

UNITED STATES DEPARTMENT OF DEFENSE
DEFENSE HEALTH BOARD

CORE BOARD MEETING

Colorado Springs, Colorado
Monday, August 17, 2009

PARTICIPANTS:

ALLEN MIDDLETON

GREGORY POLAND

ROBERT CERTAIN

NANCY DICKEY

BILL HALPERIN

EDWARD KAPLAN

JAMES LOCKEY

MICHAEL OXMAN

MICHAEL PARKINSON

ADIL SHAMOO

ANNE MOESSNER

COLONEL MICHAEL KRUKAR

LIEUTENANT COLONEL MEL FOTINES

COMMANDER ERICA SCHWARTZ

COLONEL JONATHAN JAFFIN

MAJOR MIKE FEA

LIEUTENANT COMMANDER JULIA SPRINGS

CAPTAIN NEIL NAITO

ROSS BULLOCK

CHARLES FOGELMAN

JOESEPH SILVA

PARTICIPANTS (CONT'D):

DENNIS O'LEARY

TOMAS MASON
RUSSELL LUEPKER
FRANCIS ENNIS
JOHN CLEMENTS
LIEUTENANT GENERAL MIKE GOULD
RICHARD MYERS
COMMANDER EDMOND FEEKS
WAYNE LEDNAR
COLONEL RICK LACASTRO
COLONEL KEN KNIGHT
LIEUTENANT COLONEL CATHY WITKOP
LIEUTENANT COLONEL LORI HOBBS
SERGEANT FIRST CLASS ERIC STRAND
LIEUTENANT COLONEL CHRIS COKE
ANN PETERSON
COLONEL TIM GREYDANUS
MEGAN DELANEY
LIEUTENANT COLONEL BOB WILSON
COLONEL NAOMI BOSS
RICHARD RAYBOLD
PARTICIPANTS (CONT'D):
LARRY LAUGHLIN
JAMES KELLY
LIEUTENANT COLONEL PATRICE MORRISON

SERGEANT RYAN DAVINE

LIEUTENANT COLONEL JERRY PARISH

* * * * *

P R O C E E D I N G S

(9:00 a.m.)

DR. LEDNAR: Okay. I'd like to begin. First of all, my name is Wayne Lednar and on behalf of Dr. Wilensky, our president of the Defense Health Board, I'd like to welcome everyone to this meeting of the Defense Health Board and to extend a special welcome to our new board members who are here.

We have several important topics to discuss in our agenda today, so let's get started.

Mr. Middleton, would you please call this meeting to order?

MR. MIDDLETON: Thank you, Dr. Lednar. On behalf of Ms. Embrey and as the alternative designated federal officer for the Defense Health Board, a federal advisory committee and a continuing independent scientific advisory body to the Secretary of Defense, via the Assistant Secretary of Defense for Health Affairs, and the Surgeons General of the military departments, I hereby call this meeting of the Defense Health Board

to order.

DR. LEDNAR: Thank you, Mr.

Middleton. Now, in carrying on tradition that Dr. Poland established several years ago in the Defense Health Board, I'd ask that we stand for a moment of silence to honor those we are here to serve, the men and women who serve our country. And I'd also ask if we would remember, please, that two of our Defense Health Board members have recently suffered a very close and personal family loss. So, let's please remember them and their families in this moment of silence.

(Moment of silence.)

DR. LEDNAR: Thank you. Now, please be seated. This is an open session of the Defense Health Board. Before we begin, I'd like to do a go around, first of the Board, and then for our invited guests.

If you'd please introduce yourself, your name, where you are stationed and your function so that we can all get to know each other. So, if I can start with Mr. Middleton, please sir.

MR. MIDDLETON: Good morning. Alan Middleton, the acting principal deputy assistant to the Secretary of Defense, the federal official for the Defense Health Board and I'm at the Pentagon.

DR. POLAND: I'm Greg Poland, Professor of Medicine and Infectious Diseases at the Mayo Clinic in Rochester, Minnesota. I had the privilege of being the president of this Board and now Vice-President.

Rev CERTAIN: I'm Robert Certain, I'm an Episcopal priest from Atlanta, Georgia. I had 30 years of commissioned service in the Air Force as a B-52 aviator, prison of war chaplain, and various sundry of other things including five summers here with basic cadet training. I'm a generalist and is somebody who tries to put interesting pieces of puzzles together to make them actually work.

DR. DICKEY: I'm Nancy Dickey. I'm the Professor of Family and Community Medicine and President of the Texas A&M Health Science Center. I'm one of those generalist that hope we all help us put it altogether.

DR. HALPERIN: Bill Halperin, I'm chair of Preventive Medicine, New Jersey Medical School, and chair of the subcommittee on occupational and environmental health. And I really would like to express my appreciation for all the condolences that have come from Board members. Thank you.

DR. KAPLAN: I'm Ed Kaplan, Professor of Pediatrics at the University of Minnesota Medical School in Minneapolis.

DR. LOCKEY: Jim Lockey, Professor of Pulmonary Medicine and Bramanal Health, University of Cincinnati College of Medicine.

DR. OXMAN: Mike Oxman, Professor of Medicine and Pathology at the University of California, San Diego, an infectious disease doctor and a virologist, a minuscule area.

DR. PARKINSON: Mike Parkinson, I'm currently working with a number of healthcare organizations under the umbrella called P3 Health, which I call prevention, performance and productivity, so health systems corporations, people focusing on what I consider to be the core drivers of poor health

and excessive health care costs.

I also was most recently the president of the American College of Preventive Medicine.

DR. SHAMOO: Adil Shamoo, professor at the University of Maryland, School of Medicine Molecular -- Chemistry and Molecular Biology, and I am a bioethicist.

DR. MOESSNER: Anne Moessner, I'm at the Mayo Clinic in Minnesota. I do TBI clinical care research and education, and I'm an assistant professor there, and currently chairing the TBI family caregiver panel.

COL KRUKAR: Hi, Colonel Michael Krukar, the director of the Military Vaccine Agency.

Lt Col FOTINES: Lieutenant Colonel Mel Fotines, I'm the Air Force Chief Consultant for Preventive Medicine.

CDR SCHWARTZ: Hi, I'm Commander Erica Schwartz from Coast Guard Headquarters. I'm the Coast Guard Preventive Medicine Liaison.

COL JAFFIN: Colonel Jonathan

Jaffin, Director of Health Policy and Services for the Office of the Army Surgeon General.

MAJ FEA: Good morning, I'm Major Mike Fea. I work over at the Joint Staff J4. I'm the Joint Operations Environmental Health Officer.

LCDR SPRINGS: Good morning, I'm Lieutenant Commander Julia Springs. My background is pediatrics and aerospace medicine. I'm currently the Preventive Medicine Officer at Headquarters Marine Corps.

CAPT NAITO: Captain Neil Naito, Director of Clinical Care and Public Health, NAVY Medicine, Washington D.C.

DR. BOLLOCK: I'm Ross Bullock. I'm the Professor of Neurosurgery, University of Miami, and the new incoming Chair of the TBI Subcommittee.

DR. FOGELMAN: I'm Charlie Fogelman, I'm a psychologist in private practice and mostly I make my living now doing consulting and leadership development in organization development, and coaching, and those sorts of things. And I'm here as Chair of the

Psychological Health Subcommittee.

DR. SILVA: Good morning, Joe Silva, Professor of Internal Medicine, Infectious Diseases, Dean Emeritus, University of California. My new responsibilities are to help our campus on international education programs and our medical school on its global health programs. I do everything. I even empty my own garbage cans now.

