That is  
3 excellent work, and certainly is appropriate as an  
4 indicator. So, my quibbles with this are about  
5 purely the indicators for shock, not at all about  
6 the fundamental recommendations.

7           Lastly, it's really a quibble, but the  
8 blood pressure of 70 to 80 is probably higher than  
9 needed. Blood pressures of 60 to 70 would  
10 probably be perfectly adequate as a hypotensive  
11 level, as was shown in some of the earlier work  
12 dating from World War I, and that's probably  
13 appropriate.

14           So, my overall comments are Hextend is  
15 not harmful, but it's quite expensive, and it does  
16 nothing more than saline basically, and the  
17 indicators of the level of shock are highly  
18 difficult to ascertain, and I think the military  
19 should consider an evaluation of the ambulatory  
20 blood pressure monitors for applications somewhere  
21 in the chain because they're small, light, and  
22 would not be a major addition to what's already

1 being carried. Thank you.

2 CPT TIMBY:: If I could address the  
3 blood pressure monitoring for the ambulatory blood  
4 pressure, again, those are perhaps the right  
5 answer to the wrong question issue. In the  
6 ambulatory blood pressure monitoring, we are  
7 largely as internists, cardiothoracic folks  
8 looking at hypertensive management and what is the  
9 range of the blood pressures that those members  
10 may be experiencing? Again, usually, a fairly  
11 controlled environment. You're not far forward;  
12 you're not in the back of an ambulance. You're  
13 certainly not in the back of a helicopter. So,  
14 without seeing specific literature showing the  
15 sensitivity specificity, all the good stuff that  
16 we like to see to make decisions on something's  
17 applicability, I'd like to see it in the  
18 environment by which we will be using that.

19 In the fully-equipped evacuation  
20 platform of an evacuation, and, again, we use  
21 terms Casevac and Medevac, if you have a  
22 medically-regulated evacuation platform, i.e.,

1 medical personnel on the back of the helicopter,  
2 that is commonly referred to, and, again, services  
3 different, as a Medevac. Regardless of the term,  
4 that's why we've gone to tactical evacuation to  
5 get away from that. We're looking at point of  
6 injury back to first surgical opportunity as the  
7 phase of care we're looking for. I don't care  
8 what you call it.

9           Anyway, in those platforms, right now in  
10 Afghanistan, a large part of those are happening  
11 by helicopter. In the back of those helicopters  
12 are ProPACs, which are basically a very sturdy,  
13 very rugged, very aero medical tested -- again, I  
14 go to my Air Force brethren to say those things  
15 are tested and tested, and tested in the  
16 population that we're looking at, casualties.  
17 And just in the teleconference, a late entry was  
18 John Gandy, who was the Air Force Special  
19 Operations command surgeon for a number of years,  
20 and, thus, got his membership on our committee.  
21 John's comment was that they had tried some of  
22 those small units in the back of the helicopters

1 really just in exercise play and whatnot and got  
2 blood pressures that were just all over the page.

3 And, again, a random number generator  
4 probably would have given you as much accuracy as  
5 the monitors themselves. I say that tongue in  
6 cheek. What he actually did say is the blood  
7 pressures varied by 10s and 20s whereas the ProPAC  
8 gave a very consistent, solid, little variance.

9 So, again, what their determination from that was  
10 the equipment they had worked, gave them reliable  
11 information, and they did not find that the other  
12 agents were helpful in that setting. Again, not  
13 published information, but personal communication  
14 from the Air Force Special Operations Command  
15 surgeon in their field trials of just, hey, do  
16 these things work?

17 So, again, I would argue that in a  
18 tactical evacuation phase that we have the  
19 equipment that does the right thing, and I think  
20 we have the right measures. And, again, I  
21 appreciate your comments. I think the discussion  
22 at the committee level, what was the right number?

1       Seventy to eighty, I think, was my initial  
2       proposal. We argued it back and forth. It ended  
3       up at 80 to 90. Again, I don't have a strong --

4               DR. POLAND: I think those latter two  
5       issues on should it be 70 or 80 and what kind of  
6       blood pressure -- I think are much more minor  
7       issues that aren't going to be resolved by this  
8       board. I think the more substantial one is around  
9       the fluid resuscitation.

10              So, other comments? Dr. Shamoo?

11              DR. SHAMOO: Yes. As you know, we've  
12       talked some of this over a year ago.

13              DR. POLAND: Right.

14              DR. SHAMOO: And I want to augment what  
15       Dr. Parkinson said, and it's really addressed by  
16       Dr. Lewis' comments, and that is you could see  
17       there are too many variables, and the evidence  
18       we're depending on, they're at best moderate and  
19       may be to the range of poor, moderate to poor. I  
20       agree with you this is the status of medicine.

21              In the late '40s, the only way they  
22       measure radiation effect, they put a rabbit in a

1 nuclear reactor and see if they die. I mean, that  
2 was how you start science, unfortunately. You  
3 can't do a very sophisticated work when you start  
4 at the very, very beginning. We are not at that  
5 stage here. But we can recommend just what Mike  
6 said and what we said a year ago, and, obviously,  
7 nobody has done anything about it, is to design a  
8 research protocol concomitant with their use of  
9 the current status of knowledge. The design will  
10 be difficult, technically very difficult in a  
11 combat area, and ethically challenging, but,  
12 nevertheless, there should be an attempt to design  
13 and carry out such a research. Otherwise, we're  
14 going to be back two or three years from now at  
15 the same point with moderate to poor quality  
16 evidence.

17 DR. POLAND: Sorry, I'm not sure of your  
18 name.

19 DR. CHAMPION: My name is Howard  
20 Champion. I just would like --

21 MS. BADER: Dr. Champion?

22 DR. POLAND: Can you come to the

1 microphone?

2 MS. BADER: Can you please come to the  
3 mike? That helps our recorder. Thank you very  
4 much.

5 DR. CHAMPION: Better? I would like to  
6 insert a couple of comments relative to the last  
7 speaker's suggestion that we carry out these  
8 studies in the combat setting or even in the  
9 civilian setting. There have been probably 20, 25  
10 attempts in the past two decades to marshal  
11 studies that will address the issues of fluid  
12 resuscitation in post traumatic shock, and they  
13 have all failed for one reason or other. They're  
14 extraordinarily difficult to undertake because of  
15 the case definition of patients, the confusion  
16 with other injuries, head injury in particular.  
17 The frequency is low. They account for about 3 to  
18 4 percent of patients admitted to the average  
19 trauma center. That means you have to have  
20 multiple centers on common protocols of therapy in  
21 the middle of a Saturday night implementing these  
22 things, and it's not for want of trying that we

1     have failed miserably to marshal sufficient  
2     evidence to get a study comparing resuscitation A  
3     versus resuscitation B. I don't think there's any  
4     one of us in this field who wouldn't like to be  
5     recommending alternatives such as HSD, which is  
6     not approved by the FDA, despite 20 years of  
7     attempts to do so, or freeze-dried plasma, which  
8     is used in European countries and NATO forces  
9     working alongside American forces, are using it in  
10    Afghanistan today. So, we're behind the curve,  
11    but putting the solution down to getting class A  
12    evidence for this data is a little bit somewhat  
13    distracted from reality. We have really, really  
14    tried.

15           I was the data control monitor for the  
16    Factor 7 Studies globally and read into all of the  
17    difficulties of doing this at multiple sites, let  
18    alone multiple countries. So, we're putting  
19    forward today the best we can, and we are  
20    continuing to try hard. Dallas Hack, who's the  
21    commander of Combat Casualty Care Research at  
22    MRMC, is working with Colonel Holcomb to stand up

1 a multi-center trial in the United States as we  
2 speak. It will hopefully get 20 centers working  
3 together in a cohesive fashion to begin to develop  
4 methodologies that could begin to answer these  
5 problems. But it's not here today, and it's not  
6 going to be here in three years.

7 DR. SHAMOO: I agree with you fully,  
8 and, as a matter of fact, for five years, I was  
9 the consultant to ONR's clinical trial on blood  
10 substitute, and after five years of trying,  
11 getting preliminary data, you name it, and even  
12 doing some of the work in South Africa, and the  
13 FDA stopped us. So, I am very aware of the  
14 difficulties, but I don't think we should stop  
15 trying.

16 DR. POLAND: I don't think the board  
17 will have a problem with adding some statement  
18 about encouraging and supporting randomized  
19 clinical trials, but other than that statement,  
20 it's outside our sphere of influence. Let's leave  
21 that thread of discussion and focus on what is  
22 before us.

1 Dr. Jenkins?

2 DR. JENKINS: Don Jenkins -- can you  
3 hear that? -- from Mayo Clinic, Rochester. Frank,  
4 correct me if I'm wrong, but we do have some  
5 evidence, low-level evidence, but practical  
6 evidence from the 75th Ranger Regiment. About  
7 3,500 troops over a 10-year period, this is put in  
8 a publication, that's being reviewed for  
9 publication right now, about 430 casualties in  
10 that 10-year period of time of continuous combat,  
11 32 deaths. Each of the deaths reviewed, none of  
12 them preventable.

13 They have been following this exact  
14 protocol throughout that period of time. Trained  
15 on it using Hextend, using all the tactical combat  
16 casualty care techniques that you've heard about  
17 here today, and a case fatality rate that's less  
18 than half that of the conventional forces. So  
19 they've had this in place for 10 years whereas  
20 conventional forces really have just started to  
21 adopt this in the past 2 years.

22 So I would say -- I would submit that in

1 terms of available evidence is Hextend harmful, I  
2 could tell you that Russ Cotwall and Master  
3 Sergeant Harold Montgomery would tell you that, A,  
4 it's not harmful; B, it's their fluid of choice  
5 and they're not going to take saline into the  
6 battle space with them. They don't own a blood  
7 pressure monitor. It can't be done under the  
8 circumstances we're talking about where people are  
9 shooting at them. And every bit that they carry  
10 on their back does make a difference to them.

11 So I would submit that the evidence is  
12 there. And I think those are -- while I rounded  
13 those numbers off, that's pretty accurate. You're  
14 talking about a case fatality rate that's less  
15 than 4, which is less than half of what was  
16 reported at the beginning of the war in terms of a  
17 case fatality rate of 8 to 10, which is half that  
18 in Vietnam. So I would submit that there is some  
19 evidence that's out there.

20 And to the comment about, you know, what  
21 can this group do, I would submit to you that the  
22 evidence exists in the Joint Theater Trauma

1 Registry within the Joint Theater Trauma System,  
2 endorsing research of the available evidence.  
3 Facilitating that research I think would be  
4 something that this group could surely do, to look  
5 at the actual hands-on experience from the  
6 battlefield.

7 DR. POLAND: Dr. Butler.

8 DR. BUTLER: Yes, just to follow up on  
9 Dr. Jenkins' comments, didn't want to quote data  
10 that has not yet been published, but if the New  
11 England Journal accepts it, it will document the  
12 lowest rate of preventable deaths in combat ever  
13 recorded in modern warfare. Now, how much of that  
14 was Hextend versus how much of that was  
15 controlling the hemorrhage in the first place,  
16 I'll leave it for you to decide when you read the  
17 article. But the difficulty that we have had to  
18 overcome was the 15-year-ago large volume, just  
19 flood them with lactaided ringers. And I will  
20 tell you, at the January ISR Fluid Resuscitation  
21 Conference 15 years later, there was not one voice  
22 -- not one voice -- raised in support of that

1 previous strategy.

2 So I don't think we have the final  
3 answer, but I think we have clearly moved beyond  
4 large volume crystalloids.

5 DR. POLAND: Dr. Walker.

6 DR. WALKER: I was most impressed by the  
7 potential for the advantages of lyophilized  
8 plasma. And I want to know how can the Defense  
9 Health Board facilitate getting FDA approval for  
10 this product? I think it would offer lots of  
11 advantages. It'd be, I mean, a whole order of  
12 magnitude step forward over what we're doing now.

13 DR. POLAND: I don't know. Does anybody  
14 know the answer to that question? Generally you  
15 can't have the FDA do anything. (Laughter)

16 DR. BUTLER: So the number one research  
17 priority recommended by the ISR Fluid  
18 Resuscitation Conference was exactly what Dr.  
19 Walker said, lyophilized plasma. The U.S.  
20 Special Operations Command's command surgeon went  
21 to Dr. Rice and said, hey, our coalition partners  
22 are fielding freeze-dried plasma, using it on the

1       battlefield. We need to be able to do this, too.  
2       And is still squarely -- well, I guess it's not in  
3       Dr. Rice's lap anymore. It's now squarely in Dr.  
4       Taylor's lap.

5               DR. POLAND: Sounds like people are  
6       pursuing it.

7               DR. BUTLER: So I think that may be  
8       coming to the Defense Health Board.

9               DR. POLAND: Other comments?

10              CPT TIMBY:: To add to that, my  
11       understanding is casualties that -- actually these  
12       are U.S. casualties who are evacuated to Bagram or  
13       German facilities or other NATO partners. Our  
14       service members are receiving lyophilized plasma.  
15       So, again, depending on if it's a MERC team that  
16       goes out to evacuate or if it's somebody else  
17       makes the difference as to whether you're going to  
18       get a blood product, lyophilized plasma, a  
19       physician on the back of the bird versus not. And  
20       that adds credence.

21              DR. POLAND: Okay. I think the point  
22       that we're at is we have the best available

1 evidence and we have a preponderance of that  
2 evidence. We have the imprimatur of multiple  
3 professional societies that have looked at these  
4 data and, with the limitations stated, have come  
5 up with the recommendations that you have before  
6 them. So I'd like to entertain a motion to  
7 approve the guidelines.

8 DR. MASON: So moved.

9 DR. POLAND: And a second?

10 DR. PARISI: Second.

11 DR. POLAND: Any other discussion? If  
12 not, if we could have those that approve them  
13 raise your hand. Any against? Any abstain? Okay,  
14 the motion passes.

15 Dr. Butler, Captain Timby, thank you  
16 very much.

17 CPT TIMBY:: And thank you to the board.

18 DR. POLAND: We are ahead of schedule,  
19 which is a good place to be. What we're going to  
20 do is take a break. How long is the break?

21 MS. BADER: We'll take approximately a  
22 one-half hour break. If we can reconvene at

1 11:10.

2 DR. POLAND: Okay, long break. All  
3 right, 11:10 it is. And then Dr. Halperin, I  
4 think, is going to be up to bat. Thank you.

5 (Recess)

6 MS. BADER: Please take you seats.

7 DR. POLAND: Okay, in the interest of  
8 starting on time, we're going to start. Given  
9 that we are going to stay on time, it will leave a  
10 little extra time at the end of the day for PT  
11 before dinner. Several of you were going to  
12 recommend that strongly. You know I'm teasing you  
13 because I love you.

14 All right. Our next speaker this  
15 morning is Dr. James Kelly. He's a neurologist  
16 and renowned expert on concussion treatment. He  
17 serves as the director of the National Intrepid  
18 Center of Excellence. His past positions have  
19 included assistant dean for graduate medical  
20 education at the University of Colorado School of  
21 Medicine, director of the Brain Injury Program at  
22 the Rehab Institute of Chicago, and neurologic

1 consultant for the Chicago Bears of the NFL. Dr.  
2 Kelly is consulted frequently by professional,  
3 elite, amateur, and youth athletes who have  
4 sustained concussions. In addition, he is a  
5 fellow of the American Academy of Neurology and  
6 diplomat of the American Board of Psychiatry and  
7 Neurology, past president of the Colorado Society  
8 of Clinical Neurologists, and a consulting  
9 neurologist to the Defense and Veterans' Brain  
10 Injury Center, a component center of the Defense  
11 Centers for Excellence.

12 Dr. Kelly is going to provide an  
13 information brief on the National Intrepid Center  
14 of Excellence. His slides are under Tab 3 of your  
15 meeting.

16 Dr. Kelly, welcome.

17 DR. KELLY: It's a pleasure to be here  
18 and an honor, and, Dr. Poland, the one thing that  
19 I think wasn't mentioned that perhaps is most  
20 important for this group is that I served on this  
21 board briefly as the first chairman of the TBI  
22 External Advisory Subcommittee, and it was truly

1 an honor to do so. In fact, the very first day  
2 that that committee met was the day that General  
3 Loree Sutton and I met at the end of the day and  
4 she inquired as to whether I might be interested  
5 in such as the dog as the one I hold right now.  
6 So, it was a springboard and a wonderful  
7 opportunity for me to move in that direction.

8 So, what I'll do is try to stick with my  
9 45-minute time span. I understand there's a  
10 little flexibility in that. I would like to  
11 engage the group in questions, and I don't know  
12 the format that you prefer. Should we take  
13 questions as we go or we should we wait until the  
14 end of the discussion?

15 DR. POLAND: We don't really have a  
16 preference. Do you have one?

17 DR. KELLY: I don't.

18 DR. POLAND: Generally speaking, why  
19 don't we go through your presentation and then ask  
20 for questions? Oftentimes, they get answered as  
21 we go through.

22 DR. KELLY: Very good. The Intrepid

1        Fallen Heroes Fund is an organization which began  
2        in 1982 by Zachary and Elizabeth Fisher, both of  
3        whom have passed away, and it actually resides on  
4        the aircraft carrier the Intrepid that Zachary  
5        salvaged from the scrap heap essentially and  
6        turned into the museum that perhaps you know about  
7        in New York on the Hudson. They also started the  
8        Fisher House Foundation, 50-some houses I believe  
9        it is now that exist nationwide. One is in  
10       Europe. And their fundraising efforts under their  
11       nephew, Arnold Fisher, have led to additional  
12       opportunities for medical facilities to be created  
13       for our military service members, and the bottom  
14       picture here, you see is the Center for the  
15       Intrepid. Everything, of course, in name is  
16       connected to the aircraft carrier itself which  
17       opened at Brooke Army Medical Center in 2007, and  
18       it's primarily for amputation and functional limb  
19       loss care, a true wonderful world-class  
20       institution of its own.

21                    The NICOE was officially dedicated and  
22       proffered to the DoD in a ribbon-cutting ceremony

1 just this past June 24. The building is a \$65  
2 million gift of the American people by donations  
3 to the Intrepid Fallen Heroes Fund, and I'll go  
4 through the details of what the building has in it  
5 and what the program is that we're building to run  
6 it.

7 But here, I'm sorry it doesn't project  
8 better, but there's a lovely gold leaf impressed  
9 inscription on Italian marble in the front  
10 entryway of the building which reads "To America's  
11 military heroes in recognition of your patriotism,  
12 courage, and sacrifice, a place to heal the  
13 invisible wounds of war," and this is from the  
14 American people and the Intrepid Fallen Heroes  
15 Fund. So, this dedication appears on the wall  
16 right as you enter the building and I think really  
17 does tell the story as to what this is about.

18 The NICoE, the acronym for the National  
19 Intrepid Center of Excellence, covers about three  
20 acres on the National Naval Medical Center Campus  
21 in Bethesda. It's a 72,000 square foot, 2-story  
22 building. We ultimately anticipate about 111

1 personnel in order to serve its multiple missions.  
2 And the big-ticket items, if you will, in the  
3 building that are truly the most advanced  
4 technology that we have are the 3-Tesla MRI  
5 Scanner, which I'll go into some more detail  
6 about, which will offer functional as well as  
7 anatomical imaging. The positron emission  
8 tomography scan, the PET Scan, PET CT Scan,  
9 magnetoencephalography, which is a magnetic  
10 version, if you will, of EEG, looking much more  
11 deep into the brain's anatomy, transcranial  
12 Doppler ultrasound for blood flow studies,  
13 fluoroscopy and conventional X-ray radiography for  
14 shrapnel and swallowing studies and so forth.

15           And then the Computer-Assisted  
16 Rehabilitation Environment System, the CAREN, of  
17 which there are seven in existence in the world,  
18 and five of those are owned by the United States  
19 Department of Defense. It's a very sophisticated  
20 balanced platform and treadmill combination inside  
21 a large virtual reality screen in which  
22 individuals then can move about and be tested in a

1 safe environment, and we can actually assess them  
2 as well as provide for specific therapeutic  
3 interventions.

4 The vision of the NICoE is to be an  
5 instrument of hope, of healing, of discovery, and  
6 learning. And the mission, to be the leader in  
7 advancing world-class psychological health and  
8 traumatic brain injury treatment research and  
9 education.