DR. O'LEARY: I'm not that good. Dennis O'Leary, President Emeritus of the Joint Commission and currently involved in the variety of patient safety activities.

DR. MASON: I'm Tom Mason, Professor of Environmental Occupational Health, College of Public Health, University of South Florida, Tampa.

DR. LUEPKER: I'm Russell Luepker and I'm Professor of Epidemiology and Medicine at the University of Minnesota.

DR. ENNIS: I'm Frank Ennis, Professor of Medicine, Molecular Biology and Genetics at the University of Massachusetts Medical School.

DR. CLEMENTS: John Clements, I'm the Chair of microbiology and immunology and Director of the Tulane University Center for Infectious Diseases in New Orleans.

Lt GEN GOULD: Good morning, I'm Lieutenant General Mike Gould, Superintendent here at the Air Force Academy. Welcome.

Gen(Ret) MYERS: Dick Myers, retired Air Force, Core Board member, also on the Medical Ethics Subcommittee.

CDR FEEKS: Commander Ed Feeks, Executive Secretary of the Defense Health Board.

DR. LEDNAR: Wayne Lednar, Global Chief Medical Officer for Dupont and Director of Integrated Health Services, and one of your two Vice-Presidents of the Board as servant leaders with Dr. Greg Poland.

If I can ask, in the audience if we can pass the microphone, if you'd introduce yourselves, please.

Col LACASTRO: I'm Colonel Rick LaCastro, I'm the Commander of the 10th Air Base Wing here at the Air Force Academy.

Col KNIGHT: Colonel Ken Knight, the
Commander of the 10th medical group.

Lt Col WITKOP: Lieutenant Colonel
Cathy Witkop, I'm the Preventive Medicine
physician here at the Air Force Academy.

LTC HOBBS: Lieutenant Colonel Lori
Hobbs from Health Affairs.

SFC STRAND: Sergeant First Class
Eric Strand, Special Forces medic assigned to
(inaudible) Special Forces group.

LTC COKE: Lieutenant Colonel Chris
Coke, Joint Staff J3.

DR. PETERSON: Dr. Ann Peterson,
George Washington University Research
Professor, formerly in charge of USAID's
global health care grants.

Col GREYDANUS: I'm Colonel Tim
Greydanus, I'm the Commander of the Cadet
Flight Medicine Clinic here at the Air Force
Academy.

MS. DELANEY: I'm Megan Delaney, I'm
representing the international health
division.

LTC WILSON: Lieutenant Colonel Bob

Wilson, Director of Psychological Health Clinical Centers of Care, Defense Center of Excellence through Psychological Health and Traumatic Brain Injury.

COL BOSS: Colonel Naomi Boss and I'm the Chief of Healthcare Delivery Pps at JT under JTF (inaudible).

MR. RAYBOLD: Rich Raybold, Office of the Director, Armed Forces Institute of Technology.

DR. LAUGHLIN: Larry Laughlin, Dean School of Medicine Uniformed Services University. I was an internist and infectious disease doc at one time.

DR. KELLY: Jim Kelly, Director of the National Intrepid Center of Excellence at the National Naval Medical Center, and the immediate Past President -- Chairman, I'm sorry of the TBI (inaudible) Advisory Subcommittee.

Lt Col MORRISON: Lieutenant Colonel Patrice Morrison, FMP, Flight Commander for the cadet clinic.

TSgt DAVINE: Technical Sergeant

Ryan Davine, I'm the Flight Chief for Public Health in flight here at the Air Force Academy.

Lt Col PARISH: Lieutenant Colonel Jerry Parish, Chief of the training division for the cadet wing at the Air Force Academy.

DR. LEDNAR: Thank you and welcome. On behalf of the Board, it really is a great pleasure and honor to be able to have this meeting at the Air Force Academy, and in fact to have the superintendent, Lieutenant General Mike Gould, join us for a brief time this morning.

So, General Gould, would you like to say a few things?

MR. GOULD: Sure would, thank you.

DR. LEDNAR: General Gould, thank you first of all. I understood yesterday, one of my learnings was that there is a portion of the Falcon stadium that is at 7,000 feet. Is that correct?

MR. GOULD: It is and you're a little higher than that right now.

DR. LEDNAR: Okay. So high

altitude, high expectations for that football team this year.

On behalf of the Board, we'd like to express our gratitude for your hospitality, for hosting us at this meeting, providing an opportunity for the Board to get more familiar with the Academy, the challenges you face in training our future leaders, and tomorrow the opportunity to actually get a little bit of time to spend with the cadets, and I think that will give us great insight into how we might best help you. So, thank you, sir.

We'd ask at this point if Colonel Locastro, the Base Commander, if he might say a few words to us. Colonel?

Col LOCASTRO: I'm an Italian guy from New York, if you couldn't hear my volume -- you sit around the dinner table at my house, nobody needs a microphone. But if there is anything you really do want to know about how we've attacked the challenge that we've had of H1N1 as a general goal set, Colonel Ken Knight is our med group Commander and he has really led the team that has been

proactive in addressing the issue. And just like lots of universities, and I'm sure all the other military academies that are looking at the same issue, you know, you really have to have an aggressive program.

So it's been his team that has led it. He will be here most of the day today and happy to answer any of your questions. If you want to see anything else up close or anything about the Air Force Academy, please let us know.

Having said that, we have some hand sanitizer right here. Do not leave this room unless you wash your hands, but I know this group understands that.

But once again, welcome, enjoy your time here and let us know if there is anything that we can do to make your stay more enjoyable and more comfortable. Thanks for being here.

DR. LEDNAR: Thank you, Colonel Locastro. We'd like to start our meeting really with recognizing some very important work. And before Colonel Locastro gets away,

we'd like you to be part of what we're going to do next and that's really to recognize some of the very, very important work that's been done here at the Air Force Academy on a very important public health issue.

So, Mr. Middleton and Dr. Poland.

MR. MIDDLETON: Thank you. In a moment we're going to recognize a couple of folks, but I want to make a couple of comments. If you'll indulge me on a personal moment, my very first assignment in the Air Force was at the Air Force Academy as a Second Lieutenant and I was the administrator of the Air Force Academy Cadet Clinic back when it was in Fairchild Hall about 1,000 years ago. And we had a flu outbreak, and I was one of the two or three -- I think we had one doctor make it into the clinic, or maybe two, myself as the administrator and we had a couple of technicians. And I was pressed into pharmacy duty and I was actually putting labels on bottles and handing them across to cadets through the pharmacy window during a flu outbreak. So, this is very real to me that

you folks went through this recently.

But on behalf of the department, I'd like to acknowledge those individuals who demonstrated a significant dedication and support to the Department of Defense, obviously to the Air Force Academy and to the United States Air Force, and for all their hard work when it came to this recent incident that occurred.

Certainly for those of you that have supported this effort today, Colonel Witkop and Ms. Glavin, we want to appreciate your support today.

Also, the department would like to recognize Lieutenant Colonel Patrice Morrison, Lieutenant Colonel Gerald Parish, Technical Sergeant Ryan Devine and Lieutenant Colonel Catherine Witkop for their superb leadership and exemplary approach in the containment of this novel H1N1 outbreak here, or not, at the Air Force Academy.

Assisting me in the presentation will be the Board Vice-President and Chair of both the Infectious Disease Control

Subcommittee and its Pandemic Influenza Preparedness Subpanel, Dr. Greg Poland from the Mayo Clinic, who will have a few more comments.