10 This actually comes out of the National  
11 Defense Authorization Act of 2008, written in  
12 2007, of course, at which time the Defense  
13 Department's task by the Congress was to build a  
14 center of excellence around psychological health  
15 and one around traumatic brain injury. Those  
16 became melded, if you will, under the umbrella of  
17 the Defense Centers of Excellence when General  
18 Sutton came onboard, and at that same time, Arnold  
19 Fisher raised his hand and said I'll build it,  
20 I'll build you the center. And so, as a builder,  
21 being very familiar with military structure and  
22 the kinds of things that had already gone into the

1 Center for the Intrepid down in San Antonio, he  
2 decided then with the leadership in the DoD to  
3 find the proper location, which ended up being  
4 Bethesda, and then pulled together individuals, as  
5 I'll show you, meeting many, many times over the  
6 last two-and-a-half years in order to build the  
7 center as we have it currently.

8 The key principles of this NICoE are to  
9 be a model of interdisciplinary, diagnostic, and  
10 treatment planning in a very family-focused,  
11 collaborative environment promoting physical,  
12 psychological, and spiritual healing. It will be  
13 a research hub to leverage that unique patient  
14 base. The most current, technical, and clinical  
15 resources in order to initiate innovative pilot  
16 studies designed to advance medical science in  
17 traumatic brain injury and psychological health  
18 conditions. It will also serve as an education  
19 and training venue for the dissemination of next  
20 generation's standards of care and resilience to  
21 providers, as well as service members and  
22 families, and as an innovative platform committed

1 to long-term follow-up and family contact.

2 One of the things that Arnold Fisher  
3 will push in virtually every engagement we have  
4 with him is I want a string attached to that  
5 service member so that you can tug on it down the  
6 road a year or two years and say how are you? Did  
7 anything that we just did at the NICoE matter?  
8 Did it change things? If not, can we adjust fire  
9 and help in some other way? Are there services  
10 you need in addition to what we're offering and so  
11 forth? So, that long-term follow-up is something  
12 that we have a very robust system including  
13 computer database and telecommunication systems  
14 built into the structure of the building for that  
15 purpose.

16 So, in terms of the flow across time  
17 here, in the fall of 2007, the Defense Centers of  
18 Excellence for Psychological Health and Traumatic  
19 Brain Injury, DCoE was created. NICoE was  
20 actually conceived at the very same time to be the  
21 hub. Initially, it was thought to be the  
22 headquarters for the DCoE, and then that morphed

1       into various other kinds of opportunities with  
2       time, and DCoE being then the umbrella over NICoE  
3       and the other five centers of excellence within  
4       DCoE.

5               The NICoE was proffered as a building to  
6       DoD by the Intrepid Fallen Heroes Fund in 2007,  
7       and later that same month, General Sutton convened  
8       the very first working group in order to determine  
9       what the building had to have in it, what kinds of  
10      things it was going to do, how it could serve as  
11      an institute if you will, much like the NIH model  
12      for the combination of advanced clinical care plus  
13      research and education.

14             In January of 2008 through December of  
15      2009, the initial concept of operations was  
16      created by that group with input from academic  
17      centers around the country, as well as the  
18      military leadership, and a market analysis of the  
19      clinical and research requirements, including what  
20      needed to be in the building technically was all  
21      decided. I was hired in February of last year  
22      2009, which was the endpoint of my engagement

1 directly on this board. And then in spring of  
2 2009 to summer of this year, a variety of meetings  
3 and engagements have occurred leading to the  
4 ultimate programmatic design and preparation for  
5 the initial operating capability, which we are in  
6 currently.

7           The dedication ceremony, the  
8 ribbon-cutting happened on June 24, as I  
9 mentioned. And then there was an alignment shift  
10 from TMA Health Affairs, NICOE was moved  
11 programmatically under Navy, being that we're on  
12 the Navy Hospital Campus. Naval Support  
13 Activities Bethesda is ultimately responsible for  
14 the maintenance, upkeep, and so forth of the  
15 building. Programmatically, at least to stand up  
16 the building, and the program, it made sense to  
17 the military leadership to move us, and that was  
18 officially done on August 10 of this year. And  
19 then, as planned, according to the concept of  
20 operations and the initial planning session,  
21 October, just last month, we initiated the  
22 clinical care with our first cohort of patients

1 coming through the building, and we are now  
2 beginning our third cohort of patients last week  
3 and this week.

4 The org chart looks like this. The dark  
5 blue are the personnel that are uniform military.  
6 In fact, just recently joining is Rear Admiral  
7 Select Naval Captain Tom Beaman who's in the back  
8 row over here. Tom, if you want to raise your  
9 hand. Thank you. So that if anybody wants to  
10 raise Captain Beaman in discussions, he's now in  
11 my chain of command within NNMC; and as deputy  
12 director and chief of medical operations, Dr. Tom  
13 DeGrabga, a Navy captain; Mike Hendee as chief of  
14 staff; and then we have deputy directors across  
15 this horizontal row here. And all are in place  
16 except for our research deputy director at the  
17 present time. We have to stand up the clinical  
18 operations first and foremost, and then as the  
19 organization matures, the research piece will come  
20 along.

21 As you can see, the breakout of the  
22 staff numbers, the largest number are 38 within

1 the clinical operations directorate. We  
2 ultimately anticipate 12 unstaffed, uniformed  
3 service members, about 90 civilian, and 9 contract  
4 personnel.

5 This is for us to see 20 patients and  
6 their family members on any given day in the  
7 building once we are up to full operating  
8 capabilities. The ongoing research protocols  
9 require the usual run through of IRB approval and  
10 so forth, and I'll show you that we already have  
11 two of those underway. And then training and  
12 education will occur for service members,  
13 families, and their providers, and I'll go into a  
14 little more detail about that.

15 The main mission, we are a clinical  
16 operation on that Navy Hospital Campus to offer  
17 specialized, interdisciplinary diagnostic  
18 evaluations of complex TBI and psychological  
19 health conditions. So, we're talking about  
20 combined concussion or relatively mild in the  
21 spectrum of traumatic brain injury, mild TBI, and  
22 the psychological health problems such as

1 Post-Traumatic Stress in the same individual.

2 This is to be provided to the patient  
3 and family in a holistic clinical care  
4 environment. So, we're asking that family members  
5 join the service member at the NICoE. There's  
6 also a dedicated Fisher House that has just now  
7 become available just 200 yards away. There are  
8 three brand-new Fisher Houses being built on that  
9 campus, and the first one coming online is the one  
10 dedicated to the NICoE.

11 We will produce a comprehensive,  
12 individualized treatment plan. The entire  
13 approach is to identify that service member's  
14 problems and how that reverberates within that  
15 person's family. This is not a milieu treatment  
16 program where we bring in all 20 at one time and  
17 have them go through the same program together.  
18 They come one or two, maybe three when we're fully  
19 operational on any given day, and one or two or  
20 three will be discharged on a rotating basis as we  
21 go. We will be producing an individualized  
22 treatment plan during that span of time with the

1 detailed diagnostic workup that we do, and  
2 exporting the treatment plan with that service  
3 member back to where they came from or to yet a  
4 third location if, in fact, their needs dictate  
5 such a decision.

6 We will measure the outcomes internally  
7 and with the collaboration of the receding  
8 centers, wherever they end up as to the  
9 therapeutic interventions and the treatment plan  
10 as to whether it was successful or not.

11 All of this has been orchestrated by a  
12 series of small working groups comprised of expert  
13 panels both within military ranks and in the  
14 civilian sector as volunteers that have created  
15 recommendations specifically about the clinical  
16 evaluation process and putting together this  
17 treatment plan.

18 A lot of this really as we stood up the  
19 organization required that we actually look  
20 outside and with DCoE's help in particular, looked  
21 at existing clinical practice guidelines and then  
22 creating our own standard operating procedures,

1 borrowing oftentimes from Walter Reed and  
2 Bethesda's National Naval Medical Center in so  
3 doing, and actually just modifying them to our  
4 particular needs.

5 We had to also learn what the personnel  
6 requirements would be for those various missions  
7 and the equipment requirements, and then also what  
8 follow-up metrics made sense to use, and we've  
9 been very engaged in a national project called  
10 Common Data Elements, which engages NIH and other  
11 federal partners in determining what traumatic  
12 brain injury and psychological health measures  
13 should be on a menu, if you will, so that  
14 nationwide, we all can communicate in terms of  
15 outcome measures along the same lines.

16 So, the patient that will be coming to  
17 us is an active-duty service member with traumatic  
18 brain injury complicated by some type of impairing  
19 psychological condition who is not responding to  
20 the available, more conventional therapies in the  
21 military health system wherever they are.

22 So, that individual, again, will be

1 active-duty, they have mild to moderate traumatic  
2 brain injury at least at the very beginning. We  
3 are looking for individuals who have served in our  
4 current conflicts, OEF, OIF, OND, as Iraq is now  
5 called, and that they have persistent symptoms.  
6 So, this isn't somebody that's just recently  
7 returned. We want them to have engaged in the  
8 system that they're in, wherever that military  
9 health system may be, and then if in fact there is  
10 not success, then those individuals with complex  
11 or complicated problems will be sent to us.

12 They must have no active or untreated  
13 substance abuse disorder. So, we're not an  
14 in-patient facility. We won't be doing detox and  
15 so forth. And they have to be able to essentially  
16 function in a Fisher House setting and come for  
17 outpatient care five days a week, maintain their  
18 own day-to-day routines in terms of food and  
19 transportation and so forth, not be a danger to  
20 them self or others, and not be requiring the kind  
21 of nursing care that would require in-patient  
22 hospitalization.

1           So, in terms of the referral process  
2       from this point on currently until some time in  
3       the beginning of 2011, the way this works is that  
4       we have a continuity service that provides NNMC  
5       Warrior Care Clinic right there on our campus with  
6       the referral form, and then we actually have  
7       personnel that go back and forth between the two  
8       settings. The Warrior Care Clinic then fills out  
9       the referral form and includes additional records  
10      that are within the ALTA Medical Record System,  
11      which we are a part of at the NICoE.

12           Then we have a specific internal team  
13      made up of a psychiatrist, a neurologist,  
14      psychologist, social worker right now, and those  
15      individuals then look at that information and  
16      determine which of the group of patients referred  
17      might fit the program best and meet the criteria  
18      that I just mentioned. Those decisions are then  
19      discussed with the referring primary care provider  
20      in making sure we got the information that we  
21      really needed. Referral forms are being modified  
22      as we get feedback in this process because we want

1 to make sure we're actually making it  
2 user-friendly, if you will, and then the  
3 continuity service, we don't have another case  
4 manager group within the NICoE. We have people  
5 that are in a continuity system taking the service  
6 member from a case manager, handing back to a case  
7 manager, and not putting yet one more case manager  
8 in the system. We heard from the families early  
9 on, please don't give us yet one more case  
10 manager. We have eight or nine as it is, and so,  
11 we've decided how to make that transition as  
12 seamless as we possibly can.

13 We are then changing the forms such that  
14 they will ultimately be available shortly after  
15 the first of the year in a online referral form  
16 much like the Mayo Clinic as I recall, as I've  
17 over the years referred patients to Mayo. They  
18 have an opportunity for us to do that online, and  
19 it's processed internally. We've actually visited  
20 with Mayo to learn how it is that that's done on  
21 that end and try to emulate that here at the  
22 NICoE.

1           We have social workers, as I mentioned,  
2           that are continuity managers that work with that  
3           referral process, and then the interdisciplinary  
4           team works closely in determining the goodness of  
5           fit, then the warrior's command approval is very  
6           important within the military structure. We have  
7           to get them to the NICOE from wherever they might  
8           be around the country, and right now, the line  
9           leadership is very engaged in the process of how  
10          that's going to work, what the funding will look  
11          like, how the scheduling will work in their lives  
12          elsewhere, travel arrangements, and so forth.

13                 As you know, there are a limited number  
14          of family members. I believe it's still just one  
15          family member that can actually travel with a  
16          service member for this kind of medical care. So,  
17          if we actually have two family members, which is  
18          the model we're after, it may actually require  
19          additional resources that we're investigating  
20          right now.

21                 As the individualized treatment plan  
22          begins, that opportunity then for dovetailing with

1 where they're going back to is very important in  
2 this process and what treatment strategies will be  
3 available at that particular location need to be  
4 known right from the very beginning. And then  
5 we'll establish that long-term follow-up with  
6 those individuals after they leave. There's  
7 actually quite a large data server room in the  
8 NICOE which will house our own additional data for  
9 research purposes, but will allow us the  
10 opportunity to track individuals over a long span  
11 of time who've come through the building.

12 The evaluations that will be provided  
13 include a physical and neurological examination,  
14 psychiatric and psychological health evaluations,  
15 physical rehab, so, psychiatry evaluations,  
16 vestibular, as you can see. I don't know if I  
17 need to read this entire list to you, but the idea  
18 here is it's a very comprehensive both acute  
19 assessment as in let's see this for the first time  
20 even though we're getting records from outside or  
21 where they've been, but also expand it into a  
22 rehabilitation and long-term product care model,

1 if you will, so that we are as thorough and  
2 exhaustive as possible. It will include clinical  
3 pharmacy evaluations, spiritual counseling,  
4 nutritional evaluation, substance use assessments,  
5 and so forth. And we don't have all of these  
6 individuals onboard just yet even though we've  
7 begun our care process, but we will probably in  
8 the next four or five months have the bulk of  
9 that.

10 In terms of research, this is intended  
11 to serve as a collaborative research hub,  
12 leveraging advanced technical and clinical  
13 resources that we have internally and the  
14 environment for sharing across military systems,  
15 especially by the robust telecommunications and  
16 Internet connections that we have in the building.  
17 We'll also be designing and implementing pilot  
18 studies that look at the novel advances that we  
19 can create in the building with diagnostic and  
20 treatment strategies and serving as a knowledge  
21 source for evidence-based medicine and actually  
22 deciding what is the new evidence as we go,

1 building that forward so that we contribute to the  
2 literature in that regard as best we can.

3 And, also, we'll have a large database  
4 and specimen repository for bioinformatic analysis  
5 within the military system, and we are doing our  
6 best to make sure we're not redundant, but that we  
7 contribute by the gathering of specimen and by  
8 managing the interactions with existing systems  
9 around the DoD.

10 We'll be collaborating with Veterans  
11 Affairs, with DCoE, USUHS, NIH, Walter Reed, and  
12 so forth. One of the things that we've had a  
13 little bit of challenge around is the civilian  
14 academic piece because, as you all know, as the  
15 director of NICoE, I can't just pick a university  
16 as a partner. These kinds of opportunities have  
17 to be competed, and so, under those circumstances,  
18 we're a bit challenged as to how to move forward  
19 with that. There is some movement by a community  
20 organization to help us with a dedicated nonprofit  
21 foundation which would be able to serve that  
22 purpose and do the connections and creating those

1 collaborations, but as a military organization  
2 right now, we have the same sense of being  
3 confined and are certainly playing by those rules  
4 presently.

5 Our training and education mission is --  
6 I should start here at the bottom, perhaps --  
7 primarily aimed at the warrior and family members,  
8 and there are parts of the building that are  
9 specifically dedicated to teaching that service  
10 member about what happened to him or her and the  
11 family member so that the understanding is  
12 actually a big part of what they come away with.  
13 We've already heard from some of the service  
14 members in the two weeks that the very first  
15 cohort we had go through that they came to some  
16 ah-ha moment during that span of time. They  
17 actually concluded with this piece of it that's  
18 what the problem is, that's what's wrong here,  
19 that's why it's the way it is. This is where I  
20 need to go. Those sorts of awareness and insights  
21 because of the engagement with the clinical staff  
22 in this education process aimed at helping the

1 service members and families understand the  
2 problem. Really very powerful.

3 We will also have intra-professional  
4 staff development, team-building. The  
5 interdisciplinary exchange is a big part of this.  
6 I should explain that rather than the kind of  
7 thing I've typically had in the civilian sector  
8 where I have an entire team of all these different  
9 allied health professionals and colleagues, these  
10 people are actually part of a team in the same  
11 room at the same time gathering the information  
12 from the service member and family. So, when, in  
13 fact, they're sitting in this large living  
14 room-type setting that we have at the initial  
15 evaluation, the history is taken once rather than  
16 six or eight times in that span of time, and my  
17 team then gets to hear oh, that's what the  
18 physical therapist asks and why they want to know  
19 that, and that's what the social worker asks and  
20 why they want to know it. So, the  
21 interdisciplinary exchange amongst the  
22 professionals is enhanced under those

1       circumstances and efficiencies are brought into  
2       the process and the patient and family aren't  
3       annoyed by having to say the same thing six or  
4       eight times. Then we go off into the different  
5       things that we do separately and come back  
6       together working with that family in a  
7       collaborative fashion, but the interdisciplinary  
8       staff development is a part of the process. We  
9       don't pretend that we have it all figured out, but  
10      we're getting there and teaching that that kind of  
11      exchange is a big part of this model that we've  
12      created.

13               Then there will be continuing education  
14      for existing professionals in the CME and CEU  
15      fashion, but, also, we'll be creating many  
16      fellowships so that military health system  
17      personnel from around the country can come and do  
18      a month at NICOE and learn this, take it with  
19      them, learn our protocols, create, perhaps, a  
20      different angle, bring with them their experience  
21      and teach us. We certainly don't pretend to have  
22      all of it figured it. And so, this will be a

1 collaborative exchange in that fashion  
2 educationally, as well. We will have certainly  
3 students, residents, and fellows, especially on  
4 that campus with USU and with NIH across the  
5 street.

6           There will also be a network of reach to  
7 the locations around the military health system.  
8 Initially, Arnold Fisher right from the very  
9 beginning in 2007 was saying oh, you need a bunch  
10 of mini NICoEs around the country. Let us help  
11 you figure out where you're going to build these.  
12 Well, those discussions went on for about a year,  
13 year-and-a-half, and the discussions led to the  
14 conclusion that that was not a good use of  
15 resources and it didn't dovetail with the military  
16 health system, especially at the primary care  
17 level, and what we really needed was to reach into  
18 the existing systems either with a virtual or  
19 telehealth, telemedicine reach or truly by going  
20 to these various locations around the country.  
21 And so, the idea is to have an extension of what  
22 it is that NICoE is doing at various locations,

1 especially the biggest military health systems.

2           Some of our sister organizations, if you  
3 will, within the DCoE, the other centers already  
4 have personnel in those locations, and, once  
5 again, we don't intend to reinvent the wheel or do  
6 something that's redundant. We want to work  
7 together with the existing systems, Defense and  
8 Veterans' Brain Injury Center in particular that  
9 has those locations around the military health  
10 system. The Center for Deployment's psychology  
11 has 20 psychologists around the country, and we  
12 will work collaboratively with them in terms of  
13 what they're seeing at their locations and the  
14 referral process and the follow-up process and so  
15 forth. So, this network, this web throughout the  
16 military health system from the NICoE, conceived  
17 of as the hub for that purpose should be a very  
18 efficient use of collaborative efforts.

19           And what I wanted to do at this point  
20 was just to show what the Smith Group, the  
21 architecture firm that created the NICoE did as a  
22 short -- I think it's about a three-and-a-half

1 minute video since I can't get you in the building  
2 at this meeting. So, perhaps some other time,  
3 we'll have that opportunity.

4 (Video played)

5 (Video malfunctioned)

6 DR. KELLY: Maybe you will just have to  
7 come and see it for yourselves. (Laughter) It's  
8 always something.

9 DR. POLAND: Does it look like something  
10 we'll be able to bring up or no?

11 DR. CLEMENTS: It's saying it's at the  
12 end of the video already.

13 DR. KELLY: Oh, well, sorry about that.  
14 It certainly isn't.

15 DR. POLAND: Maybe we should proceed  
16 then.

17 DR. KELLY: Yes, okay. How about if I  
18 just go? I think there are a couple more slides  
19 and some follow on for discussions.

20 (Video played)

21 DR. KELLY: Yes, it does look like,  
22 according to the time bar across the bottom, it

1 reached the endpoint. So, I don't think there's  
2 much else we can do at this point. I apologize.

3 So, at this point, I think what I'll do  
4 is open it for questions and discussion. I have a  
5 couple more slides that may come up as handy in  
6 terms of some more internal detail if I haven't  
7 already answered questions. But I apologize that  
8 you're not going to be able to get a good view of  
9 the building at this point.

10 DR. POLAND: Thank you. What an  
11 incredible resource for the military.

12 General Myers?

13 GEN MYERS: Right, Dick Myers. Great  
14 presentation. Thank you. Much needed capability  
15 in our system, and long overdue. Roughly seven  
16 years overdue, but we're getting there.