DR. POLAND: So, as you know, I have both a professional and a personal interest in this. My son is a Third Class cadet here getting ready to come back from leave into the epicenter of the outbreak in the U.S. at the time.

So I had a number of conversations with Lieutenant Colonel Witkop, was incredibly impressed with the team that she led and of course we're recognizing a few individuals today, but there are a lot of people above them and around them and below them who assisted in doing this.

And I just hope the Board will recognize that given what we know about the epidemiology of this disease and the morbidity and mortality of it in this age group, can you imagine an outbreak in a campus like setting with roughly 200 people and not a single hospitalization, not a single mortality, no

significant morbidity and the containment of that outbreak inside of 10-14 days? It is, to my knowledge, unprecedented in the history of any sort of pandemic influenza.

If you -- and I don't know that we will, but yesterday I did -- went through their dormitories and I've seen the educational messages that were sent out to the cadets. There is no egress from any building that doesn't have two hand sanitizer dispensers. You can even see it here in the Falcon Club.

The other piece that I think is important is they took the opportunity to advance materially the science here. There have not been good studies to look at transmission, for example, or duration of shedding of this virus for this novel virus, and they immediately got Epi Health and others to come here and assist them with that.

So, they not only contained this outbreak and did it in a picture perfect way, members of the Board know how many hours we've spent over the last five, six years, trying to

assist the Department in putting together what we call a playbook for influenza. They implemented that in an absolutely perfect way and advanced the science.

So we just wanted to provide them a recognition of that really material feat.

DR. LEDNAR: To all of our awardees, thank you, you really are giving us a tremendous example in your leadership.

I was talking with General Gould before we began and was mentioning that in the setting that I work, a number of the parents in DuPont have children who are getting ready to return to college or start in college. In fact they're relating to me questions that their 18-year-olds are asking of them, "Will it be safe for me to go to college?" because they're concerned about this infection. So we really have a tremendous example to learn from in terms of actually delivering it, actually doing it, in terms of a response to this issue.

And I'd encourage those here at the Air Force Academy please liberally share your

experience. There is none like it anywhere and there is a tremendous need for it.

So, on behalf of all of us at the Board, thank you for your work and for the support of the cadets. Thank you.

Dr. Silva.

DR. SILVA: Yes, I'm very impressed what occurred here and I wonder if they can put together -- or are we going to have a presentation, a fact sheet, but that should be distributed out through the educational arm in this country to be used because this is a problem facing every single campus (inaudible). And we have first hand experience what worked and didn't, and I think getting that out real quick -- and a number of associations, I think would really like to see those data and disseminate it. Thank you.

DR. LEDNAR: Actually I might ask -- I know Dr. Silva and Dr. Dickey, at least, and others I expect, might have an idea about how just that channel might be fed with the experience in a very practical way. So perhaps we can talk about that before the

meeting adjourns.

Greg?

DR. POLAND: One sort of little funny thing, each class has sort of a motto. My son is 2012 and they're "2012 never falter, never fail." They're calling class of 2013, "The in-quarantine." So I don't think the lessons will be forgotten.

DR. LEDNAR: Okay. Before we begin our first briefing, Commander Feeks has a few administrative remarks.

CDR FEEKS: Thank you, Dr. Lednar. Before she gets away, I would like to ask Lieutenant Colonel Cathy Witkop to come forward one more time. Come on down.

I want to thank the United States Air Force Academy for helping with the arrangements for this meeting. An enormous amount of work went into it on their part and it wouldn't have happened without the work of a lot of very dedicated people, but in particular, I want to recognize our point man, here at the Air Force Academy, for all the arrangements was Lieutenant Colonel Cathy

Witkop. So she managed a pandemic outbreak and the Defense Health Board all in one summer. That's impressive. I am so impressed.

All right, now, the other person I want to recognize publicly could not be here with us this morning, Ms. Teri Glavin, the Protocol Officer for Lieutenant General Gould, also did an enormous amount of work and I want the record to show that and we've made a certificate for her as well.

I'd also like to thank all the speakers who've worked hard to prepare briefings for the Board. I would like to thank my staff, Jen Klevenow, Lisa Jarrett, Elizabeth Graham, Olivera Jovanovic, and Jean Ward for arranging this meeting of the Defense Health Board.

Because meetings of Federal Advisory Committees are public and records must be kept, I ask that you please sign the general attendance roster on the table outside if you have not done so already and that includes people in the audience and members of the

media, if any are present.

For those of you who are not seated at the tables, handouts of the briefings are provided on the table in the back of the room. Restrooms are located down the hall and to the left. For telephone, fax copies, or messages, please see Jen Klevenow -- where's Jen? -- or Elizabeth Graham. Raise your hand, please?

Thank you. Because the open session is being transcribed, please make sure you state your name before speaking and use the microphones so that our transcriber can accurately report your questions.

Also, if you find that your name is easy to misspell, you might spell your name the first time you say it for the benefit of the transcription.

Refreshments will be available for both morning and afternoon sessions. We will have a catered working lunch here at the Falcon Club for the Board members, ex-officio members, service liaisons and Defense Health Board staff, as well as for speakers and distinguished guests.

Public attendees may wish to consider Ike's Grill located on the Eisenhower Golf Course here at the Academy. It is likely the closest restaurant. Alternatively, there is a Subway inside the visitor's center. There is a Burger King located in the community center area; however, none are within walking distance of this, the Falcon Club.

For Board members, ex-officio members, service liaisons, Defense Health Board staff, we will be taking a group photo at the end of the morning session today just before we have lunch. And I didn't want to wait until lunch to surprise you with that.

All right, next, if you have not RSVP'ed for the dinner tonight, or for the lunch with the cadets tomorrow, and would like to attend -- this is for official attendees only and speakers -- please notify Jen Klevenow.

Next, one of the briefings that we're going to get today, two of them actually, are from Major Mike Fea from the

Joint Staff. And Major Fea has been called back to Washington this afternoon. He is here with us, but in order to allow him to leave a little bit early, we're going to make a modification for this afternoon's agenda.

So if you would like to join with me in some pen and ink changes for this afternoon's agenda, here's how it will go: At 2:00 o'clock, as written, he will give the influenza A/H1N1 update, and then at 2:30, he will give a presentation on burn pit exposure in Iraq, and that's at 2:30. Then what was to be at 2:30 will be at 2:45, Dr. Poland's review of the PI subpanel's recommendations.

Then the fresh whole blood safety brief will go down at 3:15. At 3:45 we will take a 15 minute break. At 4:00 o'clock Dr. Charles Wade will give his brief on fresh whole blood outcomes. You can just cross out the 4:00 o'clock break. And then at 4:30, the TBI Family Caregiver subcommittee update will be on with Ms. Moessner.

We'll cross out the 4:45 brief and then at 5:00 o'clock I'll say a few words

about the Warren Serum Repository. And that is the extent of our pen and ink changes for the agenda today.

And, finally, the next meeting of the Core of the Defense Health Board will be held on November 12th and 13th of this year, in the National Capital Region, during which the Board will receive a series of updates on subcommittee activities as well as draft recommendations. This concludes my remarks.

Dr. Lednar.

DR. LEDNAR: Thanks Commander Feeks. With that, we'd like to go to our first briefing and I'll go ahead and introduce our first briefer.

Since the mission of the board is to serve the men and women who defend our country, our speaker this morning is Lieutenant Colonel Christopher Coke of the Joint Staff. He is Assistant Division Chief for EUCOM of the Joint Staff, Joint Operations Directorate.