17 My question is on priority of the folks  
18 who come through there. How do you envision that  
19 working? Are you going to intervene while these  
20 people are perhaps still at Walter Reed or up at  
21 Bethesda or other places where they're first  
22 determined to have something like TBI? Are you

1 going to intervene there, or is it -- I mean, how  
2 aggressive are we going to be in identifying  
3 people to send to this center, I guess is my  
4 question. Probably not a question for you, but  
5 for the other medical providers here because this  
6 is an opinion, but I don't think we've been very  
7 aggressive in trying to identify people. So  
8 often, they'll get discharged and then the VA has  
9 to contend with them.

10 So, the relationship with the VA that  
11 you mentioned is also very important here, but how  
12 do you see that priority working? When is your  
13 intervention going to happen and how are you going  
14 to encourage people at Walter Reed to -- I mean, I  
15 assume they will be encouraged or at Bethesda to  
16 use your capabilities, these wonderful  
17 capabilities.

18 DR. KELLY: We are working, even earlier  
19 today, the integrated TBI leadership, the  
20 integrated system leadership and I met today with  
21 Captain Beaman to talk about some of these very  
22 issues about how that's going to work out because

1       there are places already doing the doing, if you  
2       will, of traumatic brain injury care.  What we  
3       bring to it is that the psychological health piece  
4       in the same individual in a way that I'm not sure  
5       has been done before and needs to be done, in our  
6       opinion.  And so, in terms of where they come from  
7       and how it works throughout the MHS, this  
8       institute, if you will, of the NICoE itself is not  
9       going to be a clinic and a solution for seeing  
10      lots and lots of patients in a high volume.  It is  
11      intended to inform the system how it is that what  
12      we're seeing can be handled perhaps better,  
13      perhaps more urgently, quicker, picked up on  
14      earlier in the course of the problem and so forth  
15      before things get to the crisis point.

16                 And so, one of my jobs that I'm  
17      absolutely thrilled about doing is going from  
18      place to place, especially the big military  
19      platforms, and talking with the line leadership as  
20      well as the health care provider leadership and  
21      the TBI Program specialists about what they see,  
22      what their needs are, what we can offer them, what

1 their problems are in trying to get services at  
2 the various places they are around the country,  
3 and it's a remarkable opportunity for us to  
4 communicate about this and then to say okay, your  
5 most complicated cases where you're just  
6 scratching your head and saying I need some  
7 guidance on this and I need some help, I need  
8 another opinion, whatever, those are the patients  
9 that we're asking for at the present time.

10 Now, the current thinking is that those  
11 will be people who are in that very small subset  
12 who have lingering symptoms that haven't been  
13 addressed or couldn't be treated already in the  
14 systems they're in. We may later find out that  
15 that isn't going to be really the best way to go,  
16 and what we really need is a very front-end,  
17 acute, new condition, new problem, okay, you go to  
18 NICoE and then you go to some other location. So,  
19 what we're really looking at right now is to try  
20 to help those individuals that we keep reading  
21 about and hearing about as I go around the country  
22 who have lingering symptoms and they say we've

1     tried that, we've tried that, we've tried this,  
2     and nothing has worked. Your turn. You figure it  
3     out. So, right now, that's the approach we're  
4     taking, and for many of these people, it's months  
5     down the road after their return from a deployed  
6     location. It may be that we need to morph  
7     generally into some other approach.

8             GEN MYERS: I guess what it leaves out  
9     is that population has been discharged that has  
10    the issue and are at the mercy of the system,  
11    whatever that system is, or might not even know  
12    why they are the way they are. So, I know it's  
13    not in your scope, but one of the questions,  
14    because I think it is in your scope, my assumption  
15    then is that you have had some contact with this  
16    MIT collaboration initiative that ASD Health  
17    Affairs has funded.

18            Are you in touch with them?

19            DR. KELLY: Yes, the Summit Program.

20            GEN MYERS: No, no, it's a recent  
21    program that I assume other people know about, but  
22    it's --

1 SPEAKER: Dr. Tenley Albright.

2 GEN MYERS: Tenley Albright and Ken  
3 Caplan up at MIT, are you --

4 DR. KELLY: Yes, sir, we are involved  
5 with them, as well. Yes, sir.

6 GEN MYERS: Because what you're doing is  
7 -- they've got to know what you know because it's  
8 going to be part of their more extensive study.

9 DR. KELLY: We're already hooked in.  
10 Thank you.

11 GEN MYERS: Great. Perfect.

12 DR. LEDNAR: Wayne Lednar.

13 DR. KELLY: Hi, Wayne.

14 DR. LEDNAR: A question, as you've  
15 emphasized in your concept the importance of  
16 family to be involved in the care planning and  
17 care delivery. For a number of these young  
18 service members, their family is their squad, is  
19 their platoon. So, I'm wondering how your concept  
20 will incorporate how their military units, who  
21 they spend a lot of time with, can become part of  
22 the next step after they finish at the NICoE.

1           And then, secondly, as you travel to  
2       these various MHS facilities, do you feel like  
3       you're able to get an approach which gets beyond  
4       the usual medical, surgical silo and really gets  
5       across discipline approach to these patients where  
6       not just the medical needs, but the psychological  
7       needs of the patient are part of the care plan  
8       once they get to their next installation.

9           DR. KELLY: To your first question, we  
10       have defined "family" in the broadest sense we  
11       know. It's who the service member thinks of as  
12       family. And so, what we struggle with is what  
13       happens if somebody can't bring anyone, and we  
14       don't have a solution for that just yet. Right  
15       now, the patients that have come since the Fisher  
16       House hasn't been available, are coming from this  
17       part of the country right now, and they travel in  
18       each day either from Walter Reed or from some  
19       other location where they're residing while  
20       they've been getting their care in this area and  
21       are being handed off to us. And so, the Fisher  
22       House isn't online, and so, we don't have the

1 families with them.

2 We will be very shortly at the point  
3 where we'll be using that Fisher House for the  
4 families, as well. So, that the service members  
5 come by themselves, and we've already engaged that  
6 individual, and the families then are individuals  
7 either true, biological families, family members,  
8 or individuals close to them in their lives that  
9 they bring in for wrap-up sessions and that sort  
10 of thing. So, we are going to have to be creative  
11 as to how it is it works for given individuals who  
12 don't have family other than their identified peer  
13 group, and that's something we're going to need  
14 advice about.

15 As to the MHS piece of it and the  
16 questions about how it's received out there, the  
17 opportunities for what's available throughout the  
18 MHS are so widely variable, as perhaps you know,  
19 that there are some locations where we simply  
20 don't have the opportunity to send patients -- I  
21 can't imagine sending them back to certain  
22 locations because of the paucity of resources in

1 certain locations. And what I've been trying to  
2 do, and this is one of the things with Arnold  
3 Fisher not exactly whispering in my ear, but  
4 saying things to me, bring the academic community  
5 into those locations as best you can, and that's  
6 something that so many of the military leaders  
7 have asked for, as well.

8           And so, when I went to Fort Hood, for  
9 instance, I brought the lead neuropsychologist  
10 from the University of Texas-Southwestern in  
11 Dallas down so that he could be there for the day  
12 with me to engage with him to determine how could  
13 his university help under the circumstances of the  
14 very limited resources that are available in  
15 Killeen, Texas? We did the same thing at Fort  
16 Bliss. Fort Carson has University of Colorado.  
17 Fort Camel has a very sophisticated connection to  
18 Vanderbilt. And so, some places have already made  
19 those engagements and connections, and at those  
20 locations, they actually have elevated the level  
21 of sophistication that we can actually deal with  
22 in those centers, and, in many cases, learn from

1       them as to what it is they've already created and  
2       how it is they've been functioning in that  
3       setting.  But it's widely variable from San Diego  
4       to Killen, Texas.  I mean, it's just a huge  
5       difference in terms of available resources and  
6       programs.

7                 DR. POLAND:  Dr. Kelly, I understand you  
8       have another three slides or so you want to show.  
9       I know one of them is on research.  When you show  
10      that slide, could you give us maybe just a brief  
11      background on what the research infrastructure and  
12      budget will be, or do you have to go out and  
13      compete for those dollars?

14                DR. KELLY:  As it stands right now, we  
15      do not have a fixed research budget through the  
16      RTD&E process, but we are working toward getting  
17      that as a piece of what happens and then  
18      separately we're looking at philanthropic and  
19      potentially appropriations from Congress that  
20      would also be aimed at research that we will  
21      direct form the NICOE itself.

22                At the present time, we're actually in a

1 bit of a bind. So, for me as a civilian,  
2 government employee at the NICoE, I could not  
3 serve as a PI on a grant that was a DoD grant  
4 because I wasn't considered to have an internal  
5 influence, if you will, or that kind of conflict  
6 of interest bias that my position brings to that  
7 very process. And so, I'm boxed out from  
8 participating in the competitive process for the  
9 NICoE because I'm at the NICoE. And so, we have  
10 to be a little bit more creative as to what those  
11 solutions are.

12 Now, other individuals have already  
13 brought in the National Capital Consortium TBI  
14 Neuroimaging Project. Actually moved from Walter  
15 Reed over into the NICoE when the PI brought it  
16 with him, and we were able to work that piece out,  
17 but it already existed in that setting. And then  
18 we are the data repository or we will be the data  
19 repository for the big hyperbaric oxygen protocol  
20 that will start up after the first of the year.

21 So, again, our data-gathering system,  
22 our neuroimaging piece is actually a part of that

1 study. The outcomes assessment center that's in  
2 the Town of Colorado Springs outside Fort Carson  
3 and the neuroimaging and rehab piece that actually  
4 are on post. The data that's gathered there will  
5 then sent to the NICoE, and we will participate  
6 under those circumstances with that funded  
7 research. As we get down the road a little bit  
8 farther and we have other streams of research  
9 dollars, we'll be able to build our own.

10 DR. POLAND: Dr. Silva?

11 DR. SILVA: Joe Silva. You only have to  
12 concentrate on mild and moderate. Or I don't mean  
13 "only." It's a big load. What's going to happen  
14 to those that have advanced or severe levels of  
15 these problems?

16 DR. KELLY: Right now, the model  
17 typically is that the severe traumatic brain  
18 injury care that's provided in the big hospitals,  
19 Walter Reed, National Naval Medical Center, and  
20 then Brooke Army Medical Center, although,  
21 certainly, it can be done in other locations,  
22 those individuals receive the acute care there.

1 Walter Reed has a rehabilitation piece of that  
2 that's been around for years, and the Defense and  
3 Veterans' Brain Injury Center works more closely  
4 with that than to bridge to the VA System where  
5 the rehabilitation can be ongoing and much more  
6 long-term. So, that's actually farther along and  
7 more sophisticated in the care, especially for  
8 penetrating brain injury in this current conflict  
9 is superb. I mean, it's truly advanced  
10 significantly from where we had been in the  
11 civilian sector and so forth just years back.

12 We all need to learn about mild  
13 traumatic brain injury. We don't have even  
14 well-accepted protocols in the civilian academic  
15 world for how to treat this. There are multiple  
16 things that have been tried and we will be, again,  
17 one of the places where this experimentation, if  
18 you will, is implemented. But the huge numbers of  
19 individuals with that problem and with a combined  
20 psychological stress profile and TBI together is a  
21 whole new problem that these conflicts are  
22 bringing back into society that we just haven't

1 deal with before. And I think we're doing our  
2 best to push that forward.

3 DR. POLAND: Dr. Shamoo?

4 DR. SHAMOO: Jim, as usual, great  
5 presentation, as well as this is an incredible  
6 resource to our country.

7 It's going to be very highly sought  
8 after facility by those who have those problems of  
9 TBI-related problems. How are you going to select  
10 so few from literally tens of thousands of  
11 potentially complicated and the clinical care is  
12 really not well-defined yet.

13 DR. KELLY: We do anticipate that being  
14 an issue and a concern, and, in fact, as we look  
15 at those that we think have the most complex and  
16 complicated courses, we actually then are  
17 filtering out many, many others that perhaps can  
18 be dealt with if, in fact, you take a piece of  
19 what is available at one military location and  
20 then bring it to another where they are, and they  
21 don't need to come to NICoE. And so, we will  
22 actually engage in those discussions ahead of time

1 with the providers and say gee, why don't you  
2 contact so-and-so at this location, see what  
3 they're doing with this very same problem, and see  
4 if that would help under the circumstances?

5 So, once again, if you look at the  
6 numbers, we're going to, when fully operational,  
7 see about 500 patients a year. Right now, that  
8 doesn't sound like a huge number, but if you  
9 actually look at all the data points of what is  
10 we're gathering and how it is that these complex  
11 conditions will be understood better, we will then  
12 be able to discuss that more broadly throughout  
13 the MHS and influence the system. That's the  
14 entire intention here is to be that rising tide  
15 that lifts all boats, not just see patients. It's  
16 not yet one more clinic; it's truly a DoD  
17 institute for this problem.

18 DR. SHAMOO: So, what's the selection  
19 process? What is the decision-making process,  
20 because there will be potential problems among  
21 those patients and how you're going to make the  
22 selection. Do you have a flow chart, do you have

1 a committee, do you have something?

2 DR. KELLY: We have now there will be a  
3 board of advisors within the DoD leadership in  
4 Health Affairs and within the surgeon general  
5 ranks that actually guides that thinking and  
6 collaborates with their systems in each of the  
7 services so that the decisions as to quotas  
8 perhaps or which locations and all that sort of  
9 thing will be decided not just by us  
10 idiosyncratically, but by the military leadership.

11 DR. POLAND: One more question, and then  
12 I think we'll stop for lunch.

13 DR. MASON: A repast. Tom Mason. Just  
14 a quick question, picking up on what Dr. Shamoo  
15 has just alluded to and in on of your slides when  
16 you refer to your follow-up metrics, could you  
17 give us some indication as to how many times these  
18 individuals are actually going to be seen, leaving  
19 aside your clinical interventions at NICoE.  
20 Because you have 500 persons per year. With what  
21 regularity, on what schedule are they actually  
22 going to be followed-up? Who does the follow-up?

1       Because 500 persons can be large enough to address  
2       certain things depending upon how many times  
3       you're going to see them over a span of 6 months,  
4       12 months, or 18 months. Has that been worked out  
5       at all?

6               DR. KELLY: It has been discussed. We  
7       haven't settled on it just yet. If you use the  
8       civilian model, it would be one month out, and  
9       then six months out, and then a year from that,  
10       and I'm not sure that that's enough under the  
11       circumstances, and it sounds like you might agree.  
12       And I think that the level of granularity of our  
13       assessments in follow-up is going to be important,  
14       too. It's not just a matter of return to duty or  
15       not return to duty, it's not just functional  
16       independence measure and things like that because  
17       we're dealing with a completely different  
18       population than measures like that were intended  
19       for.

20               DR. POLAND: Okay. Thank you very much.  
21       Appreciate you coming.

22               DR. KELLY: Thank you.

1 DR. POLAND: Incredible information.

2 DR. KELLY: Thank you all. (Applause)

3 DR. POLAND: We're going to break for  
4 lunch, and Ms. Bader will give us some admin on  
5 that in just a moment. I will ask the members of  
6 the ID Subcommittee to meet at the far table in  
7 the room where we're having lunch.

8 Ms. Bader?

9 MS. BADER: Thank you. We will now  
10 break for lunch. An administrative session will  
11 be held next door where we had breakfast this  
12 morning. So, we invite the board members,  
13 ex-officio members, service liaisons, and DHB  
14 staff. Also, our distinguished guests. Catered  
15 lunch next door. I made an announcement earlier  
16 this morning regarding other places to eat for our  
17 guests that are not part of the official group, if  
18 you will.

19 So, we will reconvene at 1:15. I'd like  
20 to ask Dr. Shamoo, did you want to meet with your  
21 Medical Ethics Committee during lunch?

22 DR. SHAMOO: Yes, yes, at lunch.

1 Please.

2 MS. BADER: Okay, so, Medical Ethics  
3 Committee, please look for Dr. Shamoo. He'd like  
4 to have a small meeting during lunch. And we'll  
5 see everybody back here. And Dr. Halperin would  
6 like to meet with his group, as well. So, and we  
7 will meet back in here at 1:15. Thank you.

8 (Whereupon, at 12:08 p.m., a  
9 luncheon recess was taken.)

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1 armed forces.

2           Since the Board issued its guidance and  
3 endorsed the findings and recommendations of the  
4 task force during the meeting held on July 14th  
5 earlier this year, the task force has produced a  
6 final report and delivered it to the Secretary of  
7 Defense. Major General Volpe will provide an  
8 update on recent activities regarding the task  
9 force report, and I believe his slides under tab 4  
10 -- I'm just going to ask Ms. Bader to make one  
11 comment before the General starts.

12           MS. BADER: Sure. I just wanted to let  
13 everybody know that the task force had their last  
14 meeting a couple of days ago in the Washington  
15 D.C. area, where they gathered to conduct  
16 basically a hot wash, if you will, and look at  
17 some lessons learned. General Volpe will talk  
18 about that a little bit.

19           But just I wanted to make everyone aware  
20 that on behalf of the Board and the vice  
21 presidents, each task force member was presented  
22 with a coin from the Defense Health Board and a

1 letter of appreciation from Dr. Taylor, who is  
2 performing the duties of the assistant secretary  
3 of defense for health affairs.

4 Thank you. General Volpe?

5 MGEN VOLPE: Great. Well, thank you  
6 very much, sir, ma'am, the entire Board. Thanks.

7 It's good to be back again and brief  
8 you. I am Phil Volpe and Ms. Bonnie Carroll is  
9 the other co-chair on the DOD task force on the  
10 prevention of suicide by members of the armed  
11 forces. And Colonel Joanne McPherson at the end  
12 down over there is our executive secretary, who  
13 many of you have seen at multiple meetings.

14 We've briefed this Board many times  
15 before. IPRs, if you will, along the way of the  
16 deliberations of the task force. Prior to us,  
17 publishing the report and then we briefed you  
18 right around the time that we published the  
19 report.

20 And this is a follow-up to just  
21 basically discuss our activities since that time,  
22 now that the Board has completed -- now that our

1 task force has completed its mission and its  
2 responsibilities and has essentially been  
3 disbanded as a task force at this time.

4 So if we could go on to the next slide,  
5 please. As you all know, we met from August of  
6 2009 to August of 2010 with the charge of the task  
7 force is to make recommendations to the Secretary  
8 of Defense on a comprehensive policy to prevent  
9 suicide by members of the armed forces. This was  
10 directed in NDAA '09, and that was why the  
11 Secretary of Defense organized and created our  
12 task force. Next slide.

13 Well, we completed our mission, as you  
14 know, and submitted our report. Now, we had  
15 briefed the Defense Health Board a month earlier.  
16 Our initial plan was to release the report on the  
17 5th of August, and we took a couple of extra weeks  
18 because the task force felt that -- actually, the  
19 input from the Defense Health Board was very  
20 critical to make sure that we included. And so we  
21 actually -- we made some modifications to include  
22 many of the recommendations that this Board had

1       made to us in the July timeframe and had met on  
2       many occasions between that July and August  
3       timeframe.

4               We also conducted a press conference,  
5       but the report was submitted to the Secretary of  
6       Defense on the 24th of August. And that was --  
7       that completed the mission of the task force.  
8       Many of you have seen the report. I think we sent  
9       a copy to each of the members of the Defense  
10      Health Board and had seen the roll-up, including  
11      the executive summary towards the front of this.  
12      And a whole bunch -- a whole slew of appendices to  
13      support the information that we provided in there.  
14      But there were 49 findings, 76 recommendations,  
15      and then many of those recommendations were  
16      aggregated into what we considered 13 foundational  
17      recommendations. And those have all been in the  
18      report and briefed to this Board previously.

19             Since that time, we've gotten a lot of  
20      requests for briefings. And even though our task  
21      force on the prevention of suicide has been  
22      disbanded or has concluded, you know, we will

1 always make ourselves available to brief what's in  
2 the report and about the report and the findings  
3 and recommendations and our thinking process and  
4 deliberations about that. We just feel that  
5 that's our duty, and every member of our task  
6 force has agreed to do that, regardless of where  
7 they are located and the individuals -- and the  
8 groups and individuals that request us to conduct  
9 those briefings.

10 We have -- I felt very confident we've  
11 kept complete transparency the whole time and did  
12 not hold anything back as far as the deliberations  
13 go and what we placed in the report, and that we  
14 were, as an independent task force, were  
15 uninfluenced by any outside body other than the --  
16 you know, recommendations from experts out there  
17 on, you may want to look at this a little  
18 differently and input here and there. So it's  
19 been very -- I'm very confident about that.