The division is responsible for the monitoring and coordinating of all Joint Staff

actions for operational activities within NATO Headquarters and the U.S. European Command. He is also a Marine Corps helicopter pilot.

Among his many awards are the Bronze Star, the Meritorious Service Medal, Air Medal (Third Strike Award), Navy and Marine Commendation Medal and two Navy and Marine Corps Achievement medals.

Lieutenant Colonel Coke has also been selected for promotion to Colonel. Congratulations, Colonel.

Colonel Coke will provide an overview of U.S. military operations worldwide. His presentations may be found under tab two of the meeting book.

Colonel Coke, thank you.

LtCol COKE: (off mike) are about 99.8% accurate, but they change, and as you'll see we'll talk about the Joint Staff just for a short moment, but players are changing dramatically this summer, so don't hold too much truth to some of the things, but generally about 98% on track.

This briefing I'm going to talk

about what's kind of going on in the world from a operational standpoint and U.S. military. I'm also going to talk a little bit about what keeps us up at night. What is on our minds in the Pentagon and within the Joint Staff, OSD.

As introduced, I am a Joint Staff type, but my operation floor has been in the Baltics, Africa, and of course Iraq.

The last thing is, again, thank you for allowing me to be here and be a part of this.

Okay. And to continue my thanks, I'm always humbled and honored to talk and mildly be associated with doctors because truly if you look from the revolution, I'm not telling y'all anything new, but from the revolutionary period to now we have seen mortality rates decrease tremendously from, you know, one-to-one to one-to-seven, to ten nowadays. And that effort is on part of y'all. Certainly the circumstances of warfare and what we're fighting today contributes, as well as the type of equipment which y'all

directly impact that our soldiers, and marines, airmen, and sailors wear into combat. And then most importantly the actual care that they have when they do sustain injuries.

One example I'd like to talk about, and it's an individual that was wounded, Brad Millinger, in 2005 in Usava. He was shot in the thigh. It pretty much splintered his femur. And within minutes stabilized and then (inaudible) the truck from Balad to Landstuhl and then back home, all within a very short period of time. And, you know, the good news is that: one, we get him back, you know, in a few months, years, whatever it takes for that soldier, or marine, airman, sailor, to be fixed; but, also, they get to be with their family again, which is of most importance.

So, again, thank you for all that you do. Real quick, and I'm not going to dwell on this, but that scar represents -- and you probably can't see it maybe in your book -- where I come from where the Joint Staff is organized as all staffs are. But we provide two things, obviously chartered -- we're

determined to provide the best military advice to the senior leaders, the President and the Secretary, but the other function is to support our war fighters, support or combating commanders and really where the rubber meets the road, make sure that they have everything that they need to be able to get the job done.

All right, I'm going to dance around the world real quickly, just kind-of touch on a few areas. I will start right here. It's kind of serendipitous to be here. At NORTHCOM when we talked about defense and Cheyenne Mountain and all that goes on there, but obviously homeland defense is first and foremost. But they also have other things going on when we think about relative to the south, in Mexico, y'all are going to be doing a lot of discussion on H1N1, but the other fact that is that Caldron and the really clamp down on narcotics activity has created a lot of interaction, obviously across our borders, weapons flowing south, drugs flowing north. And we'll talk about South America a little bit, about how the impact of successes

in Columbia -- I'm starting to steal from future slides -- is actually like squeezing a water balloon, but forcing that activity north with Caldere is having to deal with. But anytime you kick a hornets nest, you expect activity, so NORTHCOM remains busy. SOUTHCOM already stole the show on the counter narcotics activity. A lot of good work in Columbia. In particular, it's not just going down there and doing their business, not just going down there and showing them how to do their business, but actually train the trainers, enable them so that they can be able to train and equip and perform these type of operations. And you'll see this throughout the world, the idea is to enable, be a partner, and to provide the ability so that they can do their own work within a short amount of time. And a lot of success in Columbia.

The other neat thing about SOUTHCOM is we have a lot of (inaudible) security engagement. And I'll talk about one of the hospital shifts deployment in a future slide

as an example of that.

EUCOM, neck of the woods for me.

Still a lot of activity. First and foremost is supporting ISAF and all things in Afghanistan as well as Iraq. But we also have Kosovo, that still is an enduring mission. We're actually going to see -- you hear about a lot of withdrawals in other places, but the NATO pack is basically approved to go ahead and start withdrawing from about 16,000 international forces (inaudible) early part of next year and actually start withdrawing those forces. So a lot of success in Kosovo despite what's taking place in the northern part of (inaudible) and things like that. Israel obviously the Gaza incident that took place over this last Christmas and smuggling and interdiction of arms, you know you've got the standard players coming out of Iran, coming out of Syria and Hezbollah that is supporting that turmoil. And then of course trying to marry what's taking place in Gaza with Palestine proper in the West Bank and trying to merge those together so that we can perhaps

take the next step into a two space solution, which still seems to be, and is, on the agenda.

CENTCOM the hub of activity around the world. Really, three things come to mind and we'll talk about each of those individually here in a second, but Iraq, Afghanistan and counter piracy.

Counter piracy continues to be a little bit of a lull right now just because of the weather and surface conditions in and around Somalia waters, but last Christmas time we did stand up a new task force, CTF 151, that focuses specifically on counter piracy. And this is an international effort. You've got Atlanta, which is a UN -- a E.U. effort. You've got NATO, with a standard naval time airtime group shippage, you know four to five ships that are actually deploying outside of the Mediterranean area to the Gulf of (inaudible) and into the waters of Somalia.

So it is true international -- and then of course you have a lot of bilateral efforts, China and other countries. Obviously

Korea front to center and Taekwondo of recent and continued rocket activities coming out of there.

Continued efforts to try to stall and get back to -- even though they prefer not to, but get back to the original (inaudible). It draws a lot of requirement for presence (inaudible) so you'll find, as it always has been, a continued requirement to draw on maritime (inaudible).

When we look at China and Taiwan and the influence now of over a year of (inaudible), we're seeing more normalization if one could even use that word between those two countries. Then of course the recent hurricane (inaudible) that basically impacted quite a bit.

And the last thing I'll just touch on (inaudible) command, is the Philippines. And basically the success again, similar to the Columbia but going in there looking specifically at (inaudible) type issues and training the Philippines. And they've had a very good success dealing with some of their

insurgent type activities.

AFRICOM, my newest partner, stood up last October, pretty much self-standing. It only sits with about 3500 folks though and it's still resource dependant. A lot of (inaudible) security, a lot of activity in training, particular in the Trans Sahara area. When we think of Africa we think of ungoverned spaces or partially governed spaces, particularly when you talk about Somalia, nexus to piracy and to the activities that have taken place. So trying to enable just not their own militaries, but also their governments to better themselves.

And then just as depicted with the arrows, everything intertwines, everything affects each other. One can't really talk about success in Afghanistan without talking about success in Pakistan, without talking about Pakistan India relationships, everything intertwines and that is very important as we look at this from a national strategy standpoint and the complexity of how all these play together.

Okay. Back to Iraq. You know from all times highs of the serge, we're down to below 130,000 folks there, truly building on the idea to transferring security to their own forces. And that's where we're at, moving folks out of the cities and giving them the means to continue with building on their own security and we will look to drawing down to about 50,000, no more than late summer next year.