20 On 8 September we briefed the Wounded,  
21 Ill, and Injured Overarching Integrated Product  
22 Team at the Pentagon. We also had a meeting with

1 the DoDIG, and that had to do specifically with  
2 the investigations portion -- standardizing  
3 suicide investigations across DoD, because the  
4 DoDIG is the primary office that considers all  
5 investigations within DoD and writes the  
6 regulations and policies that the services follow  
7 on that. And so, they were very interested in  
8 what we had written in there and, again, we went  
9 into open discussion with them at that meeting.

10 And then we briefed on 17 September the  
11 Wounded, Ill, and Injured Senior Oversight  
12 Committee, headed up by the Deputy Secretary of  
13 Defense and the Deputy Secretary of the VA. And  
14 we briefed our summarized findings and  
15 recommendations in each of our four focus areas as  
16 we have outlined them in the report, and so that  
17 they fully understood what our report said.

18 On the 23rd of September, we were  
19 involved -- and we will continue to be involved --  
20 with briefings to audiences, you know, webinars,  
21 seminars, and those kinds of things in conjunction  
22 with other bodies that have also investigated or

1 reviewed suicidal behavior and suicide prevention  
2 and have made -- have additionally made  
3 recommendations with their expert bodies along the  
4 way. And the RAND Corporation is one of those who  
5 have provided a report, and there's other  
6 organizations out there, too.

7 In reviewing all of these -- they're  
8 very consistent and collaborative. Each has a  
9 little unique twist and focus area, a little  
10 different, in suicide prevention. But overall  
11 they're very complimentary of each other, these  
12 various bodies.

13 On the 7th of October, we had a great  
14 session with Admiral Mullen in the Pentagon and  
15 his staff. The chairman is very interested, as in  
16 all the service senior leadership are interested  
17 in suicide prevention. Very much concerned about  
18 the number and rate of suicide and what we are  
19 physically doing on this. And Admiral Mullen  
20 basically gave his staff -- charged his staff to  
21 look at what current recommendations in the report  
22 -- what recommendations in the report can we do

1 right away. Because he sees this as a crisis and  
2 believes it will get worse, the suicide rate,  
3 before it gets better. So looking to start  
4 implementing our recommendations right away and  
5 seeing how he could use his influence within the  
6 Department to make that happen.

7 October, we also had a meeting with the  
8 Deputy Undersecretary of Defense for Readiness.

9 And this is key, because the Deputy Undersecretary  
10 of Defense for Readiness is one of the individuals  
11 that would be involved with one of our  
12 recommendations that we established as DoD suicide  
13 policy division within the Undersecretary of  
14 Defense for Personnel and Readiness. And so, they  
15 already appear to be linked in, getting background  
16 information, asking the right questions, reading  
17 through the report, and looking also at writing  
18 the response that the Secretary of Defense will  
19 provide to Congress as DoD forwards our report up  
20 to Congress. And I will talk about that in a  
21 second.

22 On 21 October, we had an opportunity and

1 briefed the Defense Senior Enlisted Leaders'  
2 Conference. All of the senior enlisted from  
3 around the services and the combatant commands  
4 were at the Pentagon for a semi-annual conference  
5 that they do and they requested that we brief them  
6 on our findings and recommendations for suicide  
7 prevention. And we focused it on that in Senior  
8 Enlisted Corps, and some of the things that we saw  
9 that would be beneficial for them in their suicide  
10 prevention programs through their organizations  
11 and units around the Army, Navy, Air Force, and  
12 Marine Corps.

13 On the 28th and 29th, as Colonel Bader  
14 mentioned, we did the task force hot wash. Two  
15 focuses of this hot wash were, I wanted to make  
16 sure that before the task force completely  
17 disbanded, that we picked up some lessons learned.  
18 So we're actually going to publish lessons learned  
19 about everything from putting our task force  
20 together to our methodology in producing the  
21 report, some of the things we learned along the  
22 way, clinically and operationally of the task

1 force, and provide that to the Defense Health  
2 Board and to DoD Health Affairs in case any other  
3 future task forces would be interested in seeing  
4 some of the lessons that we learned in our  
5 deliberations and how we went about with our  
6 methodology to produce this report in a one-year  
7 timeframe.

8 So, we decided to do that. And then we  
9 also wanted to make sure we aligned up our  
10 strategic messages appropriately, because we  
11 believe that there'll be ongoing interest in  
12 requesting members of our task force to either be  
13 parts of other task forces or communities or  
14 subcommittees, or organizations within DoD and  
15 outside DoD on suicide prevention. And  
16 additionally, we are anticipating that at some  
17 point we may very well be summoned to testify  
18 before Congress, since this was generated through  
19 the NDAA '09 from Congress to establish this task  
20 force in this process. And if that came, it  
21 probably would be after OSD or the Secretary of  
22 Defense would submit their -- his response or

1 DoD's response to our report, which is due to  
2 Congress somewhere around the 24th of November of  
3 this year. So, sometime at the -- towards the end  
4 of this month, which is 90 days after we submitted  
5 our report, was the requirement.

6 And then we've already been requested to  
7 speak at the VA-DoD Suicide Prevention Conference  
8 as part of a panel. Suicide prevention overall  
9 between the VA and DoD in the future. Next slide.

10 Okay. I mentioned the report. You all  
11 have it, and in that report I said it's a pretty  
12 thorough recommendation of our findings and  
13 recommendations. And a whole lot of background  
14 and supporting material that is in there, and our  
15 approach and methodology to publishing this  
16 report.

17 I always -- I mentioned those 13  
18 foundational recommendations. But there's three  
19 takeaways we always brief for members of the task  
20 force that we brief. And one of the large  
21 recommendations that we have made is, these three  
22 recommendations, particularly, are considered by

1 our task force as not only key foundational  
2 recommendations but must be addressed and is sort  
3 of a little unique or different from other task  
4 forces and bodies that have looked at suicide  
5 prevention who have focused more internally into  
6 the services.

7 And one of them is to establish a  
8 suicide policy division in the Undersecretary of  
9 Defense for Personnel and Readiness. There  
10 currently is no full-time staff body that looks at  
11 suicide prevention in all of DoD. It is entirely  
12 embedded within the services. And there is no one  
13 to get resources for the services to standardize  
14 nomenclature, standardize reporting procedures,  
15 standardize investigations, and to help  
16 collaborate with advisory bodies outside DoD as  
17 suicide prevention unfolds in the future. And so  
18 that was a large recommendation that we had made  
19 in there.

20 The second one you see there is to  
21 reduce stress of the force. Our task force  
22 clearly found a supply/demand mismatch on the

1 force. What we found was just absolutely amazing  
2 that our servicemen and women -- remarkable.  
3 They're remarkably resilient, but remarkably take  
4 on the mission and do what they're told and,  
5 patriotically, and loyal, regardless of what the  
6 task is ahead. And we utilize them a lot for the  
7 national security of the United States and they,  
8 you know, bear the burdens that come along with  
9 that. The physical and psychological damage that  
10 occurs from meeting those demands.

11 And I use the word "damage" because lack  
12 of a better word. But it's this accumulation of  
13 stressors, repeated separations with families,  
14 repeated disconnectedness, putting your life on  
15 hold for deployments, and then repeat deployments.  
16 And the overall OP tempo and stress on the force.  
17 And a lot of the things that are in the Army  
18 suicide prevention report specifically address  
19 that same topic as well when they talk about the  
20 lost art of garrison leadership. There isn't  
21 quite enough -- the same amount of time to do all  
22 the mentoring and coaching and leadership

1 oversight -- professional development that we were  
2 doing at one time before these wars started,  
3 because there's so many tasks and things to do to  
4 support the fights downrange and the missions that  
5 we're churning and burning and going over and  
6 over.

7           So, this was very important to  
8 acknowledge that there is stress on the force and  
9 it's fatigue. And again, it's remarkable what our  
10 men and women do that, you know, I -- the term out  
11 there is "suck it up and drive on." But, you  
12 know, they do what they're told to do and it's  
13 absolutely amazing, regardless of any barriers or  
14 anything in the way.

15           And so we owe it to them to look at  
16 suicide prevention and everything we could do to  
17 help them normalize their lives again, both  
18 physically and emotionally, and spiritually and  
19 psychologically as they return and meet the  
20 missions for our nation.

21           And then the third point there in  
22 suicide prevention is a leadership issue. And

1 this was very important because it tends to be  
2 tucked into the medical community in a lot of  
3 places, but it is clear that it is a leadership  
4 issue.

5 Now what we saw in our task force that  
6 strategic leaders are very much engaged. But then  
7 it starts to disintegrate as you go down to junior  
8 leader positions. In other words, junior leaders  
9 and mid-grade leaders aren't as well-versed and  
10 engaged in suicide prevention because of the op  
11 tempo and everything that's -- all the demands on  
12 their plate from day to day, as our strategic  
13 leaders are. And we have to find a way to make  
14 time to get them more engaged and create those  
15 positive command climates where it's going to make  
16 a difference. The small unit level is where it's  
17 going to make a difference. And so it needs to  
18 stay in the leader's lane, not in the medical  
19 lane. We could never underestimate the impact of  
20 leadership on suicide prevention, or anything else  
21 that we do. And I think we've known that pretty  
22 well throughout the history of the United States

1 military.

2           And we also clearly saw the difference  
3 of very positive, engaging leaders who get it and  
4 the differences in the outcomes of their soldiers,  
5 sailors, airmen, marines. And we've also seen the  
6 effects of leaders who are not well-enough  
7 trained, junior leaders who are not well-enough  
8 trained, prepared, to deal with those difficult  
9 human things that occur to people along the path.  
10 And/or negative command climate or toxic command  
11 climate, whatever the term is, and its impact on  
12 suicide prevention.

13           We still hear today stories -- I get  
14 e-mails all the time -- of the junior officer or  
15 the junior NCO that stands in front of their  
16 formation and creates the impression or belief in  
17 their -- in the folks in their charge that it's a  
18 weakness to seek help and/or, you know, you're not  
19 a good warrior if you have these weaknesses or  
20 those kind of things. And those messages need to  
21 change at the junior level. There's still that  
22 perception out there. As well as the stigmas that

1 go along with -- not only in suicide, but behavior  
2 health in general out there.

3 So, we always use these three key  
4 takeaways as our really strategic messages that we  
5 want to get out there on there. And that suicide  
6 is preventable, and having any of our nation's  
7 warriors die by suicide is unacceptable. It's  
8 unacceptable. Because we get asked that all the  
9 time, what is an acceptable rate? Well, I don't  
10 think we should establish an acceptable rate.  
11 Many people say, well if you're below the civilian  
12 rate, you know, is that an acceptable? Well, we  
13 shouldn't look at it that way. We should try to  
14 prevent every -- we should put our best effort  
15 forward for our men and women who are serving in  
16 uniform to prevent suicide to the maximum extent  
17 possible. Next slide.

18 All right. Then I'll open it up to your  
19 questions and you can see on the bottom there is  
20 our link to the report. Everything is out in the  
21 open. There's nothing hidden or whatever that you  
22 need to do. We're completely transparent. So,

1 link to the report and also the press conference  
2 in there.

3 And we'll continue to provide the press  
4 with information as they request information, too.  
5 Because our strategic messaging is very important,  
6 and is also in our recommendations -- foundational  
7 recommendations on suicide prevention.

8 So, sir, with that in mind I'll be happy  
9 to answer any questions.

10 DR. POLAND: Thank you very much. Dr.  
11 Kaplan?

12 DR. KAPLAN: Thank you very much,  
13 General Volpe. Back to the second to the last  
14 slide where you talk about the SECDEF submitting  
15 the report to Congress and then congressional  
16 requests. Do you anticipate that the report will  
17 in any way result in congressional hearings or  
18 congressional action? Or will it -- or do you  
19 anticipate that it will be up to DoD to take  
20 action on this very complete report?

21 MGEN VOLPE: Yes, sir, thank you. Well,  
22 first, it is up to DoD to take action on the

1 report. But I believe that there will be  
2 significant interest, especially if the rate  
3 remains the same and/or goes up. But I think  
4 there will be significant interest at the  
5 congressional level, simply because they were the  
6 ones who put it in the congressional language to  
7 create the task force.

8 But also because they're -- they have  
9 ongoing testimony now from all of the services on  
10 suicide. I think it's all mixed together, but  
11 testimony on suicide prevention, post traumatic  
12 stress disorder, and traumatic brain injury. It's  
13 sort of lumped together right now for the services  
14 to testify.

15 So I believe that once the Secretary of  
16 Defense OSD provides their response to our report,  
17 that there will be -- and we're anticipating that  
18 we, members of our task force, will be summoned to  
19 testify, too, at some point. I mean, all we can  
20 really do is just anticipate that, be prepared.

21 And we will -- and basically our role in  
22 that is to stay with and talk about the report

1       itself.  What's in the -- because that was our  
2       duty was to make these recommendations and why we  
3       made those recommendations.

4               DR. KAPLAN:  Thank you.

5               DR. POLAND:  I'll ask Mr. West if he  
6       wants to make any comments in regards to this.

7               MR. WEST:  Okay.  Thank you, Dr. Poland.  
8       Thank you.  And for the report and for the hard  
9       work that went into it and for your discussion  
10      just now.

11              Let me ask you a couple of things that I  
12      think you touch on in your report, but I just like  
13      to hear your comments on.  A collection of  
14      measurable indicators that as they either go up or  
15      down, you'd think you can also detect a rise or  
16      fall in the rate of suicides.

17              Let me give you an example.  OP tempo.  
18      As it goes up, the -- I think your answer pretty  
19      much suggested by your report is there's a whole  
20      bunch of factors.  And so just one going up might  
21      be compensated by others.  But that's an example.  
22      Or this one, numbers of chaplains per service

1 members. I mean, is there a collection of those  
2 things that if we looked at measurable indicators  
3 -- not discussable indicators, measurable ones.  
4 That as they fluctuate you will see a discernable  
5 change in the rate of suicide?

6 MGEN VOLPE: No, sir. That research  
7 hasn't been done to provide a source to create  
8 metrics to measure those sorts of things. And  
9 that's one of the reasons why in our report we  
10 recommended supporting further research in the  
11 area. And there is research that's going on  
12 there.

13 What we did find, though, as a  
14 measurable -- I don't know if it's measurable from  
15 a quantifiable standpoint. But measurable was  
16 that service members, their perception of  
17 behavioral health, seeking behavioral health --  
18 help-seeking behavior -- is a lot better when we  
19 embed behavioral health individuals and chaplains  
20 in units with them. They establish relationships,  
21 the barriers are down, and they tend to seek those  
22 individuals when they're having stress-related

1 problems or other problems in their life which  
2 maybe put them at risk for suicide. So that is a  
3 recommendation that's in our report that the  
4 services should heavily study embedding more  
5 behavioral health personnel with the troops in  
6 various activities.

7 MR. WEST: Okay. Thank you. And then  
8 this second one, which I leave to you to consider  
9 personally.

10 Taking into account your recommendations  
11 and the obvious interest, what do you expect to  
12 happen as a result of your report?

13 MGEN VOLPE: Yes, sir. What we expect  
14 to happen is to see the development of an  
15 implementation plan. And that implementation plan  
16 includes those 76 recommendations.

17 Now I will tell you that one of the  
18 things, sir, that has been going on because of our  
19 transparency during deliberations, we've worked  
20 with the services throughout our deliberations and  
21 briefing and sharing information. And many of  
22 these recommendations are already being considered

1 by the services and they're already, you know,  
2 developing their particular programs or response  
3 to those recommendations on there.

4 So, you know, our hats off to the  
5 services because they're already doing a lot.  
6 They've been doing a lot. But one of the  
7 recommendations -- one of the findings in here was  
8 that one of the difficulties we've had while  
9 they're doing a lot for suicide prevention, no one  
10 has ever taken the time to do just what you just  
11 said, sir. And that's build in program evaluation  
12 to know which programs are working and which are  
13 not to get the outcomes for suicide prevention and  
14 the results.

15 And so thus, they're doing a lot but  
16 nobody really knows which programs are good or not  
17 or working or not. And so, the services are  
18 looking hard at that right now with their current  
19 programs and also developing new initiatives based  
20 on our recommendations.

21 But an implementation plan by DoD, I  
22 would think, where they list each recommendation

1 and say which ones they'll accept, which ones are  
2 short-term, which ones are mid-term, and here's  
3 how we're addressing each of these recommendations  
4 and how we'll look at it.

5 But again, I think our first  
6 recommendation is probably the most important.  
7 And that is, to establish a full-time office of  
8 folks that do nothing but look at from a suicide  
9 prevention policy division. We specifically said  
10 "policy" because the programs still need to be  
11 with the service. The service secretaries and the  
12 service chiefs and their Title 10 authority, they  
13 need to run their programs for their service. But  
14 there is, certainly, ripe and beneficial to share  
15 best practices, have standardized reporting  
16 procedures and measuring tools, and those things,  
17 and also to get resources for the services for the  
18 suicide prevention programs. But having a policy  
19 division at the OSD.

20 Yes, sir.

21 DR. POLAND: I have a comment for you to  
22 consider and then follow up with a question. And

1 let me take a run at this. I think I've talked  
2 with you once before about it privately. But let  
3 me flesh out the idea publicly.

4 You mentioned, and I completely buy the  
5 idea of suicide prevention being a leadership  
6 issue and how it's necessary at the small unit,  
7 really junior leadership level, to start  
8 inculcating that in the command climate.

9 And an exponentially efficient way that  
10 I can think of in terms of beginning that task is  
11 to utilize our service academies. The interesting  
12 thing is, we have the collocation of behavioral  
13 science departments capable of teaching in  
14 research and 16,000 of our nation's future  
15 leaders, all of whom from hour 1 at one of those  
16 academies began to experience stress and challenge  
17 that is unique in their lives. And they begin to  
18 develop a perception of how you deal with this, or  
19 of how, as one cadet told me, well if this was a  
20 serious issue they'd be teaching us something  
21 about this. If they were serious about it.

22 So -- and when we were at West Point I

1 talked with the woman from the behavioral science  
2 department who briefed us. And then Labor Day was  
3 Parents Weekend at the Air Force Academy. Several  
4 of us have sons or daughters that are at the  
5 academies. Ms. Bader has sons in each of two  
6 academies.

7 So, my daughter is a psychologist. She  
8 and I briefed the major findings of the task force  
9 and then results of some of her research to the  
10 medical clinic command there and to the behavioral  
11 sciences department. So both the Air Force and  
12 West Point eagerly latched onto this idea.

13 About four weeks after that, one of the  
14 senior cadets at the Air Force Academy took his  
15 own life. Within 12 hours, a second was  
16 intercepted and fortunately was not successful.  
17 So, this is an immediate, acute, sharply-felt  
18 issue and I just think that, you know, in a 4-year  
19 cycle you will have sent 16,000 leaders out. By  
20 this time next year, you would have 4,000 second  
21 lieutenants out there who could be informed by a  
22 curriculum and an understanding from the very

1 beginnings of their military career how important  
2 this is to them as a future commander.

3 So, just a thought. The second is a  
4 question. I heard a snatched on the radio, I  
5 believe, that -- maybe it was the Army. But a  
6 large grant or research project had been funded on  
7 the order of 17- or more million. Am I right  
8 about that? Or, maybe it was funding of a program  
9 in suicide prevention? Anybody aware of this or  
10 had heard anything?

11 MGEN VOLPE: Joanne, do you know?

12 MR. DANIEL: Sir, Chris Daniel from  
13 Medical Research and Materiel Command. As you  
14 probably know, the majority of the psychological  
15 health research either through the Defense Health  
16 Program or through the Army is coordinated at Fort  
17 Detrick. And I think what you're referring to was  
18 the announcement of an approximately \$17 million  
19 effort. It's a consortium, I don't have the facts  
20 with me to specific members of that consortium.  
21 But it will focus over the next couple years on  
22 really the epidemiology and the -- as you know,

1       there's a lot more research that's going on.  But  
2       I think it will address some of the things that  
3       you, sir, talked about in terms of the measurement  
4       of the effectiveness of a lot of the things that  
5       have gone on.  But it's really predominantly  
6       focused on epidemiological work as opposed to the  
7       actual programs themselves.

8                     But if you want even further  
9       information, I can try to get that back to you.  
10      But I can at least tell you that you were right  
11      that within the last week that's been announced.