I'll take a moment to talk about Jason Dunham, Marine, Medal of Honor recipient. Just this last couple of weeks the USS Jason Dunham was commissioned. Again, this was in Iraq, a pretty heroic act of throwing himself on a grenade with a helmet and suffered basically about eight, nine days (inaudible) if I'm not mistaken. A part of that helmet is going to be the masque to the ship, per say, is going to be embedded and has been embedded into that ship. So his memory lives on.

Afghanistan. I'm going to have to caveat everything that we still have General

McChrystal's 60 day assessment going on that should be released fairly soon. The other big thing is we've got the elections coming up here very shortly, scene setters for how we're going to go forward.

One thing I can allude to is the fight that's taking place. It is different, but it is still a counter insurgency fight. What does this mean? One could refer back to the General Cruel Act and things like the Three Block War. And I've sort of depicted here, here are some folks that are responding to an IED in the middle of a fire fight. A marine during operation (inaudible) which just kicked off in the northern part of the Helmand province. The idea is to get that security type so that it can be an enabler for the election.

Simultaneously, same block, literally, you have medics that are just not providing medical aid to, you know, Afghanis but also teaching them how to do it themselves, so enabling in that respect.

Then around the other corner are

marines that are basically securing the pathways and the means so that people can go to the poles and actually elect their own government. So in that process teaching and enabling the Afghan military to do that. So, you know, three concepts of this Three Block War are a better depiction of foreign operations, and tied to this is obviously the interagency because of the holistic or whole of government approach.

You know, very much tied to this is you know the coffee growth and the narcotic activity, which feeds so much of the revenue in Afghanistan and how do we switch that out with something. Obviously corn doesn't you know result in the same revenue that, you know, the coffee plant does, but you know that draws on our agricultural expertise in this country as well as others. So when we think about whole of government, we're just not talking about security and the balance between security and governance, but we're also talking about other areas that tie into this as we look at Afghanistan.

The other -- and I mentioned before -- is a recognition and that success in Afghanistan means success in Pakistan. So continue to reinforce Pakistan and their security as they work towards things such as the activities in the Swat Valley and encounter their own insurgency.

The last thing I just want to talk a little bit about is continuing promise in 2009. The hospital ship just got back, USS Comfort just got back, from a tour in South America. About 650 medical professionals from across the services and non-governmental organizations, international partners, to include 20 CVs, focus of the medical team, range of healthcare services ashore, and just not -- and an example is in Haiti where they went and provided medical prevention training in addition to, you know, putting band-aids on people. So very successful deployment this last Spring.

Okay. Just a quick buzz on what keeps us up at night. And one could predicate all of these next two slides on balance. When

we talk about the draw down in Iraq and the build up in Afghanistan, it's a balance between the two. We don't lose the gains that we've had in Iraq at the same time we're building Afghanistan to a pace that we can start (inaudible) and countering Iraq's turning around the insurgency there.

And it's just not us. It's important to recognize that the international partners in Iraq are down to about zero right now, but the international partnerships in Afghanistan have grown tremendously and continue to grow. We continue to work with countries such as Georgia. Just recently in the news we just sent trainees there this last weekend to start preparing them for as they did in Iran -- I'm sorry, in Iraq, to also go and do in Afghanistan.

Pakistan and India: obviously two turbulent countries that have nuclear weapons. We talked some about Israel and Gaza. The one thing about Iran, nuclear proliferation being the foremost, but the instability that that's providing within that region. Also, the

shipping of illicit materials to Gaza, to Hezbollah, Hamas, and Syria and other destabilizing folks.

Again, we talked about the homeland and North Korea and lastly piracy, though kind of in a trough right now. We'll, you know, re-emerge, we're fairly certain about that, once the waters get more conducive to the piracy operations in the Gulf of Aden.

Long-term, again here we go, strategic balance. And this is in the broader sense in that we're looking at, you know, how do we posture ourselves for 2020. How do we look at the future fight? How do we prepare for that in a sense of training, equipment? What do our weapon systems need to look at?

At the same time, fighting the fight that we have right now. And oh, by the way, look at an expense budget that is probably going to be coming down. So, a lot of reprioritization, a lot of you know change in focus. Everybody has read the Secretary's article, December/January, as far as looking at more a balanced military in the sense of

being able to fight both conventionally and unconventionally, asymmetric and symmetric type warfare.

The recognition of Cyber continues to be a plaguing issue. Whether it's self-inflicted or whether it's inflicted by such players as China.

We touched on the ungoverned spaces. And, again, this is an area of continual concern as far as being able to really -- particularly, like in Somalia -- do what we can to support the African union and other international players, as well as ourselves to build their governments.

And then lastly, you know, we talk about strategies and we talk about, you know, a lot of focus being in Afghanistan right now. That is the Chairmen's that is, you know, the defense and the President's, you know, that's our number one goal right now, but there are other strategies that are at the same time being built and reinforced such as, in the Middle East and other places around the world to keep those to a level of consummate, to

keep those where we have postured and we have the presence to be able to deal with whatever may come up. So we're not surprised such as this time last year, again, with Georgia and Russia's interaction and all of a sudden "Wow, what's our Russian strategy?" And realizing there was a little dust on that.

All right, transformation -- always got to throw in a video here. This is a landing. Some of y'all have seen this and --

(Video playing)

LtCol COKE: Oh, you probably couldn't hear me. That's also done at night time, so a particularly challenging environment for all of us no matter where you stood.

And then that same helicopter -- well, I'm lying there -- but a similar helicopter is up on a stick now at the front gate of New River. So, all things do come to an end.

I use this not because I'm a 46 pilot and I'm so grim about having to move onto something else, but more that it sort of

marks a change and it marks that nothing is static and that as, you know, in my case we go from a 46 to a B22. In the military we go from a posture of very defined boundaries and look at, you know, symmetric type threats to now more an asymmetric. We look at, you know, the battlefielding quite different where the boundaries aren't so clear and concise. So, if I was doing, this is my opinion, to look at what is our biggest challenge, obviously is the fight today, but it's also being able to look forward and to continue to project into the future and make sure that we're ready for tomorrow's fight.

With that, I'm not sure where I'm at on my timeline, but again thank you very much.

Are there any questions that I could answer?

DR. LEDNAR: Dr. Kaplan.

DR. KAPLAN: The list of insomnia producing possibilities that you mentioned is certainly one that worries us all. I'm particularly worried about how health care or lack thereof, for example, H1N1 -- I realize

I'm not supposed to say that here at the Air Force Academy, but -- how that would impact on the various issues that you've raised and perhaps you or someone can comment on what preparations, what ongoing surveillance is down to each one of those levels of combat or potential combat.

LtCol Coke: I couldn't address, specifically, obviously what is y'all's realm as far as what's being done on the medical front. I can tell you that for an example USS Foxtrot, I believe, with (inaudible) was supposed to conduct an exercise with the Jordanians, it's infinite moonlight as an annual exercise. And they actually -- the Jordanians said, "Hey, thanks but no thanks this time around" because aboard that ship there had been, I think, 13 to 15 cases of H1N1.

So that's a direct impact. Obviously what took place here at the Academy, all the services have seen within their different bases and that obviously affects deployment and actually, you know -- when

particularly like aboard ships where it's a lot more conducive to spreading. So, yeah, I think we're seeing a lot more than bottles around different places, but that is the affect that we have seen, certainly.

DR. LEDNAR: Okay. General Myers.

Gen MYERS: It's Myers, M-Y-E-R-S. First of all, I think this briefing is really useful because it helps put things in context for our work. I mean it gives us the operational context for everything else we do.

Question, if it's possible -- and I don't know if it's possible, but -- an enhancement to this briefing, since we only get this several times a year, would be to tell us what's on the minds of the Chairman and the Combatant Commanders and the Joint Chiefs of the Services in terms of the health issues that they're worried about.

And I know the Chairman has very specific concerns and I don't know if the Board is all aware of those, and I'm sure the Combatant Commanders all have concerns depending on their area of responsibility, and

certainly the services have issues.

And given that a lot of that is operational and it changes throughout the year, is that possible that your good folks in J4 that could plug into the operational aspects of that and kind of give us even more context for what we're doing?

LtCol COKE: Yes, sir. I think that'd be very easy. It might need to be a little bit more time, but I think we could match a brief with our Surgeons and tie those in so you're not just listening to -- we can narrow that focus down to a specific --

Gen (Ret) MYERS: Well, if others think it would be useful, but I mean the operational part is very important, but there's also -- I know there's concerns in each of those theaters for other issues that we don't hear on a regular basis.

SPEAKER: (off mike)

Gen (Ret) MYERS: And you might want to put in the concerns of the Surgeons General of the Services too just to, you know, if they're different. They shouldn't be

different because they're working the COCOM's issues, hopefully, and they're also working the Chairman's issues, but thanks.

DR. LEDNAR: Colonel.

MAJ FEA: This is Major Mike Fea from the J4. The cases that are in theater, I've been working daily with CENTCOM, in particular, but all the COCOMS out there. And these cases are being reported. That goes to the public health service centers, in turn it goes up to the Armed Forces Health Surveillance Center. The folks in the Global Emerging Infectious Disease and Response System guys is taking this. They have products. I'm actually going to show this in my briefing this afternoon, but we keep a constant eye on it and we have published for self protection measures, given them guidance in general admin publications from the Joint Staff to say "Here's what you need to consider."

I'm going to talk a little bit this afternoon about our planning efforts. And so we are doing that. The Chairman, we actually

did have a crisis management exercise at the end of June with the Chairman and what we did is we presented a worse case scenario, 1918 second wave, and said, "Here's your case fatality rate. We may not have a vaccine. Your antivirals may not be affective at this point."

And so we walked him through it and he had several concerns. And I'll talk about that this afternoon of, how do we capture this and how do we make sure we take care of our soldier/sailor/airmen/marines, as well as the family members. How do we take care of all this?

DR. LEDNAR: What I heard in General Myers' request was not just sort of the medical sort of assessment and sort of technical judgment related to the operational review, but in some sense the Chairman's thoughts and the Combatant Commanders' thoughts, not medical people, the Line Commanders in terms of what keeps them up at night about some of the health issues facing their missions and their people.

Gen (Ret) MYERS: That's exactly right.

DR. LEDNAR: Dr. Parkinson and then Dr. Lockey.

DR. PARKINSON: Again, I apologize for my voice, but an excellent overview, which is superb two points. If you haven't read it, it's a short book. It was on the New York Times best seller probably about six or eight months ago by the journalist and CNN correspondent. I think his name is Zacharia or something like that. The name of the book is something called The Rise of the Rest.

And what it essentially says is the U.S. has not fallen as much as the rest of the world has risen over the last ten years, so the Chinas, the Indias, the Russias, the Brazils. And what he's afraid of is that our political structure and our organizations are not rapid cycle time enough to respond to the new reality of the world.

And what you've got here is a total global engagement coming out of General Paxton's job. And what a job. But the

concern I have, as a citizen, is that the structures in existence, called the United Nations, called existing treaties, do not allow us to act sufficiently fast to have an impact in a way that is a good expenditure of my tax dollars, frankly, or all the good people in DOD.

So, at some point, it would be fun to understand the role of these types of operations in looking at the structures that we work with across other countries to execute our mission. You can't -- this is not a (inaudible) U.S. mission and many people would criticize us for saying, "Boy, is this an overreach." So it's just a comment and if you haven't read that book, please do. It might be an area to look at.

The second piece though is the whole area of the full upround, as we used to say in the Air Force and the military, but corporate America is realizing that whether they use the term corporate athlete or resilient company is the level of performance that they expect in a global enterprise is much more than what they

had for a traditional worker in the U.S. And so they are creating totally new programs to do a fully capable employee and team to build resiliency and a level of performance far beyond what they expect at Proctor and Gamble, GlaxoSmithKline, global companies that are revamping completely.

The Army just came out with a whole new training doctrine called the Army Influence. Leadership is influence. It is not command and control. So I think to Mike Oxman's point earlier, if we are going to be proactive as a Defense Health Board, we need to say, "Is there a role for this Board in defining what is the resilient corporate athlete equivalent of a military service member in your environment?"

Because I will tell you that I think we're playing catch-up to the level of skills and competency, physical, emotional, spiritual, which is why we've got some of these problems at the other end, whether it's PTSD or TBI or lack of -- we don't have the models. And no one is going to come to us and

ask for that model. But corporate America is building it because they want to be around another 100 years just the way P & G was 100 years ago, and they cannot do it with the current construct.

So longwinded, I apologize, but it raises huge issues in both organizationally and also in terms of the work of the Board, I think, going forward.

Thank you. Reactions are welcome, by the way.

DR. LEDNAR: Dr. Lockey and then Charlie. Dr. Lockey.

DR. LOCKEY: I enjoyed your presentation. Maybe I'm naive in this, but I was wondering under Cyber threat was the long-term interest items, is that where you list the EMR, electromagnetic radiation attack? Is that where that's listed because it's potential affect on homeland security, delivery of medical care, because shutting down electronics, combat readiness? Is that on the horizon or is that something that we don't need to be worried about?

LtCol COKE: I don't know. First of all, you're outside of my depth on a specific area. Cyber, my understanding, is specific to the networking within computers. I think the EMI that you're talking about would come under a different construct, but I'm not knowledgeable to be able to speak to that.

DR. LOCKEY: The reason I raise that concern is that in the field setting, that would shut down a field hospital. That would shut down evacuation. That would shut down communication. And I'm just wondering if anybody is looking at that issue or maybe it's a non-issue because I don't know the ends and outs of it that well, but I do have some concern about it.

DR. LEDNAR: Dr. Fogelman.

DR. FOGELMAN: I just wanted to respond to what Mike Parkinson said. Actually there are some of those efforts going on and among the things that the psychological health subcommittee is looking at and talking about is exactly this question of resilience building. And some of the members of our

committee have visited in Philadelphia with both the academic folks and the corporate folks who are building new models. So we're trying to figure out how best to get our hands and brains around it in order to bring it back here.

DR. LEDNAR: Okay. We're going to bring this agenda item to a close.

Colonel Coke, thank you for your briefing and your update and your interactions with the Board over the years. We've really appreciated it. And, again, congratulations on your selection for the promotion. Thank you.

LtCol COKE: Thank you.

DR. LEDNAR: Okay. Our next speaker of the morning is Dr. Elizabeth Anne Peterson.

Dr. Peterson has an extensive background in both the United States and international public health and medical practices and has become a decisive voice in global policy agendas. She is a research professor at the George Washington University for health development in conflict zones and

multisectorial approaches to improving health and nutrition, with experience in Afghanistan.

Dr. Peterson has held various noteworthy positions in the past, including Assistant Administrator for the Bureau for Global Health at the U.S. agency for AID. U.S. representative on the global fund to fight AIDS, tuberculosis and malaria; and Health Commissioner for the State of Virginia. Now there is a tough job.