12                    DR. POLAND:  Okay, thank you.  My final  
13      question, then, seeing no others is, is there  
14      anything more the Board can do to help?  You have,  
15      and your committee, have brought -- I guess the  
16      word I would use is a lot of vitality to this  
17      issue.  And really, have done it in a very  
18      scholarly and yet feasible set of recommendations.

19                    Is there anything more we can do to sort  
20      of keep this up on everybody's radar screens?

21                    MGEN VOLPE:  The only other thing I  
22      would say, sir, is to look at a mechanism,

1 possibly through one of the subcommittees here on  
2 the Defense Health Board? Specifically to look at  
3 the healthcare portions of the recommendations  
4 that we make in here. Because remember I said  
5 suicide prevention belongs in the leader's lane,  
6 not funneled into the health care lane, per se.  
7 But health care -- behavioral health care -- is an  
8 important component of suicide prevention.

9           And we make a number of recommendations  
10 that have to do with behavioral health, the  
11 continuity of behavioral health, the  
12 documentation, management during transitions, and  
13 even training programs for behavioral health  
14 personnel to get them up to speed. Because as you  
15 know, one of our recommendations was just because  
16 you have a degree on the wall in psychology or  
17 psychiatry does not make you qualified to  
18 understand suicidal behavior and suicide  
19 prevention. You need additional training in that,  
20 in those kinds of things.

21           So I -- my recommendation would be now  
22 that our Board is -- has completed its mission and

1 is disbanded, that in order for -- that it would  
2 be useful for the Defense Department if the  
3 Defense Health Board continued to track this and  
4 possibly track it -- the medical portions of it,  
5 the health care portions, behavioral health  
6 portions -- through the mental health  
7 subcommittee.

8 And of course -- and if you needed  
9 experts on suicideology to be a part or an  
10 advisory to that, our members are -- we want to  
11 make a difference. I mean, our goal is that we  
12 prevent suicide. Save lives, prevent suicide.  
13 And strengthen the force while we're doing it.

14 DR. POLAND: It's an excellent  
15 suggestion. We will do that.

16 MGEN VOLPE: And so, that would be it.

17 DR. POLAND: Charlie first, and then any  
18 other members of the Psychological Health  
19 Subcommittee that want to offer any comments?

20 MR. FOGELMAN: Well, I think there is  
21 only one other here.

22 Would be happy to take that up. But

1 don't we have to be asked a question? This comes  
2 back to the continuing issue of what it is that we  
3 talk about and what the products of the  
4 subcommittees are.

5 If you could give us two or three  
6 specific policy or program questions you'd like  
7 answers to, we'll follow up on them. It has to  
8 come through the board, I guess. Greg will tell  
9 you how this has to happen. Then we can do it.  
10 Otherwise, we're always happy to talk to people  
11 and engage. But if we're going to have a product  
12 we need to be asked for a product.

13 DR. POLAND: Bill?

14 DR. HALPERIN: Maybe just one other --

15 DR. POLAND: Your microphone.

16 DR. HALPERIN: Sorry. Bill Halperin.

17 Maybe there's one other follow-up.

18 One of the focus areas is surveillance  
19 and investigations. So, perhaps, you know, with  
20 your help if we knew more specifically what  
21 surveillance of what entities, et cetera, that we  
22 could track that as we continue our engagement

1 with the deployment health surveillance centers  
2 and research centers and so forth.

3 But it has to be more specific than just  
4 sort of the broad area of surveillance. What  
5 specifically did the group want to see? And then  
6 as we go do our evaluations we can find out  
7 whether this is forthcoming.

8 DR. POLAND: Good point. Okay, Bob, did  
9 you have any comments you wanted to make? No?

10 COL CERTAIN: Not right now.

11 DR. LEDNAR: General Volpe, first thank  
12 you to you and Ms. Carroll and Colonel McPherson  
13 for all the leadership that you've brought to this  
14 issue in really 12 months. Accomplished really  
15 quite a lot.

16 As I'm thinking back to all of the  
17 levers that might be pulled to improve this issue,  
18 I think back to what our warriors faced from those  
19 returning from Vietnam. And into communities that  
20 were not welcoming to the service that they  
21 provided.

22 As your task force did its work, do you

1 see an opportunity for the communities -- not only  
2 on post but around our installations -- to do  
3 things in a way -- it might include their  
4 employers -- to be supportive to this issue we're  
5 trying to get better at?

6 MGEN VOLPE: Yeah, but I mean, let me  
7 say first of all, our communities are very  
8 supportive, I think, around the country for  
9 military members -- all components -- and their  
10 families. I think it's more of a thing that they  
11 may not know how to better support or not  
12 empower, to support certain aspects of it.

13 So there are certainly that could be  
14 done in communities -- particularly for the  
15 reserve component, who don't live near our camps,  
16 posts, stations, bases, and stuff. Where we can  
17 help educate and empower the religious community,  
18 the various chaplains of different denominations  
19 on what to look for and what to see in service  
20 members that have been demobilized that live in  
21 their communities. On how to recognize it and how  
22 to get them back into a helping professional that

1 can do the care. The same thing with behavioral  
2 health individuals out in communities and stuff.  
3 Understanding what service members do, the demands  
4 on them, and what to look for, and stuff, I think,  
5 would be very valuable.

6 So, I think it's more of an education,  
7 knowledge -- empowering them, making them better  
8 at helping our service members. It's not a matter  
9 of will. They all want to and they're all very  
10 supportive of our servicemen. And I don't know if  
11 that answered your question, but.

12 And there are ways -- I mean, I know of  
13 there's an organization called the Citizen -- it's  
14 called the Citizen Soldier Support program. But  
15 it's not just soldiers, Army. It's all service  
16 members. And they focus mostly on what  
17 communities could do to better support the  
18 military out in their communities and stuff. And  
19 it focuses a lot on healthcare and it focuses a  
20 lot on spiritual assistance, too.

21 DR. LEDNAR: Thank you.

22 DR. POLAND: I had asked my question

1 about what more could we do hoping to hear the  
2 sorts of comments that we did, and I think we will  
3 further work the issue. We have assets in our own  
4 subcommittee structure where we can sort of keep  
5 this alive and push on this a little further. We  
6 can answer specific questions and will endeavor to  
7 do so.

8 So, thank you very much for your  
9 leadership on this.

10 MGEN VOLPE: You're welcome. And we'll  
11 be happy to brief -- anyone with any interest  
12 we'll be happy to brief individually and sit down  
13 one-on-one about the report and some thoughts on  
14 this, or as a group, so. (Applause)

15 DR. POLAND: Okay. Dr. Dinneen is not  
16 going to be here, thanks to Hurricane Thomas. And  
17 he's stranded on an island somewhere, so maybe not  
18 a bad place to be stranded, I don't know. Depends  
19 on how fast the wind blows.

20 So we're going to move right to Dr.  
21 Halperin's portion of this. As you know, Dr.  
22 Halperin serves as the chair of the Military

1 Occupational/Environmental, Health, and Medical  
2 Surveillance Subcommittee. And in addition, he  
3 chairs the Department of Preventative Medicine at  
4 the New Jersey Medical School as well as the  
5 Department of Quantitative Methods for the School  
6 of Public Health at the University of Medicine and  
7 Dentistry of New Jersey.

8 Dr. Halperin has formerly served as the  
9 chair of the Committee on Toxicology of the  
10 National Research Council, and is certified by the  
11 American Board of Preventive Medicine as a  
12 specialist in occupational medicine, as well as  
13 general preventive medicine and public health.

14 His experience in epidemiology ranges  
15 from field investigations of outbreaks to more  
16 subtle investigations of the association of  
17 chemical exposures with a variety of outcomes, as  
18 well as occupational injuries. His presentation  
19 slides are under tab 6.

20 And while we all know and love Bill, let  
21 me just say my personal thing that I'd like to  
22 commend Bill for -- as is true for many of our

1 members. Even in areas far afield from his  
2 expertise, he listens very carefully and you  
3 always know Bill by the very thoughtful,  
4 insightful, and scholarly questions that he brings  
5 to bear on any topic. And I've just personally  
6 appreciated that about you, Bill.

7 So, the podium is yours.

8 DR. HALPERIN: Well, thanks, Greg. Sort  
9 of jack of all trades, expert at whatever.

10 Yes, and I'm also retired from the U.S.  
11 Public Health Service, where I served for 25  
12 years. And I have absolutely no idea how to use  
13 this gizmo. How do you -- okay, so that's how you  
14 use it. Okay. So if you go there -- so, this  
15 goes forward? Yes, it does. And it goes  
16 backward. Very good.

17 Well, thank you very much. The  
18 presentation is going to be fairly brief. It's  
19 just an update of what it is that the subcommittee  
20 is doing. The major focus -- let's see if I can  
21 get -- is the light the center thing? No. Is  
22 there a pointer on here? Yes, a pointer. Okay.

1           So, subcommittee charges and status.  
2       The first thing that we're going to be talking  
3       about is where we are with the review of the  
4       Department of Defense Centers for Deployment,  
5       Health, Research, and Clinical Centers. The  
6       paramount want that you've heard from the  
7       subcommittee about before -- you all know about --  
8       is the Millennium Cohort Study. So, the question  
9       is, what are the three centers doing? Where are  
10      we with the review of these three centers?

11           The next question that we're going to  
12      talk about is to bring you up to date on the  
13      questions posed to our subcommittee by the  
14      inspector general. You remember that several  
15      years ago -- I think it was years ago, it seemed  
16      like it -- we did a review of the investigation  
17      conducted by CHPPM of chromate exposure at Quarmat  
18      Ali in Iraq, and I'll bring you up to date on  
19      where we are with the inspector general's  
20      questions to us about this investigation.

21           And the third thing I'd like to talk  
22      about today is the request for review coming from

1 the Assistant Secretary of Defense -- am I  
2 mangling that? That's true, Assistant Secretary  
3 of Defense -- about burn pit exposure in various  
4 places. But burn pit exposure to effluent coming  
5 off of the fires, whether it be diesel exhaust and  
6 micro fibers that are involved or the plastic and  
7 products of plastic combustion such as dioxin, et  
8 cetera, that may be coming off of burn pits.

9 So I'll bring you up to date on where we  
10 are on each of these three things. Before I do  
11 that I would like to at least acknowledge  
12 everybody who is on the subcommittee. The people  
13 without stars are people who were officially put  
14 on the committee. The people with stars are the  
15 ones that we kind of dragooned into service and  
16 are sort of unofficial members of the committee.  
17 And they've all played a great role, but that is  
18 the distinction between the stars and the  
19 non-stars.

20 So, in September 17, 2002 -- this is way  
21 back -- Dr. Winkenwerder, the Assistant Secretary  
22 of Defense, gave a -- made a request of the Armed

1 Forces Epidemiology Board. And that was for some  
2 group at the Armed Forces Epidemiology Board to  
3 meet with the three DoD Centers for Deployment  
4 Health, Research, and Clinical Center directors to  
5 receive mission briefs so we could find out what  
6 it is that they were doing. And then, secondly,  
7 to develop in coordination with the directors an  
8 appropriate strategy to accomplish an ongoing  
9 program review and appointment of an AFEB select  
10 subcommittee -- that's us, the Military  
11 Occupational/Environmental, Health, and Medical  
12 Service Committee -- to serve as a public health  
13 advisory Board to the DoD Research and Clinical  
14 Centers for Deployment Health, all right?

15           It's a lot of words, but I think that  
16 there were really two missions that we're supposed  
17 to accomplish. One is, go out and get smart about  
18 what the three centers are doing. And then three,  
19 try to play some role in an advisory capacity to  
20 the centers in an ongoing basis. So this is not a  
21 mission that's supposed to start and stop, we're  
22 supposed to have an ongoing relationship with the

1 centers.

2 This goes back to 202. Well, the review  
3 of the Deployment Health Research Center, which is  
4 in San Diego at the San Diego Naval Base was  
5 completed on May 11-12 of 2010. There was a  
6 subcommittee -- a report with recommendations  
7 which were presented at the West Point meeting at  
8 August 18-19, and were approved by the DHB core  
9 Board. Those recommendations have now been -- I'm  
10 definitely going to blow this -- they've been  
11 signed off by the Assistant Secretary's office, or  
12 acting in that stead, and are now going to be  
13 assigned back for implementation to --

14 MS. BADER: Back to FHP&R to review the  
15 recommendations.

16 DR. HALPERIN: To review the  
17 recommendations and implement as --

18 MS. BADER: And then develop a plan --

19 DR. HALPERIN: -- as they feel  
20 appropriate --

21 MS. BADER: Yes.

22 DR. HALPERIN: Okay. And if you

1 remember all some of those recommendations were --  
2 if you will, the most general recommendation was  
3 for an advisory group for the Deployment Research  
4 Health Center in San Diego that would expedite  
5 reviews. There are now several review groups, the  
6 recommendation was for limiting it to one review  
7 group and having members of the Defense Health  
8 Board be active members of that review group.

9           So we've essentially completed, if you  
10 will, our mission at San Diego. Now it's time to  
11 move on to the review of the Deployment Health  
12 Clinical Center at Walter Reed and the Health  
13 Surveillance Center at Aberdeen, and that will be  
14 started, hopefully, in the next few weeks to  
15 months or so. And the way we'll do it is the same  
16 way that we did the first one, which is I'll go  
17 out with a staff member, try to get smart myself,  
18 if you will, reconnoiter or find out the big  
19 issues, and then bring the full subcommittee back  
20 in and do a thorough review.

21           It seemed to work effectively doing it  
22 this way for the first center. So, that's what

1 we're up to for the second and third centers.

2 Now, on -- just a little bit of  
3 background on Quarmat Ali for those people who  
4 don't know the substance or the details, which is  
5 probably pretty rare around this group. The site  
6 that we're talking about was contaminated with  
7 chromates. The chromates were used for rust  
8 prevention in water treatment. When soldiers,  
9 contractors, National Guard, regular soldiers got  
10 to the site there was contamination. It wasn't  
11 recognized for a while, once it was recognized  
12 there was a CHPPM field investigation, which  
13 resulted in interventions, along with  
14 interventions that were made by the contractor at  
15 the site. Anyway, this whole story was reviewed  
16 by our subcommittee, which we did under the  
17 strictures of it being confidential, secret  
18 information at that time.

19 We made a report, it went back through  
20 to the appropriate folks, and then there were  
21 subsequent questions about how we came to some of  
22 our conclusions, what we thought about a spectrum

1 of health issues, and so forth. We drafted a  
2 response, that response was reviewed by our  
3 subcommittee members, and was sent to the  
4 Inspector General -- I guess it was optional  
5 whether we wanted to participate or not. We  
6 decided to participate by providing that  
7 information, and it's been there since September  
8 16 and I presume that this will rise again at some  
9 point. But at this point it's temporarily closed  
10 case.

11 On July 19 of 2010, there was a request  
12 from the Assistant Secretary of Defense office for  
13 us to review 2 things. One was -- oops -- one was  
14 a DoD report on -- it's actually not a report.

15 It's a DoD proposal for future environmental  
16 sampling to be conducted at burn sites, burn pit  
17 sites, in the Middle East. It's really a research  
18 protocol, if you will. And the second is a report  
19 of an epidemiologic study that was done by DoD of  
20 health effects from prior exposure at other such  
21 sites in the Middle East.

22 And the teleconference was held on

1 September 10 to discuss ways in going ahead with  
2 this review. One of the issues involved was that  
3 our subcommittee, while very good, competent,  
4 excellent as you've seen from the list of people,  
5 really didn't have sufficient expertise in  
6 specific areas, such as exposure assessment, in  
7 monitoring techniques, and so forth.

8           So what we did is, we identified experts  
9 outside of our committee, mostly in academia.  
10 They were approached by Christine Bader. They --  
11 apparently most of them if not all agreed to serve  
12 and now are waiting for further communication from  
13 the Assistant Secretary's office about how and  
14 when we can get going with one or both of these  
15 reviews. But we have agreed to do both of them.  
16 And that's where that stands.

17           This summarizes what I've already said,  
18 was that we had to augment the subcommittee in  
19 certain areas. And this lists those areas;  
20 epidemiology, clinical occupational medicine, and  
21 so forth.

22           And with that, I will stop and take some

1 questions and welcome Craig Postlewaite who  
2 arrived here. He may want to answer some of the  
3 questions as well.

4 DR. POLAND: Thanks for the update,  
5 Bill, on the activity of your subcommittee. Any  
6 comments or questions? Any of the Board members  
7 have?

8 Good. Okay. Thank you, Bill.

9 DR. HALPERIN: You're welcome, thank you  
10 very much. (Applause)

11 DR. POLAND: Good in uniform, there, Dr.  
12 Parkinson.

13 Our next two speakers are also members  
14 of -- illustrious members of the board are Dr.  
15 Michael Parkinson and Dr. Joseph Silva. Dr.  
16 Parkinson is past president of the American  
17 College of Preventive Medicine, and recently  
18 served as vice-chair of the American Board of  
19 Preventive Medicine and executive vice president,  
20 chief health and medical officer of Lumenos, a  
21 pioneer of consumer-driven health plans and a  
22 subsidiary of WellPoint.

1           A retired Air Force colonel, he formerly  
2       served as associate director of medical programs  
3       and resources in the Office of the SG. Dr.  
4       Parkinson also served as deputy director of Air  
5       Force medical operations and chief of preventive  
6       medicine. While assigned to the U.S. Public  
7       Health Service he provided oversight for federal  
8       programs and public health, geriatrics, and  
9       preventive medicine training.

10           He served on the National Advisory  
11       Committee of the Robert Wood Johnson Foundation  
12       Healthcare Purchasing Institute, assisting  
13       employers to purchase higher quality care. Dr.  
14       Parkinson is a recipient of the Air Force Legion  
15       of Merit, Distinguished Service Award of the  
16       American College of Preventive Medicine, and  
17       distinguished recent graduate award from the Johns  
18       Hopkins School of Public Health.

19           Dr. Silva currently serves as professor  
20       of internal medicine in the division of infections  
21       diseases and immunology at the University of  
22       California Davis School of Medicine. In addition

1 to his academic appointments, he served as  
2 consultant for Kaiser Permanente Hospital for the  
3 VA hospitals in Ann Arbor and Northern California,  
4 and is staff physician at the U.S. Air Force  
5 Medical Center at Lackland Air Force Base.

6 Among his numerous awards and honors are  
7 the Distinguished Physician Award from Sacramento  
8 Sierra Valley Medical Society, and from the  
9 California Hospital Association.

10 They're going to provide joint updates  
11 regarding the psychotropic medication and  
12 complimentary and alternative medicine. You'll  
13 hear them call it CAM work groups. And their  
14 presentation slides are under tab 7.

15 Gentlemen? The podium is yours.

16 DR. PARKINSON: Thank you, Dr. Poland.  
17 And good afternoon everyone.

18 As I said, Dr. Silva and I were asked by  
19 Dr. Lednar and Poland to chair this, although it  
20 relies very heavily on the expertise of Dr.  
21 Fogelman's committee. A number of the members in  
22 what we see as a kind of a cross-cutting effort of

1 major impact and importance to the Department,  
2 which is why it comes to us.

3 So, the question to the Board -- which I  
4 have actually asked Ms. Bader if at the end of our  
5 formal slides if we could just project the  
6 question or at least have it handy, because I  
7 think it's going to be critical to our work on  
8 Wednesday -- really has two parts. To request  
9 guidance for the prescribing and the proper use of  
10 psychiatric medications and, secondarily, to  
11 request guidance for the use of complementary and  
12 alternative medicine treatments.

13 And this is speaking to the use of these  
14 modalities for active duty members in the  
15 operational theater and perhaps throughout the  
16 entire continuum of care in the military health  
17 service. And really is the scope issue, which Dr.  
18 Silva will speak to in his comments.

19 The current membership which relies on  
20 some of our members of the board here you'll  
21 recognize, as well as some members external to the  
22 Board, has a good cross- section of folks who are

1 both active in the psychiatric and psychological  
2 health arena as well in the health care systems  
3 and care delivery arena, which I think is very  
4 important as well, particularly as the scope of  
5 this question begins to get into such things as  
6 benefits, civilian peacetime care, transition to  
7 the VA system, et cetera.

8           We had an organizational teleconference  
9 on the 21 October. This was just a grounding  
10 effort, I think. It was very valuable for us to  
11 discuss some of the impending issues, which Dr.  
12 Silva will review in his comments. But really  
13 just to meet some people, telephonically, at  
14 least, for the first time in an abbreviated but  
15 very useful kind of a foundational effort. Our  
16 first meeting is this Wednesday. We will use that  
17 to acquire a lot of information about the  
18 background of the question so that we can be  
19 informed on the topics. And as Ms. Bader  
20 mentioned, the final report and recommendations --  
21 it's relatively tight timeline for something that  
22 could be as broad as what we perceive in the

1 question. So, that's why scope is all the more  
2 important. Either the scope is different than  
3 what, at least, I read, or the timeline has to be  
4 significantly extended. We can't put a size 9  
5 foot into a size 6 shoe.

6 So, on November 3 we want to talk about  
7 the scope and priority areas. We will discuss  
8 with the service psychiatrists exactly their  
9 perceptions of these two areas and their role in  
10 it. We will have a review by the mental health  
11 advisory team on the data of medication use,  
12 psychotropic drugs, in theater. What are the data  
13 sources we can rely on to find the prevalence of  
14 use of these drugs in theater. And also at a high  
15 level, the evidence base for the use of  
16 medications for PTSD and acute stress disorder.

17 Joe, is this your slide? Am I in your  
18 area?

19 DR. SILVA: No, that's yours.

20 DR. PARKINSON: These are mine, okay.  
21 Because some of these I know nothing about. I'm  
22 just kidding.

1           No, this was an area, I think, that  
2       frankly reflected some of my meandering comments,  
3       probably, on the telephone conference call on our  
4       last. Is that certainly a case definition of what  
5       is and is not "CAM" and what is it's use in the  
6       Department of Defense on the continuum of  
7       mind/body issues. We have military facilities  
8       where we actively promote GNC stores. Not picking  
9       on GNC, they're based in my hometown of  
10      Pittsburgh, but there's a lot of things in those  
11      types of outlets and in the types of  
12      advertisements that float around military bases  
13      that could broadly be considered CAM. Are those  
14      embraced? Are they not? Either in policy or in  
15      treatment with our troops.

16           We need to know something about the  
17      capability of in-theater psychiatric care,  
18      certainly about the baseline prevalence of the use  
19      of these medications. There's been a tremendous  
20      amount of literature about the widespread use of  
21      psychotropic medications in the general civilian  
22      population. I, myself, have not seen a single

1 employer where it's not the leading category of  
2 drugs that are prescribed for employees and their  
3 families, for example.

4 And then, we want to break out into work  
5 groups based on what we learn in the morning, in  
6 the afternoon, to use our expertise to formulate a  
7 plan going forward.

8 Still mine?

9 DR. SILVA: You can take it.

10 DR. PARKINSON: Okay. (Laughter)

11 DR. SILVA: We're well-rehearsed.

12 DR. PARKINSON: This is the  
13 Alphonse-Gaston. I got it, you take it. Okay.

14 The scope of interest is very important,  
15 particularly are we talking just about in theater  
16 or are we talking about transition out of theater,  
17 or are we talking about transition to the TRICARE  
18 benefit? So if you go back and review the  
19 question, what is written in the question then  
20 refers to the attachments. The attachments really  
21 have words like "the benefit." Benefit  
22 determination is very different than in-theater

1 treatment or something using psychotropic  
2 medications and CAM.

3 What are the definitions for  
4 psychotropic medications and CAM? Do we have  
5 uniform utilization of the terms across the  
6 services and within the Department vis-`- vis  
7 civilian practice? And what is the availability  
8 of these various treatment modalities within the  
9 military, generally within the TRICARE benefit,  
10 within the theater operation?

11 And certainly we're into the --  
12 immediately into the bailiwick of what are  
13 FDA-approved versus non-approved uses for these  
14 various substances. And certainly, even so much  
15 as to what does the NIH, the complement and  
16 alternative medicine branch, have to say about the  
17 framework for the definition of these issues as  
18 well as a way to think of them from an evidence  
19 base, realizing that by definition many of them do  
20 not meet the evidence base that clinically we  
21 would think would be appropriate.

22 Dr. Silva?

1 DR. SILVA: I want to thank my  
2 ex-friends, Drs. Poland and Lednar, for putting me  
3 on this committee. (Laughter) On the telephone  
4 call I sort of had a feeling when I was a young  
5 kid of scratching on a bees' nest, and I heard a  
6 lot of noise underneath. And so that's how I  
7 viewed this problem, and how do we get our hands  
8 around it. And I think it's a very important  
9 problem.

10 If one goes to the font of all current  
11 human knowledge, Wikipedia, which I've done, just  
12 to look how many drugs are in each of these  
13 categories, it's astounding. There's over 80 on  
14 the psychotropic side. But if you punch in other  
15 terms such as psychiatric or psychoactive or  
16 psychopharmaceutical, you can get different types  
17 of drugs. And then the CAM list, I sent you -- I  
18 didn't even count it up, Mike, but I think you  
19 have a bigger chore. So that's a real problem,  
20 defining in theater and what are we talking about.

21 Now, if one looks at where the problems  
22 are coming from I think there's no doubt that this

1 is a perfect storm. There are really two  
2 elements, like the movie. Wind and rain. And  
3 when you come down to this, we're really talking  
4 about the items of patient expectation. There's a  
5 huge industry out there built over these products,  
6 word of mouth. And when people are stressed, they  
7 are going to demand things.

8 The other side are the pharmaceutical  
9 industry themselves, including those that make  
10 CAM. And I think there's going to be a real, real  
11 problem. We've already started to pull out some  
12 data as to what are some of the psychotropics that  
13 have inappropriate use physicians in terms of  
14 pushing their drug outside the limits by approval  
15 from FDA. And I'm going to give it to the  
16 committee; we've already sent it on.

17 There's an interesting court case that  
18 came out of this nonprofit -- I'm sorry,  
19 ProPublica. It's a nonprofit organization which  
20 many of the drug houses use to funnel dollars  
21 through to physicians. And we're not talking  
22 about small amounts of change here. I was amazed

1 at what the problem was. But if you look at the  
2 data, there are about eight companies -- I won't  
3 read them. Dupont's not there, Mike, so you can  
4 relax.

5 They had 384 physicians received over  
6 \$100,000 a year since 2009. They had 2 in the  
7 last -- I'm sorry, they had 43 in the last 2 years  
8 who have received over \$200,000. And then there  
9 are two people driving a Lexus who had over  
10 \$300,000 a year.

11 And there's no doubt the companies have  
12 been at this for ages. They have a lot of schema  
13 how to push the drugs in the limit. And so, they  
14 use it out of approved drug use. And in fact,  
15 there are estimates now that about 20 percent of  
16 all drug use offline is a common figure that's  
17 quoted. So, this is a huge industry. Besides the  
18 fires and the TV ads, ask your doctor, the effects  
19 of a lecture getting to health care providers --  
20 there's still a very, very powerful force and it  
21 does push physicians and healthcare providers to  
22 try to experiment with drugs.

1           So, the tasks are pretty bold. But I  
2 think we can get a handle on it, because one that  
3 clearly we can address on what are the current  
4 uses, and some of these people legitimately need  
5 to be on these agents when they go into theater,  
6 they are useful. I was amazed to find out that  
7 during World War II over 60 million doses of  
8 amphetamine were uses on the Allied troops' side.  
9 And also I found a reference in Sierra Leone when  
10 they had the children warriors that it was common  
11 they got mixtures of gunpowder, cocaine, and  
12 amphetamine. So there are mind altering drugs  
13 that are used to sort of jazz up the troops.

14           The other thing, I don't know if we can  
15 get a handle on but there are side effects to  
16 these agents that we hardly ever talk about unless  
17 they're really bad. We may get some inkling at  
18 that if we can data mine some of the pharmacy  
19 banks as to what side effects have been after  
20 return from theater.

21           But with that, I'd like to open it up  
22 and have Mike field some of the questions, because

1 my codeine is wearing off and I'm in pain.

2           Anyhow, we're open to your thoughts.

3 We're going to go into this naove and hopefully be  
4 able to carve out a product that will be worthy of  
5 this Board to approve. So.

6           DR. POLAND: Thank you guys for your  
7 report there. And we have time for any questions,  
8 comments, any directive ideas anybody has,  
9 whatever it would be.

10           DR. SILVA: And, Charlie, we're going to  
11 be heavily dependent on your committee to react  
12 here, too. That's obvious. So.

13           DR. POLAND: Dr. Luepker.

14           DR. LUEPKER: Yeah, Russell Luepker.  
15 So, presumably active duty people are receiving  
16 these medications by prescription through normal  
17 channels. And presumably that's findable. But  
18 all the CAM medicines, how would you learn about  
19 that? Usually off the supermarket shelf or at  
20 General Nutrition.

21           DR. PARKINSON: Well, Russ, that's an  
22 interesting question. Because if you had to do a

1 similar study in the civilian there's any number  
2 of traditional epidemiologic tools that we can do.  
3 You could do surveys, you could basically do  
4 purchasing by geographic areas, you could do --  
5 but it's relatively crude. And to go back to the  
6 first and foremost question is, what's in scope  
7 for this particular -- this topic?

8 I, for one, would like to have a very  
9 discrete, defined typology for what is CAM. It is  
10 probiotics, it is vitamins and supplements, it is  
11 hypnosis, it is -- you know, zing, zing, zing,  
12 zing, zing. And, hopefully, we don't have to make  
13 that up, it's out there. And that's kind of what  
14 my education is going to be. Charlie, maybe you  
15 want to comment here.

16 But I think that within that we then  
17 have to ask the question, are we talking -- I  
18 think our first and foremost goal is about  
19 operational performance in theater. And that is  
20 both operational performance, is it just to  
21 maintain current operational performance? Or is  
22 it to actually, as Joe alluded to, to enhance

1 operational performance? Go/no go pills, as they  
2 were called in the Air Force. That was a standard  
3 treatment that we did for long missions in  
4 Vietnam. So, is that in scope? Are we talking  
5 about performance-enhancing operational  
6 psychotropic medications? Or are we talking about  
7 just operational deleterious drugs?

8           Again, those are the things that we'll  
9 work through. But I do want to mention a thought  
10 that I had this morning for the group, putting on  
11 my role as a Board member. When I listened to Dr.  
12 Jim Kelly's presentation about the Intrepid  
13 Center, if you look at the mission -- and I tagged  
14 it in my book -- but you go back and you look at  
15 the mission slide at the Intrepid Center, actually  
16 there's about an 85 percent mission overlap with  
17 the question that we've been asked by the DHB.  
18 Individualized, multi-factorial treatment plans  
19 for individuals to be able to optimally function.  
20 This is active duty members, so one of the  
21 recommendations over lunch that I had to Christine  
22 is perhaps we want to ask and suggest that if Dr.

1 Kelly would like to be a member of our group,  
2 because he actually has to apply in a very real  
3 time to people who have been in theater to make  
4 the more operationally function with a combination  
5 of TBI and psychological stressors. So, it might  
6 be something to think about to knit together our  
7 efforts a little more closely.

8 Just for your information, there was the  
9 original question but then there is about a page  
10 and a half of all of these questions that, as the  
11 Board will recall, are appended to the question  
12 itself. Which is where each one of these  
13 questions gets successively broader and broader  
14 and broader, if you will, in mission creep or  
15 scope creep that both Joe and I feel, while  
16 interesting, probably is not achievable by March  
17 31. So that's what we need to do is to find how  
18 deep and how broad do we need to go.

19 DR. SILVA: Let me just add to the CAM  
20 area. Russ, I think your question is good. And  
21 of course the troops receive packages all the time  
22 from people. So if it's not available in the

1 local market -- although a lot of stimulatory  
2 agents out there, packaged in a lot of unique ways  
3 worldwide, then they can get their families to  
4 send it.

5 And if you go into these 7-Eleven  
6 stores, you're getting gasoline, look at what are  
7 big sellers now to teenagers, young drivers. I  
8 just discovered this when I ran across a couple of  
9 these products in psychotropics. They're loaded  
10 with caffeine. They're called power drinks,  
11 they're chewing gum. You can take five- and  
12 six-hour doses of incredible amounts of caffeine  
13 to remain awake. And I bought a pack of the gum.  
14 It was very expensive, \$3.43, which --

15 DR. PARKINSON: But you're awake --

16 DR. SILVA: But I'm awake now.

17 (Laughter) And I'll tell you, you could really  
18 get jazzed up. When I used to be a coffee  
19 drinker, 8, 10 cups a day, I think one of these  
20 things has the equivalent, easily, to 3 or 4 cups  
21 of coffee drank over an hour or so.

22 Anyhow, it's pandemic out there.

1 DR. POLAND: We'll be putting it out  
2 instead of snacks for the board. (Laughter)

3 DR. PARKINSON: Well, if you could just  
4 -- and again, just step back for a minute. And  
5 you could turn an entire -- at least a supplement  
6 to the American Journal of Medicine or, you know,  
7 for number 2 and number 3, two separate  
8 supplements to talk about what is the evidence,  
9 the real, perceived, or extrapolated evidence for  
10 the treating of some of the most common anxiety  
11 stress disorder. I mean, so, again, this is so  
12 broad in the attachment that that's why we really  
13 rely on the Department for guidance here.

14 DR. POLAND: Okay, thank you very much.  
15 (Applause) We're going to do a little more agenda  
16 shuffling here. We're going to take about a  
17 20-minute break and then we're going to ask  
18 Colonel Hachey to do his brief on H1N1 look-back,  
19 which is scheduled for tomorrow. This will allow  
20 two things. Time for PT today, and time for PT  
21 tomorrow.

22 Dr. Butler previously worked with the

1 Navy SEALs, he'll be leading the core board in  
2 this endeavor.

3 (Laughter)

4 (Recess)

5 DR. POLAND: Can we have folks take  
6 their seats? We'll get started, because I know  
7 you'll want to do your run while the sun is still  
8 out.

9 Okay. Our next speaker is Colonel Wayne  
10 Hachey. He currently serves as the director of  
11 preventive medicine and surveillance in the Office  
12 of the Deputy Assistant Secretary of Defense for  
13 Force Health Protection and Readiness. He has a  
14 background in both nursing and medicine. During  
15 his nursing career, Colonel Hachey held faculty  
16 appointments at the University of Nebraska and  
17 East Carolina University. He also held  
18 administrative and clinical positions as a  
19 director of a nurse practitioner program and as a  
20 neonatal clinical nurse specialist nurse  
21 practitioner.

22 Prior to transitioning into medicine,

1 Colonel Hachey served as a clinical nurse  
2 specialist in the U.S. Army at the Walter Reed  
3 Army Medical Center.

4 We've asked him to do sort of a  
5 look-back on the accomplishments and critical  
6 lessons learned regarding Department of Defense  
7 H1N1. It's under tab 10. Like me, I'm sure  
8 you'll find that almost nothing else is as  
9 fascinating as pandemics. (Laughter)

10 COL HACHEY: A second only to seasonal  
11 flu, yes. Well, it's been said that no plan  
12 survives their first contact with the enemy. But  
13 despite that, DoD didn't do too bad as far as our  
14 planning and the H1N1 pandemic. We did start our  
15 engagement that actually predated the national  
16 strategy for pandemic influenza, so DoD was always  
17 a step ahead. And then we partnered with the  
18 National Pandemic Influenza Plan in with other  
19 federal governments and agencies. And because of  
20 that groundwork, I think we were in a much better  
21 position.

22 When the pandemic actually hit we were

1 able to meet our mission requirements while  
2 operating in a pandemic environment without  
3 mission degradation. And we adapted to changes in  
4 the disease characteristics with changes in our  
5 resources and changing in planning.

6 Well, if any of you follow NPR, it's  
7 time for the numbers. So, the number of  
8 beneficiaries seeking care for flu-related  
9 symptoms was actually four times higher than what  
10 we saw in the typical flu season. So it did have  
11 an impact on DoD. Ambulatory visits were up five  
12 times -- actually, a little more than five times.  
13 And the direct care system -- and threefold in the  
14 purchased care system. ER visits were up fivefold  
15 in the direct care system and eightfold in the  
16 purchased care. And inpatient admits were up 5  
17 times in the direct care versus 2.8 in the  
18 purchased care sector.

19 So across the board, whether you were in  
20 a direct care metric or a purchased care metric,  
21 utilization was up across DoD. And the overall  
22 cost was, let's see, \$156.7 million above a

1 typical seasonal flu, with 71 percent of that cost  
2 going towards active duty and dependents, which is  
3 a little bit of a flip-flop. Where in most  
4 seasons the folks were being hospitalized and  
5 running up your bill are those who are over 65.

6 As far as DoD deaths, we had two active  
7 duty deaths, six family members, and three  
8 retirees, which is not unlike a typical seasonal  
9 flu. During the past six years, our seasonal flue  
10 rates for deaths range from one to two. So, this  
11 is clearly within the bounds of, again, a typical  
12 season.

13 However, just like one suicide in DoD is  
14 too many, one death from influenza is also too  
15 many. And this is one of our DoD deaths. On  
16 October 30, 2009, this was a previously healthy  
17 7-year old. On the third day of a flu- like  
18 illness he developed worsening symptoms and was  
19 brought to one of the region's premier military  
20 medical treatment facilities and was diagnose with  
21 croup. The next morning he was better, but by the  
22 afternoon he was walking unsteadily and was found

1 to be cyanotic and rushed to the nearest ER. He  
2 was pronounced dead two hours later, and was later  
3 diagnosed with 2009 H1N1.

4 So, what did we do as far as planning  
5 for the pandemic? Well, DoD combatant command,  
6 service, and installation plans were all in place  
7 before the emergence of the novel flu strain. The  
8 problem is that they were primarily based on an  
9 H5N1 threat and not on an H1N1 threat, which  
10 turned out to be very different.

11 There was some initial confusion between  
12 WHO phases and U.S. government phases. Many of  
13 the combatant command pandemic influenza plans  
14 were based on U.S. Government stages rather than  
15 WHO phases. That confusion was exacerbated when  
16 the federal government elected to follow the World  
17 Health Organization's pandemic flu phases rather  
18 than the U.S. Government phases. With many of the  
19 combatant command triggers, again, based on the  
20 U.S. Government phases. So there were many  
21 folks, at least outside of the medical arena, were  
22 left waiting for that trigger to happen before

1 they initiated some of their plans. However, the  
2 medical community quickly adapted from a bird flu  
3 threat to a 2009 H1N1 threat.

4 Another problem we found is that the  
5 policies were primarily focused on uniformed  
6 personnel. So for anybody in uniform, we pretty  
7 much had you covered. However, there was limited  
8 inclusion of civilian personnel in most of the DoD  
9 policies. The civilian personnel office, however,  
10 quickly issued guidance to meet identified gaps.  
11 But there was a period of time in-between the time  
12 that the gaps were realized and the time that the  
13 guidance went out, where there was some confusion  
14 on the ranks of our civilian personnel.

15 Another problem was, we all said, okay,  
16 you have to identify who is essential. Because if  
17 we have a shortage of vaccines or if the disease  
18 severity increases we want to know who need to  
19 give, let's say, antivirals to. And some folks  
20 were able to pare down what essential actually  
21 was. Other people had more difficulty doing that.  
22 Where some combatant commands felt that everybody

1 in their command was essential, to include the  
2 folks who were giving you your eggs in the morning  
3 to the missileers with their fingers on the launch  
4 buttons. So, that did lead to some difficulty as  
5 far as paring down limited resources, if we had  
6 had to go to that extent. Nonetheless, plans and  
7 policies were quickly modified to meet the new  
8 requirements.

9 Workplace policies. DoD was able to  
10 leverage the Office of Personnel Management and  
11 OSHA guidelines, aid in implanting work first  
12 protection policies. However, there was no  
13 uniform policy regarding civilian employee  
14 absentee monitoring or reporting. And one of the  
15 reasons why that was a problem is primarily HIPAA.  
16 That we weren't able to force employees to tell us  
17 why they were absent. So even though that was a  
18 gap as far as our ability to ascertain why folks  
19 were absent or what the impact was on our civilian  
20 workforce, our hands were pretty much tied due to  
21 regulations outside of DoD.

22 A few years ago we had an exercise to

1 see if we could do teleworking, and on a small  
2 scale it looked pretty good. However on a larger  
3 scale we found that we didn't have enough laptops  
4 to go around to implement wide scale telework  
5 getting to -- to facilitate social distancing.

6 Shifting gears to surveillance. The DoD  
7 surveillance system was really a key component in  
8 the initial recognition of the pandemic, and  
9 ongoing surveillance efforts. If you look at  
10 where the surveillance eyeglass was set for most  
11 of the folks in the U.S., they were all looking  
12 towards Southeast Asia. And that's where the bulk  
13 of the surveillance was.