Dr. Peterson will provide the board with an overview of Afghanistan's health sector. Her presentation slides may be found under tab three of our meeting books.

Dr. Peterson.

DR. PETERSON: Thank you and good morning. It is an honor to be here and I'm hoping to follow Lieutenant Colonel Coke's wonderful model and get through it on time. So I will tell you that what you have in your briefing book is a longer version than I will be presenting today in hopes of having enough time to do questions at the end of this time.

I will also say that I have really

enjoyed and been surprised at the amount of time that I have been able in my career, recently, to interface with DOD and with the military, starting when I was Commissioner of Health in Virginia, 9/11 and the attack on the Pentagon. The Pentagon is in Virginia, so the initial response was there, but also on the USS Mercy as the liaison during the tsunami response and then in Afghanistan. So the excellence that the Department of Defense brings to their work is something that I really appreciate.

I'd like to bring you to Afghanistan today. And let me see if I can get this to work. There we go. This is what we usually hear about when we hear about Afghanistan, or the big political issues, Pakistan, Afghanistan, Taliban.

What I'd like to talk to you today about is in a little corner, the women, the children, the daily life, the Afghanistan that I see and would like to bring you to, the buying food when the food prices is making food more and more expensive, going to a

health sura and meeting with the elder, the men, the Muslim and in fact Taliban men, who are talking about their women who die in childbirth, their children who do not grow up, and that peace in Afghanistan would bring a peace dividend of improved health and hope for their family.

So what was the situation in Afghanistan from a health perspective? In 2002, life expectancy was in the high 40s, just less than 50, under 5 mortalities, 257 deaths per 1,000 live births. The major causes of disease and death for children under the age of five, same thing that they had been for a millennium, pneumonia, diarrhea, malaria, with malnutrition undergirding all of that. And the malnutrition is increasing in Afghanistan now with the food prices.

But really spectacularly, maternal mortality. What's maternal mortality here in the U.S.? The State of Virginia, close to the national average, seven maternal deaths per 100,000 live births. In a high risk population, 14 deaths. In Kenya, it's 300 per

100,000 versus 7. In Ethiopia it's 700 per 100,000. Afghanistan 1600 per 100,000. And in one corner of Afghanistan, in Badakshun never before measured, 6400 per 100,000. Unbelievable rates of maternal mortality. And it's still one of the four countries that have wild polio, especially on the border with Pakistan.

And yet there is real hope. The ministry of public health in Afghanistan is the only ministry that does not have a shadow of Taliban counterpart. There is an education ministry that the Taliban is doing, and there is social services that the Taliban is doing. There is no shadow industry for the Ministry of Public Health.

Part of it, I think, is they've done a phenomenal job. The Ministry of Health has had a focus and strategic response to the health needs as it came in post 2002. They did a rapid expansion of primary healthcare focused on the rural areas when they have all the donors, including some of the U.S. government, wanting to put visible big stuff

in Kabul. They said, "No, we need to be going out and addressing the needs of the people in the rural area."

They put together a package, not everything that needed to be done, and believe me everything needs to be done, but a focus package of the most cost effective intervention that would do the greatest amount to improving the health of the women and their children. They worked very hard at building their own capacity, building transparency into the operations of their government and they put together an assessment system so they could measure their progress in a hard place to measure things, and identify the gaps.

And what has it done? Access to services by women has gone up significantly from 2003 to 2006. There is greater equipment, greater drugs, greater ability of family planning in a country where the total fertility rate averages six. So a woman would, on average, have six children during her lifespan. It's gone up enormously and child mortality is decreasing, 23% within the

last four to five, six years. Unprecedented.

I've worked in dozens of countries and I have never seen this quick, this focused, this good a response to a very dire situation. The woman on the left is a community health worker who is caring for her population. The achievements that have been accomplished by the people of Afghanistan have been through this expansion of services, but the three major players who have made it possible according to the Ministry of Public Health, is USAID, the World Bank, and the European Commission. They are the three donors that have funded this basic package of everything that the Ministry of Public Health is doing.

What's not going so well? Not everything is going so well. We actually don't know what's happening in maternal mortality. We told you how bad it was. Then I told you how much better it is in child survival, that's because it's hard to measure and especially in the conflict zone, it hasn't been measured recently. And despite the

incredible improvements in health in Afghanistan, as you probably realize from the press and everything else, there is decreasing trust in the government of Afghanistan.

The different parts of the government of Afghanistan that are involved in health are only just now beginning to meet together. We had a conference in May where the Minister of Public Health met with the Surgeon General for the Army and for the police and they sat down there, in Washington, and began to put together a memorandum of understanding to begin to work together in an even better way.

There are gaps in equity, in quality of services, in addressing the urban population, as Afghanistan becomes more urbanized, and mental health. DOD certainly knows what conflict and war does to your own soldiers. These people, this entire nation, has been living in conflict war and violence for decades and decades. And from the Minister, down to a community health worker, to the woman, they will all say, "Oh, yeah, I

have mental distress from living for years in this conflict zone." And little has been done to address that to-date.

Getting female health care workers to the south is still a problem. Only women are allowed to see and treat the Pashtun women, but the Pashtun women are not allowed to go out and be trained to take care of their neighbors. So getting the female health care workers in the place that it's needed is still really difficult. And we're having trouble finding out exactly what is happening in the conflict zone.

What's the U.S. government doing? I came back from my third time to Afghanistan specifically for this project, to look at who is doing what in the U.S. Government to support the Ministry of Health in Afghanistan; to look at opportunities for communication and coordination and to make recommendations on what the U.S. government at large could do better in the future. It was commissioned by USAID, but it had a multi-agency steering committee including Department of Defense,

Health and Immune Services, and State Department.

So I will just very quickly run through a little bit about what each of the agencies are doing in Afghanistan. USAID has the advantage and disadvantage of a long history in doing development. It's an advantage because they've learned a lot of lessons, they know how to do development and health programs. They've also failed numerous times. And if you live and work in Washington, you know that how the difficulty of doing development well has redounded to USAID's reputation and, in fact, there are some lessons learned there that are hard learned for the agency.

In Afghanistan, they have been instrumental in training more than 20,000 community health workers. So lay people working out in villages, thousands of midwives. Unusual for AID, they built facilities early on. That was when I was still at AID and they helped implement the basic package that the Ministry of Public

Health is doing through the NGO, it's essentially the service provision of health in Afghanistan is commissioned out, contracted out to the NGOs in the country.

They've built the data system that gives some of the tracking and transparency within the country and they have a quality assurance project that the Minister of Health said, "Please can you scale this up to the entire country?" And begun doing multisectorial approaches working with Ag (agriculture) and education and microenterprise for dealing with issues like malnutrition and food security.

Some of the limitations that USAID has is they're not working everywhere. The country is split up between World Bank, EC, and USAID. And most of the U.S. government's other work is either in Kabul or with the Department of Defense, EEC (inaudible). USAID has not been working there, that makes it harder to collaborate. The other limitation is that their footprint is very small. They have difficulty getting their senior

experienced people to come and spend the time in Afghanistan that is needed.

Department of Health and Human Services, very unusual portfolio for them. They are -- and this was driven by Secretary Tommy Thompson that I work closely with, a project that is specifically focused on one hospital, a maternity hospital, in Kabul to try and build a model of excellence in training there. They get about \$5 million dollars a year directly from Congress. They're working on the training program. They have strong involvement by the Center for Disease Control, the training and service provision is done by the Indian Health Service, our American Indian Health Service. And what they found is that it's a little more difficult to make improvements than they thought. And that just getting the doctors to do better, diagnosis and treatment, and c-sections, does not necessarily mean that the women do better.