14 However, DoD was looking both offshore  
15 and inward. And it's because DoD had that 360  
16 view that DoD surveillance activities were  
17 actually responsible for picking up the first four  
18 cases of the H1N1 strain here in the U.S. And  
19 that represented three different components of our  
20 influenza surveillance program.

21 As soon as we realized that something  
22 was different out there, the DoD surveillance and

1 public health community were put essentially on  
2 alert to look for further cases, particularly on  
3 those installations that were along borders with  
4 Mexico.

5           And then our surveillance assets were  
6 able to continue to provide timely information to  
7 DoD leadership. However at times, the frequency  
8 of the data calls, at least by some perspectives,  
9 seemed to be somewhat excessive at times. DoD  
10 leadership had a rather large need to have the  
11 latest numbers on pretty much a real time basis,  
12 which led to some problems with reporting by our  
13 surveillance community.

14           Nonetheless, the Armed Forces Health  
15 Surveillance Center fostered a communication  
16 network between our laboratory and public health  
17 community, along with Health Affairs to identify  
18 key issues and quickly adapt policies to meet  
19 ongoing requirements.

20           Another issue was our laboratory assets.  
21 When the pandemic first started it was only the  
22 state public health labs and two DoD labs that had

1 the FDA-approved diagnostic platforms. And that  
2 was primarily due to the CDC's choice of which  
3 platform they were going to request FDA approval  
4 for.

5           Shortly thereafter the FDA, through an  
6 emergency use authorization act, approved the ABI  
7 7500 fast platform, which we had a lot more of.  
8 So the result was that, for example, that USAFSAM  
9 -- the Air Force increased their typical annual  
10 capacity of about 5,000 samples per season to 23  
11 samples. And with that emergency use  
12 authorization, then there were ample diagnostic  
13 platforms across DoD, and for that matter across  
14 the civilian sector.

15           Initially our sampling was targeted  
16 towards confirmation of disease in local  
17 populations. And then later after we established,  
18 yeah, it's here, it's in all our communities, then  
19 what we wanted to do is just confirm disease in  
20 hospitalized and high-risk populations. However,  
21 the labs did experience an increased workload,  
22 primarily because of the line still needing to

1 have that data as far as exactly how many cases  
2 they had in their population, despite medical  
3 guidance for more targeted testing.

4 Also, there was a number of requests for  
5 assistance to the states. And at first we were  
6 unable to provide that because our hands were  
7 pretty full, which is DoD testing. And later, we  
8 weren't able to provide as much assistance to the  
9 states as they would have liked because of their  
10 reluctance to enact the Economy Act or the  
11 Stafford Act, which would have permitted DoD  
12 assistance and also payment for our assistance.

13 Shifting gears, antivirals. Oseltamivir  
14 represented the bulk of the DoD stockpile, and  
15 that was primarily because we were planning  
16 against an H5N1 threat. We had 8 million  
17 treatment courses, 1 million at our medical  
18 treatment facilities, and that was under local use  
19 and use authority; and then 7 million additional  
20 treatment courses in 3 strategic depots, 1 in the  
21 Philadelphia area, 1 in the Pacific, and 1 in  
22 Europe. And our antiviral policy mirrored the

1 CDC's with the exception of expanded use to  
2 maintain operational capability.

3 So the policy was first medical  
4 discretion for use. Very limited outbreak  
5 prophylaxis, by all means provide antivirals for  
6 all those hospitalized with confirmed or suspected  
7 disease. Provide antivirals to all those with  
8 high risk conditions who have suspected or  
9 confirmed disease or suspected or confirmed  
10 exposure. But if you weren't in a high risk  
11 population group and you had mild symptoms, then  
12 our guidance was that you didn't necessarily need  
13 to provide antivirals. The only exception would  
14 be if operational requirements mandated treatment  
15 based on mission and not necessarily medical risk.

16 This chart just gives you an idea of  
17 what our antiviral use was. The kind of melon  
18 color is outpatient use. The blue is inpatient  
19 use. And just like the epi curve that we saw with  
20 the pandemic and you can see that we had a fair  
21 amount of antiviral use. And this is primarily  
22 all oseltamivir.

1           However, there was very limited use of  
2     the antivirals that we purchased for our pandemic  
3     flu stockpiles. Most of the antivirals that were  
4     used were the higher priced antivirals. Same  
5     antiviral, just we paid four times as much for it.  
6     And there was a -- for some reason there was a  
7     reluctance by many of the services to approve the  
8     release of the antivirals that we had provided for  
9     them for more tactical use.

10           So, our stockpile went largely unused,  
11     despite a number of pleas to please use the cheap  
12     stuff and please use the stuff that we've  
13     stockpiled for pandemic use.

14           The way ahead for antivirals? Again,  
15     our antiviral stockpile was predominantly  
16     oseltamivir. And again, that was based on the  
17     H5N1 threat. Since then we've received  
18     supplemental funding to replace the few doses of  
19     oseltamivir that we, in fact, did use from the  
20     stockpile. We're also adding rimantadine to the  
21     stockpile to at least permit multi-drug therapy.  
22     We're also increasing zanamivir, both locally and

1 in our strategic stockpile so that zanamivir will  
2 represent about 30 percent of our overall  
3 antiviral stockpile. We also have funding  
4 flexibility that would permit the addition of new  
5 antivirals if they become available.

6 Probably the greatest source of angst  
7 across DoD was related to vaccines. And actually  
8 I had just gotten security clearance for giving  
9 this about 20 minutes before I started, and they  
10 requested that we delete this picture. So, please  
11 enjoy it before it goes away. (Laughter)

12 But vaccines were pretty much the bane  
13 of everybody's existence. Both the immunizer and  
14 the folks over at Health Affairs and the services.  
15 Part of the problem is that first we didn't know  
16 how much we were getting. They were shifting  
17 vaccine projection at least as far as our  
18 operationally-based vaccine. So, up until May of  
19 2009, we were all under the assumption that we'd  
20 be following under the National Vaccine Allocation  
21 Prioritization Plan. In which case, DoD was  
22 supposed to get 700,000 doses right off the top,

1 first vaccine off the production line. And then  
2 after other high priority groups were filled, we  
3 were supposed to get 650,000 doses. And then a  
4 little later on, 1.5 million doses.

5 Plan presumed that, again, we were  
6 dealing with an H5N1 threat. However, once the  
7 2009 H1N1 turned out to be a little less severe  
8 than what we were thinking of as far as a bird flu  
9 threat, the U.S. government abandoned this plan  
10 and shifted to a different plan.

11 Which led us to June of 2009. And at  
12 that point, DoD agreed to purchase 2.7 million  
13 doses with 1 million doses delivered  
14 early-October, followed by 1.7 million doses no  
15 later than -- they said late-October, maybe  
16 beginning of November. So, by the first week in  
17 November, we were sure that we would have our full  
18 2.7 million doses and we planned accordingly.

19 Then, in September 2009, we were  
20 notified that while vaccine projections were maybe  
21 a little higher than what was anticipated, and  
22 that we'd be getting vaccine at a slightly lower

1 rate. We began to receive vaccine in late-  
2 October. Vaccine delivery notification usually  
3 happened about 24 to 48 hours before we actually  
4 had it in hand. So as far as projecting when we  
5 were going to be getting vaccine and where it was  
6 going to be going became somewhat problematic.  
7 And we completed our 2.7 million doses, actually,  
8 on Christmas Day. So, a bit different from what  
9 our initial projections were.

10 The other problem is that we bought  
11 vaccine but we really didn't own the vaccine, that  
12 HHS controlled all vaccine allocations. And there  
13 were three different programs that DoD  
14 participated in. These were not by choice.

15 So, the first was our operational  
16 vaccine, and that's the 2.7 million doses. And  
17 you can see that we got that a little slower than  
18 what we had initially planned. And our order was  
19 completed a bit later than what we had initially  
20 planned. However, the allocation was controlled  
21 by HHS.

22 Another program that -- on that targeted

1 primarily uniformed personnel, health care  
2 workers, and some DoD civilians. The other  
3 program that we dealt with was the state  
4 allocation program. And this was the same program  
5 that everybody in the rest of the country dealt  
6 with. So each state was given a per capita amount  
7 of vaccine to be distributed among their  
8 population. So, the installations enrolled as  
9 immunizers. So, Walter Reed just like Georgetown  
10 and GW and the Mayo Clinic all had to say, yes, we  
11 are going to provide vaccine. And then they were  
12 given vaccine based on their population. And this  
13 could only be used for healthcare workers and our  
14 dependent population.

15           The third program that DoD participated  
16 in was the federal employee program. And this was  
17 targeting U.S. Government employees. And it  
18 turned out that when they totaled up all the  
19 numbers, DoD has about a third of all the U.S.  
20 Government civilian employees. So we were asked  
21 to use our distribution system to get vaccine out  
22 for that population group.

1           Now up until then, HHS had refused to  
2           supply vaccine for our OCONUS dependents. With  
3           our participation in this program, the agreement  
4           was that we would be getting extra vaccine through  
5           the federal employee program for use for our  
6           overseas dependents. So they wound up being  
7           covered that way.

8           So, we had three different programs,  
9           three different rules of engagement, three  
10          different populations that those vaccines could be  
11          used by, which created a fair amount of confusion  
12          at the local level.

13          So, switching back to our operational  
14          vaccine. Our vaccine prioritization. First to  
15          receive that operational vaccine were deployed and  
16          deploying forces. So, the folks that got vaccine  
17          first were USCENTCOM and U.S. forces Korea. Also,  
18          our health care workers, large training venues,  
19          and ships afloat.

20          So, that targeted the folks that we felt  
21          were at highest risk for disease transmission.

22          The problem was that when you send your first

1 aliquot of vaccine to deployed people, then that  
2 meant that active duty members at OCONUS  
3 installations would be getting their vaccine much  
4 later. That in the face of their dependence  
5 getting vaccine much earlier through the state  
6 allocation program left two different populations,  
7 the uniformed people that did not have access to  
8 vaccine, and the dependents that did. So,  
9 somewhat of a switch from what oftentimes happens  
10 during seasonal flu seasons.

11           The other problem was that, again,  
12 USCENTCOM and U.S. forces Korea received the first  
13 aliquots of vaccine that DoD was given. U.S.  
14 forces Korea pretty much immunized most of their  
15 people almost nanoseconds after it hit their  
16 shores, maybe a couple of days. But USCENTCOM, it  
17 wasn't until December that they were able to  
18 actually get all of the vaccine that they got  
19 upfront into arms. So that delay in actually  
20 getting vaccine into service members diverted some  
21 vaccine that we could have sent here OCONUS.

22           Another problem was that the -- we left

1     it up to the services to define who was deploying  
2     and, again, who critical personnel were.  And  
3     those definitions varied from service to service.  
4     So, there were some inequities as far as the  
5     amount of vaccine that went out to the services,  
6     particularly when we were targeting the deploying  
7     forces.

8             The other problem was that everybody  
9     wanted vaccine.  So, when we queried the services  
10    in OCONUS with their -- what their entire vaccine  
11    request was, it actually exceeded our end  
12    strength.  So, the number of folks that they said  
13    needed to get vaccine actually exceeded the number  
14    of folks that they actually had, which also led to  
15    some problems as far as distribution.

16            Another issue as far as vaccine?  
17    There's about a three week delay by the time that  
18    DoD received vaccine that you can see in the kind  
19    of pink boxes, and the times that it actually got  
20    into arms.  And there's a number of reasons for  
21    that.

22            One reason is that vaccine stayed in the

1 depot for one to two weeks after we received it.  
2 The depot worked on a five-day workweek with a  
3 time off for holidays. So, that led to some  
4 delays. Had it been a more severe pandemic we  
5 hope that they would have adopted a 24/7 workweek.  
6 The other problem is that the depot could only get  
7 -- it was about 100,000 doses a week, just as far  
8 as capacity and throughput, which led to another  
9 delay.

10 The -- let's see. I already said that.  
11 The last thing is that as vaccine trickled down to  
12 the MTFs, the desire for vaccine was kind of  
13 waning a bit. So, command emphasis probably was  
14 not quite as stringent as it would have been  
15 earlier in the pandemic when the disease threat  
16 was higher.

17 And despite that, regardless of how  
18 quickly or how slowly we had gotten vaccine, it  
19 didn't seem to impact on our epi curve. Again,  
20 the red bars here are outpatient visits, the blue  
21 hospitalized visits for ILI rates across DoD. The  
22 percentages are when we saw vaccine.

1           So you can see that the epi curve was  
2           already really plummeting by the time we started  
3           receiving any appreciable amount of vaccine. So,  
4           the impact we had on the pandemic as far as  
5           maintaining operational effectiveness was  
6           primarily due to all of the other stuff that we  
7           had in our plans as far as social distancing,  
8           antiviral use, close surveillance, and probably  
9           not vaccine.

10           The -- again, the other program that we  
11           had was the vaccine for dependents. We already  
12           mentioned that each installation received a  
13           prorated amount through HHS allocations for  
14           dependents, healthcare workers, and retirees. And  
15           DoD policy made this vaccine available for active  
16           duty members if they had a high-risk medical  
17           condition. We felt that if we had a pregnant  
18           active duty mom out there that, yeah, even though  
19           we didn't have the right color vaccine if we had  
20           vaccine on the shelf we wanted to make sure that  
21           they were protected.

22           But again, the end result was vaccine

1 was available for dependents before it was ready  
2 for or available for active duty members. And the  
3 HHS rules of engagement prohibited cross-use of  
4 vaccine.

5 Now, some states -- one in particular.  
6 Actually, Minnesota noticed that, you know,  
7 there's this disconnect. That your active duty  
8 members don't have vaccine and your dependents do.  
9 And they approached a number of medical treatment  
10 facilities and said, would you like a little  
11 extra? At which we said, sure. So, in some  
12 instances the states recognized that there was a  
13 disconnect there and did come to DoD's rescue.

14 Other states, however, were less  
15 friendly and didn't want to give us any vaccine.  
16 I won't mention which one -- New Jersey.

17 (Laughter) But nonetheless, it was kind of yin  
18 and yang as far as the states treated DoD.

19 Another problem was that to provide  
20 vaccine for your dependents and retirees, again,  
21 you had to register as an immunizer. If you were  
22 one of the unlucky installations that serviced a

1 number of states, you had to register with each  
2 one of those states and each state had different  
3 reporting requirements. So, it left a number of  
4 the installations feeling a bit schizophrenic in  
5 dealing with a number of states as far as getting  
6 vaccine for their dependents and retirees. And  
7 like the Sudun community, vaccine supply came long  
8 after the peak in demand.

9           And one other thing about this is that  
10 we were never really able to capture what our  
11 vaccination rates for our dependents were.  
12 There's only one service that does that well, and  
13 unfortunately it's the Air Force, not the Army.  
14 And the other services, their immunization  
15 tracking systems do not capture dependents. So  
16 knowing what's happening in the DoD community was  
17 somewhat lacking. We had a good handle as far as  
18 who in uniform was immunized but, again, not our  
19 dependents.

20           And actually I already mentioned this,  
21 just the U.S. Government civilian employee  
22 program. And again, by the time vaccine was

1 available, then the demand had dropped off.

2 One bright note is that one of the deals  
3 as far as DoD getting vaccine is that we would  
4 provide vaccine to the Department of State and the  
5 U.S. Coast Guard. The Coast Guard because they're  
6 a uniformed service but they're not part of DoD.  
7 They're a kind of like an orphan child where the  
8 Department of Homeland Security owns the Coast  
9 Guard but they thought DoD was going to supply  
10 them vaccine, and DoD thought that Homeland  
11 Security was going to be supplying them vaccine.  
12 So they were kind of left somewhat in a lurch.

13 So, the Coast Guard was supplied a  
14 vaccine from our operational stockpile. Vaccine  
15 to the State Department, however, was delayed due  
16 to regulatory requirements. Shakespeare was right  
17 as far as what we should be doing with lawyers,  
18 and because the vaccine was purchased in the prior  
19 fiscal year, we couldn't transfer it to another  
20 U.S. Government agency because we couldn't be paid  
21 for it with the next fiscal year's dollars.

22 SPEAKER: What a country.

1 COL HACHEY: So, that led to some  
2 delays. But each one, the Coast Guard and the  
3 Department of State, got 50,000 doses.

4 Again, vaccine tracking. Each service  
5 has its own vaccine tracking system. With,  
6 unfortunately, less than optimal integration of  
7 the three tracking systems as far as an overall  
8 DoD picture. And again, only the Air Force  
9 effectively captures dependents and retirees.

10 Also, the use of non-electronic  
11 immunization administration records resulted in  
12 some delays in entry with an unknown degree of  
13 lost data across the system. Another problem was  
14 that the reservists and National Guardsmen could  
15 receive vaccine from civilian sources. And  
16 transcription of their immunization status to DoD  
17 databases had variable compliance.

18 Despite that, we did reasonably well.  
19 And this is as of March 30th. Colonel Krukar had  
20 sent me an e-mail just before this that our  
21 numbers actually look a little better after a few  
22 months have passed. But if you look at the active

1 duty forces, we're all pretty much close to 90  
2 percent. And again, these numbers all have gone  
3 up since this last report.

4 So overall, DoD was fairly effective as  
5 far as getting vaccine either into arms or into  
6 noses, depending on the vaccine type.

7 Communication. A use of the H1N1 watch  
8 board and the MILVAX Web portal were effective  
9 communication tools to inform commanders, service  
10 members, DoD stakeholders, and beneficiaries. One  
11 example is DoD pandemic flu watch board that we  
12 briefed the board on previously had 8 million hits  
13 between April and January. And MILVAX website was  
14 averaging about 35,000 hits per day. So, our --  
15 at least our websites were a well-known before the  
16 pandemic started and used fairly effectively.

17 Another thing that we used was some  
18 flash messaging services that targeted our  
19 pharmacists. If we needed to get word out today  
20 so that each medical treatment facility, their  
21 providers knew by close to business day, we used,  
22 again, MILVAX, their communication network to the

1 pharmacists who then relayed it to their  
2 providers.

3 Some installations also had call  
4 centers. But communication was variable at local  
5 levels as far as regarding vaccine availability,  
6 particularly in large metropolitan areas where  
7 some of the dependents had some confusion -- for  
8 that matter, the installations had some confusion  
9 as far as what was available in their local areas.

10 So, what are some things that we can  
11 fix? Well first of all, funding. Supplemental  
12 funding was received for the purchase of antiviral  
13 medications. So, again, we're putting that  
14 towards a replacement of oseltamivir stocks,  
15 buying more zanamivir or Relenza. Also, some  
16 rimantadine. And again, if the next best thing to  
17 white bread comes out as far as a new antiviral,  
18 we'll have the ability to purchase that.

19 Another thing that we've received  
20 supplemental funding for is more personal  
21 protective equipment for use by our healthcare  
22 workers. And that's replaced existing stockpiles

1 and to actually increase stockpile levels.

2 A third component in supplemental  
3 funding was to also increase our surveillance  
4 capability. On a year-to-year basis we've  
5 requested POM funding for enhanced surveillance.  
6 The maintenance of our existing stockpiles -- once  
7 it costs money for storage and stability testing.  
8 And then, ongoing antiviral and vaccine  
9 acquisition. However, that overall program is in  
10 jeopardy if that funding is not received. And  
11 that is still being reviewed.

12 More stuff that we can fix. You know,  
13 one thing that we did learn is that as a  
14 department we need to be a lot more proactive as  
15 far as making sure that vaccine purchased by us is  
16 owned by us, then used when and where we want to  
17 use it. So that we're not, essentially, held  
18 hostage by another U.S. Government agency who, in  
19 all fairness, had a bigger piece of the pie to  
20 provide vaccine for. We're also expanding our  
21 antiviral portfolio. And one thing that's going  
22 to be fielded, at least in a pilot form shortly,

1 is a uniform immunization tracking system where  
2 all three services will be using the same system,  
3 so we will be able to have a good idea of what our  
4 immunization rates are across the DoD spectrum.

5 And another thing that is new is that  
6 using the DoD pandemic influenza plan. DoD plans  
7 are now being adjusted, not to center just on  
8 pandemic influenza, but to encompass all  
9 biothreats. So, we have more of a flexible  
10 response to a wide array of threats.

11 So, one thing we've learned during the  
12 past pandemic. You know, it really does matter  
13 what you buy. You know, give you a second to --  
14 and this, too, will be the last time you see it,  
15 because it was pulled by our security folks. So,  
16 enjoy. (Laughter)

17 So, as far as response options. You  
18 know, the choice is ours. We can take either  
19 approach and with, essentially, ongoing funding  
20 and the lessons that we've learned from this past  
21 pandemic, we got off fairly easily once there was  
22 a relatively mild severity. But if the next one

1 is more like an H5N1 threat, then hopefully we'll  
2 be the duck with his head above water.

3 And any questions? (Applause)

4 DR. POLAND: Comments or questions?  
5 Frank?

6 DR. ENNIS: Thank you, Colonel Hachey.  
7 It -- we've talked about this before, this  
8 committee. But -- and probably the blame resides  
9 with HHS. But, in fact, it was a failure. All  
10 the vaccine was given after the outbreak. So,  
11 although a lot of people were immunized, it wasn't  
12 given at the appropriate time.

13 And I think forbearers on this committee  
14 would roll over in their graves if they knew the  
15 DoD lost control of the ability to immunize  
16 against influenza in a timely fashion. The  
17 decision was made high up. But I don't think DoD,  
18 you know, was effective in immunizing the troops  
19 last year.

20 DR. POLAND: Joe.

21 DR. PARISI: Thank you very much for the  
22 presentation.

1 I had a question about the tracking  
2 system that you're developing. Do you have a time  
3 frame for that? I mean, it seems like that would  
4 be a very -- a much more efficient way of ensuring  
5 that the troops are immunized at the appropriate  
6 time.

7 COL HACHEY: Let's see. Colonel Krukar  
8 can correct me -- or actually, I'll just let him  
9 speak.

10 COL KRUKAR: That universal immunization  
11 tracking system is being established, and still  
12 some requirements are still ongoing for this. But  
13 it's going to be given back over to DHIMS to begin  
14 implementation, and the plan is for March of next  
15 year. And then with the full rollout to the MTFs  
16 beginning 1 October of next year.

17 So we're still about a year away from  
18 this.

19 DR. POLAND: Bill?

20 DR. HALPERIN: Bill Halperin. Do you  
21 foresee in the future being able to do vaccine  
22 effectiveness in real time with some of the

1 systems you're developing?

2 COL HACHEY: Actually, that's a good  
3 question. We -- probably not real time, but as  
4 the pandemic progressed through the -- actually  
5 through the Armed Forces Health Surveillance  
6 Center we were able to get kind of an ongoing  
7 tally of how things were looking.

8 But unfortunately, you need, you know,  
9 fairly substantial numbers to get some reliable  
10 data. And particularly the way we got vaccine,  
11 you know, it kind of trickled on in. So, the  
12 other problem was disease ascertainment. It was  
13 some problematic, at least last time. So, if we  
14 have like an H5N1 threat where, you know, you know  
15 you have disease because you're dead, then I think  
16 things might be a little easier as far as getting  
17 answers like that. But with the -- at least with  
18 the past pandemic, once we weren't quite sure how  
19 many cases were unreported, especially early on,  
20 that would be a problem.

21 DR. HALPERIN: The disease ascertainment  
22 I understand as a problem. But I didn't actually

1 understand the comment about the OSHA regs because  
2 I didn't think that federal employees were covered  
3 by OSHA.

4 So, if the DoD wants to know why  
5 somebody's out?

6 COL HACHEY: Oh, that was not OSHA.  
7 That's -- actually it's HIPAA --

8 DR. HALPERIN: HIPAA?

9 COL HACHEY: And that governs the  
10 civilian workforce. So, for our active duty  
11 force, yeah, we own them. But for our civilian  
12 workforce we still have to follow HIPAA  
13 regulations. And for that matter, for our  
14 uniformed folks, the same thing applies.

15 DR. WALKER: So this pandemic flu didn't  
16 occur at the same seasonal time that the flu  
17 epidemic does? Is there any way to prepare for  
18 that happening?

19 COL HACHEY: Actually, I think we were  
20 -- as far as DoD, I think we were well prepared.  
21 You know, again if it wasn't for the DoD influenza  
22 surveillance system working year-round, that we

1 wouldn't have picked up those cases. And our  
2 plans were in place, our stockpiles were in place.  
3 So it was just a matter of essentially pulling the  
4 trigger and saying, it's here.

5 So, at least from our perspective, the  
6 seasonality was less of an issue. Except for the  
7 vaccine production.

8 DR. SILVA: Joe Silva. Thank you for  
9 tonight's presentation, again, Wayne.

10 Those deaths that occurred. Were they  
11 analyzed for receipt of vaccine? Did they get  
12 Tamiflu on the ride down towards death or any  
13 other antibiotics? Had they been dissected yet?

14 COL HACHEY: Let's see. I only know of  
15 a couple of them. I don't know all eight. But  
16 the one that we presented today did not receive  
17 antivirals. I believe at least one of the active  
18 duty members had not received antivirals. And  
19 actually let me take that back -- one additional  
20 dependent also didn't receive antivirals. And the  
21 lion's share of the folks were pre-vaccine, if not  
22 all.

1 DR. LEDNAR: Wayne Lednar. Colonel  
2 Hachey, you mention on your next to last slide  
3 that going forward the DoD is planning on  
4 adjusting its approach to encompass all  
5 biothreats. So my question is, how will you do  
6 that? What will be the data sources that you'll  
7 sort of keep your finger on the pulse of what  
8 these threats are and where they are? And then,  
9 have you thought at all about how you'll  
10 prioritize those threats?

11 COL HACHEY: Well, as far as knowing  
12 what's out there and what's happening, that would  
13 be just our surveillance system that's already  
14 tracking all of those threats anyway. So, there's  
15 no shift there.

16 As far as the prioritization of the  
17 threats, that may become a problem. And the  
18 reason for that is funding. That I'd say the  
19 threats that are more tailored towards intentional  
20 releases may receive more funding than those that  
21 are released by Mother Nature. So, there is that  
22 potential of prioritization based on funding

1       rather than on the threat to the force.

2               So that is an issue that we do need to  
3       look out for.

4               DR. POLAND:   Dr. Shamoo?

5               DR. SHAMOO:   Adil Shamoo.   I guess now  
6       we laugh about these hiccups.   But our job is to  
7       help them in prevention and treatment.   And this  
8       vaccine was a prevention.

9               If H1N1 was as virulent as everybody  
10       thought of, each one of these hiccups could have  
11       cost us tens of thousands of lives and there would  
12       have been a big scandal.   And I'm thinking, what  
13       can we do to help mitigate those barriers ahead of  
14       time rather than wait for another epidemic -- or  
15       potential epidemic.

16              DR. POLAND:   Just to correct maybe one  
17       misperception.   That while vaccine was late, there  
18       was still plenty of antivirals in place that, you  
19       know, would have mitigated those tens of thousands  
20       of deaths.   But, yeah, I think a major issue is,  
21       as several members have pointed out is, the  
22       vaccine was too little too late and that's not

1 something DoD can do anything about. It is  
2 something that the federal government is vitally  
3 interested in and has released -- I've forgotten  
4 now, was it about \$3 billion in funding for cell  
5 culture and other techniques to try to accelerate  
6 the process of vaccine manufacture?

7 The problem is discovered in March,  
8 early April. It literally took six months, just  
9 as predicted -- well, they actually predicted it  
10 would be faster. But it takes six months to make  
11 the vaccine.

12 So I think, you know, from my  
13 perspective a couple of things are noteworthy.  
14 DoD was the first to pick up cases. It had the  
15 first draft plan, it was the first organization  
16 integrated into the federal work groups. The only  
17 one that sat on the ACIP. It had among the best  
18 outcomes. It had the highest immunization rates.  
19 It had, given the limitations that are imposed  
20 upon it, had, I think, some of the best  
21 distribution policies, procedures, and  
22 stockpiling. And perhaps most emblematic of

1 optimism for the future is what you just heard.  
2 DoD, in this instance, I think, could be  
3 characterized as a learning organization. They've  
4 done a look-back at what worked well and what  
5 didn't. Other groups haven't done that yet. And  
6 I think those will be helpful in going forward.

7 The other thing worth mentioning is that  
8 initially myself and then it transitioned to John.  
9 A member of our board, actually sat on -- I've  
10 forgotten the technical name of it, John. The --

11 DR. CLEMENTS: I'm sorry, John Clements.  
12 It's the VSAWG. It's the Vaccine Scientific  
13 Advisory Working Group for Safety of the H1N1  
14 Vaccine.

15 DR. POLAND: And DoD is a major  
16 contributor to that safety database, primarily  
17 because of the extent -- the breadth and depth of  
18 the data capture that they do have.

19 Mike, do you want to make any additional  
20 comments in regard to this presentation?

21 COL KRUKAR: I can. We have  
22 participants who are part of the biz reg. And in

1 this working group, out of my office -- and I  
2 think that at the end of this month, I think, Dr.  
3 Clements, is when the preliminary findings may be  
4 presented.

5 DR. POLAND: So I think, you know, what  
6 we'll take back on the ID subcommittee is this  
7 very transparent set of lessons learned and work  
8 those in terms of what we might advise in terms of  
9 future improvements.

10 But all in all, given the constraints  
11 imposed on DoD, I think it was a job well done.

12 DR. SHAMOO: Well, thank you for  
13 informing me. I really appreciate it. You're  
14 more familiar with it, obviously.

15 DR. POLAND: Other comments? John.

16 DR. CLEMENTS: John Clements again. But  
17 I do think we were extraordinary fortunate here --

18 DR. POLAND: Oh, no question --

19 DR. CLEMENTS: -- in many respects. I  
20 mean, this turned out to be a virus that was close  
21 to one that was already in -- one that we could  
22 make relatively quickly in an FDA-approved

1 fashion. Had this been an H5 or something that  
2 was non-influenza, the challenge would have been  
3 horrendous because we would have been stuck with  
4 trying to produce a non-FDA approved vaccine in --  
5 using systems that have not been thoroughly tested  
6 the way that influenza has. So I think there are  
7 a lot of things to learn here from what worked,  
8 but I think we should also be mindful that the  
9 challenges of something else crawling over the  
10 horizon are going to be huge if it turns out to be  
11 something other than influenza.

12 DR. POLAND: Yeah. Dr. Clements makes a  
13 good point for H5N1. While there was an  
14 FDA-approved vaccine, it induced what was thought  
15 to be protective titers of immunity in about 50  
16 percent of people after 2 doses at least a month  
17 apart. Which would have, again, been a very  
18 different scenario than this one. So, indeed we  
19 were lucky.

20 COL HACHEY: In one of the --  
21 recognizing that the vaccine was such an issue, in  
22 our ongoing funding request one of the things that

1 we want to do is to continue to stockpile vaccine  
2 like we have stockpiled the H5N1 vaccine. So that  
3 the leading threat is always represented on our  
4 shelf.

5 So, you know, again with H1N1, everybody  
6 was kind of taken by surprise. But if it does  
7 wind up being one of the frontrunners that we had  
8 been surveilling all along, then our goal is to  
9 have vaccine on the shelf so that we're not  
10 waiting for vaccine to be produced.

11 The other thing that we purchased is  
12 vaccine adjuvant. So even if we have a less than  
13 optimal match, at least the animal data and some  
14 limited human data suggest that if you take your  
15 H5N1 vaccine with a substantially lower dose, you  
16 only need one dose for good protection and, in  
17 fact, good cross-protection even if the strain  
18 isn't a terribly good match.

19 So, providing we have funding, we are  
20 hoping to be prepared as far as having a DoD-owned  
21 and controlled vaccine supply so that we can start  
22 an early immunization program if the need presents

1       itself.

2                   DR. POLAND:   Dr. Lednar, and then  
3       Colonel Krukar.

4                   DR. LEDNAR:   I think as we think about  
5       learning from this past experience and preparing  
6       for the next, I think there's an element of  
7       context that we should keep in mind.

8                   Especially in Europe there is quite an  
9       active discussion right now that this pandemic was  
10      embellished, over described.  Made into more than  
11      it was, in terms of severity and threat.  I think  
12      there's plenty of objective evidence to say that  
13      that's not a fair assumption, but it is quite a  
14      drumbeat in Europe.

15                  In the next pandemic there will be some  
16      who will remember that the push to get immunized  
17      against a pandemic threat turned out to be minor,  
18      and next time, therefore, why bother?  Or a loss  
19      of trust in some public health authorities in  
20      terms of what they say.

21                  So, what this may add up to is I think  
22      we may need better ways to communicate, more

1 persuasively communicate based on objective  
2 evidence, than we do right now. Because it's  
3 going to, in the future -- unless it's a very high  
4 case fatality threat, we're going to have a lot of  
5 people who are going to be disinclined to take  
6 advantage of the preventive intervention.

7 DR. POLAND: Colonel Krukar?

8 COL KRUKAR: And to help with the  
9 preventive intervention, TRICARE management  
10 activity has issued a rule whereby any DoD  
11 beneficiary can now receive the influenza -- the  
12 H1N1 or pneumococcal vaccine -- at no charge to  
13 the individual at any retail pharmacy location.  
14 Which means, any CVS or Walgreen's they can go out  
15 and get that now. They issued that last December.

16 DR. POLAND: Dr. Kaplan?

17 DR. KAPLAN: Perhaps I missed it, Wayne,  
18 but what's the current status of H5N1 this year?

19 COL HACHEY: It is still plugging along.  
20 The areas that have had human cases are still  
21 having to have -- still having human cases. It's  
22 not increasing, but it is pretty much a steady

1 state.

2 DR. KAPLAN: Geographically?

3 COL HACHEY: Same areas. It hasn't  
4 reached this hemisphere yet, but it is still  
5 active. Indonesia still has activity. Egypt has  
6 a fair amount of activity.

7 DR. POLAND: Dr. Ennis?

8 DR. ENNIS: I wanted to ask the  
9 question, Wayne, about the enhanced surveillance.  
10 So, the surveillance in the U.S. picked up those  
11 cases. Is the DoD going to support the enhanced  
12 surveillance activity in places such as Southeast  
13 Asia on a continuing basis?

14 COL HACHEY: Providing we continue to  
15 get funding.

16 DR. ENNIS: And I -- this question is  
17 probably for you, Greg. But if someone just  
18 mentioned that perhaps the DoD will have more  
19 control over purchasing vaccine and administering  
20 it in the future than it had last year. So is  
21 there a progress or is there some understanding  
22 that the DoD will return to being an independent

1 purchaser of vaccines and not be relying on  
2 directives from other government agencies?

3 COL HACHEY: The problem this time --  
4 comparing this with H5N1. So with H5N1 we have  
5 been buying vaccine. It's ours, we use it however  
6 we want. With H1N1, it was a national buy by HHS.  
7 And that was a decision above the organizational  
8 chart that DoD sits. So, in circumstances like  
9 that, then I think -- and I can't speak for DoD  
10 leadership. But I would hope that given our past  
11 experience with H1N1, that some of our leadership  
12 may be more vocal as far as making sure that DoD  
13 has its own supply upfront.

14 But that's well out of anywhere I'll  
15 ever see in the organization.

16 DR. POLAND: Russ?

17 DR. LUEPKER: Yes. Colonel Hachey,  
18 you've -- this is Russell Luepker -- you said at  
19 least half a dozen times "if we get funding." I'm  
20 curious about what the cost of this program was,  
21 and why you feel that there's a threat to funding?

22 COL HACHEY: Well, over the past 5 years

1 we've been spending anywhere from -- depending on  
2 the year -- between \$100 million and about \$150  
3 million for pandemic flu-related activities.

4 Of that, usually -- again, about \$50  
5 million goes toward surveillance with somewhere  
6 between \$60- and \$70 million for medical  
7 countermeasures.

8 That was true up until FY10. In FY10,  
9 our budget was cut from a little over \$100 million  
10 to \$50 million, with most of that -- actually all  
11 of that -- being earmarked for surveillance. Out  
12 of that \$50 million we took back \$8 million, and  
13 that's just to maintain our current stockpiles.  
14 To essentially pay the rent for our vaccines, for  
15 our antivirals, needles and syringes, ventilators.  
16 So just maintaining what we have, and no new  
17 expenditures.

18 We've received \$160 million in  
19 supplemental funding. And with that we're paying  
20 for more personal protective equipment, enhanced  
21 surveillance, and replenishing our antiviral  
22 stockpile, and increasing the portfolio of our

1       antiviral stockpile.

2                   For year-to-year requirements what we  
3       need is about \$100 million.  And right now we are  
4       budgeted again at \$50 million for the next 5  
5       years.  One of the things that's being discussed  
6       -- almost as we speak, I believe tomorrow -- is  
7       whether to increase our baseline funding from that  
8       \$50 million mark back to around \$100 million plus  
9       inflation over the next 5 years.  And that's the  
10      big "if" as far as funding.

11                  So, the \$50 million pretty much keeps  
12      the wheels turning a little slower than what they  
13      were doing before.  And anything above that lets  
14      us essentially keep track of inflation and to also  
15      keep abreast of any new medication developments  
16      that come around that we might want to add to our  
17      portfolio.

18                  DR. POLAND:  Dr. Parkinson.

19                  DR. PARKINSON:  Yeah, Mike Parkinson.  
20      Very useful summary for me, Wayne.  Because as  
21      someone who's not a primary influenza expert,  
22      sometimes information overload -- which was not

1     what we had.  But, you know, you get a lot of  
2     static noise.  And what we probably need, if it's  
3     not already been done, Dr. Poland, is to  
4     crystallize the absolute crystal clear message of  
5     this hot wash to Secretary Gates and through the  
6     ASD(HA).

7             Namely, that had we had a real threat,  
8     despite all the firsts you mentioned -- but they  
9     should be noted -- we would have missed the mark.  
10    Because we over-relied on a government  
11    distribution system that, historically, we now  
12    have real data.  And would suggest that we  
13    immediately assure that that's our number one job,  
14    is the fitness and the readiness of the force.  To  
15    do what we have to do.  And this is a major  
16    concern.

17            I wouldn't, obviously, get into funding  
18    levels.  That's not our job.  But if it's that  
19    crystal -- Dr. Ennis, I appreciate your comments  
20    -- we just need to put it in simple text.  And  
21    maybe it's been done, but it's not really in a  
22    briefing, per se.  It's in a short, factual

1 summary --

2 DR. POLAND: I could see that being very  
3 useful.

4 DR. PARKINSON: -- to the Secretary.

5 DR. POLAND: Yeah.

6 DR. WALKER: Well, not only will the  
7 next one likely be much worse than this, but this  
8 one's much worse than many of us think it was, if  
9 you look at such figures as years of life lost.  
10 Because the fact that it attacked younger  
11 individuals.

12 DR. POLAND: Right. Okay. I think we  
13 have completed our duties for today. Ms. Bader,  
14 do you want to give some admin remarks and we'll  
15 be dismissed?

16 MS. BADER: All right. Sounds great.  
17 For board members, ex officio members, service  
18 liaisons, speakers, and invited guests, tomorrow  
19 morning, again, we will start off with an admin  
20 session at 8:00 in the morning. Registration  
21 starts at 7:30. We'll have a session from 8:00 to  
22 9:00, and then the open session will begin at

1 9:00.

2 For those of you joining us for dinner  
3 tonight, please convene in the lobby by 6:00 p.m.  
4 The group dinner is scheduled for 6:30 at  
5 Restaurant 3 located at 2950 Clarendon Boulevard  
6 in Arlington, for those who will be driving. It's  
7 only, again, about a mile and a half away. And  
8 for those who will be leaving and taking the Metro  
9 after this meeting, it's right across the street  
10 in Roslyn down Fort Myer Avenue.

11 So, again, we will reconvene the open  
12 session tomorrow morning at 9:00 a.m. For folks  
13 that will attend the administrative session, 8:00  
14 next door, just like we started this morning.

15 We're going to adjust the agenda for  
16 tomorrow afternoon, and I'd like to ask that  
17 Colonel Mott, Lieutenant Colonel Gould, and  
18 Captain Naito be available to brief at 11:00. We  
19 have an administrative session planned for lunch,  
20 so please -- I know many of you if you're not  
21 doing PT prior to your flight and you want to head  
22 out early, if you could just try to make your

1 plane reservation for after the lunchtime that  
2 would be greatly appreciated.

3 (Whereupon, at 3:57 p.m., the  
4 PROCEEDINGS were adjourned.)

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CERTIFICATE OF NOTARY PUBLIC

DISTRICT OF COLUMBIA

I, Christine Allen, notary public in and for the District of Columbia, do hereby certify that the forgoing PROCEEDING was duly recorded and thereafter reduced to print under my direction; that the witnesses were sworn to tell the truth under penalty of perjury; that said transcript is a true record of the testimony given by witnesses; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this proceeding was called; and, furthermore, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

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Notary Public, in and for the District of Columbia

My Commission Expires: January 14, 2013