In fact, they've had some increase in mortality rates as more severe patients

come to them and they do not have the nursing and anesthesia care to go along with their improved skills and the medical doctorate. And the CDC tracking has helped them identify this problem early, so believe me, they are on it right now.

The rest of the things that HHS is doing in Afghanistan really fits with their -- I call it -- comparative advantage, the things that they do really well, disease tracking and training in disease control. So CDC's epidemiology training program, the disease early warning system. So there was a potential avian influenza outbreak on the border between Pakistan and Afghanistan and that system picked it up and the Minister of Public Health responded very nicely. The problem was they forgot to tell the military U.S. DOD encampments and PRTs sitting in exactly that same area that there was an alert.

So, if it had been real, if it had been H1N1, the system had not connected between the disease early warning and our own

staff in the country and the personnel in the country.

They do laboratory capacity blood safety, polio, TB, and some unusual things, occupational health, injection safety is beginning. The other big one, which is very nascent, is our sense of the substance abuse, mental health services association. That has been involved in trying to get a mental health strategy for Afghanistan together. It's been very clinically focused on psychosis and psychiatric disease and schizophrenia, and less focused on general mental health, depression levels, within the country. And I'm hoping that with our analysis there will be some shift back to the community based major mental health issues that need to be addressed in Afghanistan.

Department of State has a mandate to be the coordinating body and they have a lot of new ambassador level staff. They have a DC based coordination body, but in point of fact, they haven't been very interested or involved in coordinating. It's been happening because

the rest of the Departments in the country, the other Agencies, really want to see it happen.

They do have programs. Their population refugee and migration program addresses health needs of return Afghan refugees, mainly in the city. And with all of the narcotics and opium issue, they have begun a number of drug rehab programs. Again, isolated from everybody else's doing drug rehab and their having to redo some of their programming in order to be more successful.

Department of Defense, you heard some of this already. These are the major missions and each one of them is happening in Afghanistan. Obviously forced health for the troops is the number one mission for the health folks.

Very strong forced health and training for the Afghan National Army and the Afghan National Police, with a lot of mentoring, training teams that are out there. The new one is the "health sector development." And from my perspective as a

public health professional that's done global health since 1982, a long time ago, this is actually two missions.

There is the civilian health care embedded in this and then there is the health development. And those are actually two distinct missions and distinct sets of skills that are embedded in both of those things.

And one of the distinctions compared to the other agencies, no surprise, large footprint. Lots of personnel, lots of people with great excellence, medical skills, brought to there and willing and wanting to share their expertise. The DOD personnel we met in Afghanistan, you know, their heart is, you know "How can we improve the situation here? How can I connect with the Afghan to help them to do better for their people?"

The other really distinctive area is how much money DOD has in their SUR funds, there's odoco funds and others but it's really the SUR that dominates. Very little of those commander funds go to health, but what there is, is so large and so rapidly moveable, it is

a force in and of itself in Afghanistan.

Again, the people that we met were fabulous, well trained, really caring, but many of them found that they were not able to use the skill sets they had. They were very highly trained for one thing and the situation in Afghanistan was different. That in fact they were not prepared for the job that they were being asked to do. They didn't understand Afghan health systems, what was an appropriate level of intervention. Often they would say, "Ah, you know, if I had known this when I first got here, I would have done things completely differently," or, "I wish I'd known that (US)AID existed for me to learn some of these things."

And the idea that the excellence that we have in our systems for our forced health is not the same as excellence in dealing with civilian health development in a country like Afghanistan.

And the same thing goes for the people who are making SUR dollar decisions. They've never done development. They don't

know what the implications are for how they do their work.

These are quotes from some of the personnel we interviewed: "We learned in Iraq that just throwing money at a problem or personnel, does not solve it." That there are short time frames for action, that there are few strategic goals that they're trying to accomplish and they often didn't look at the long term consequences of the decisions that they had made to do that follow-up. So that there is a need to link the indicators and the funding, and the actions that they're taking to strategic affect and to figure out a way, and actually USAID has the same difficulty of short tours where they need to plan something in one tour and measure the results of, you know, the next person or the next person down from that.

This is probably one of the unexpected and most interesting things we found is we did our work, and that was unrealized expectations can cause unintended harm. So the base in Afghanistan, the health

situation is very bad. And in most places where we were, and in Afghanistan itself, huge improvements. Normally that gain is something people go -- if I was in Africa where I lived for many years -- "Wow, look how much better things are." But one of the discoveries we made was if in fact you had created an expectation that you would reach a higher level than you actually did, you created a gap, a dissatisfaction gap, that led to less happiness. A dissatisfaction with the U.S. government and with their own government even though there was huge actual gain.

A couple of examples: the system is set up so that a clinic, a basic health clinic, is to serve X population. And a commander will go in and say, "You know, for an extra two or three thousand dollars, I could go from a basic health center to a community health center. The population is growing. In five years this is exactly what they're going to need."

I go, "Oh, that makes sense. Very efficient." And then one of our Afghan

colleagues said, "As soon as you build that larger building, you have moved from the actual and upped that expectation. And when you do not staff with the extra doctors and nurses and drugs, you have now -- instead of having (inaudible) basic health center, they are not displeased with you because they don't have the community health center."

I've never seen that in Africa and I was not expecting it here. Same thing when we go on village medical outreach (inaudible) medicine and then the Afghan doctors in (inaudible) only has what he has and we have now created dissatisfaction with the Afghan health system, even when it's an improvement over what was there before.

In the south and east, in our conflict zones that we are most worried about, one of the very interesting observations was these are fast growing populations. They have some of the fastest, highest reproductive rates. The population was never well estimated. And the estimates have not kept up with the population growth. So the services

which have been promised to them that are based on all of this clinic set-up, are now gross underestimates. And they regularly have stock outs. They regularly do not have the services that they are supposed to.

And the problem isn't anybody's willingness to send it. There is oversupply in (inaudible) and undersupply in Helmand province. It's an underestimate that has led to gaps in services. Something that could easily be addressed. And clearly, as you can see from some of these examples, health and security in a conflict situation and dissatisfaction with government are all intertwined in Afghanistan.

Some quotes during our survey: "We didn't really know what USAID did." They were in the 10th of their 12th month of tour of duty.

"The complexity is an obstacle made much worse by turnover." Over and over people said, you know, "We weren't prepared and by the time we learned what needed to be done, we're out the door." True for DOD. True for

(US)AID. True for (the) State Department. HHS just sends people over in sequence over and over again.

DOD wants now to get some advice from (US)AID and civilian agencies, but there are too few of them and believe me, they're too slow in response to be able to keep up with how fast DOD can move and within the other agencies that is really true. And then the Ministry of Public Health, please just give us one person in the U.S. government to talk to or one coordinating body and not all of these different agencies.

So the time is now. Distress is actually quite high in Afghanistan, not so much from the war itself, but from their own interagency responses, their own desire to serve and do well, the excellence and the preparedness that they expect as being part of DOD, the distress is high. They want to coordinate and collaborate and talk about -- it feels like they're the Jetsons dropped into the land of Frenstin and they weren't expecting that.

And the next stage was to look at where should the U.S. government go strategically. I won't go through all of this, but there was a white paper in the Spring that laid out the priorities for the U.S. Government overall and it's about security. It's about getting to the end of the conflict for every agency, not just the military, not just state department, but for all of the different agencies and to build the Afghan government so it can do what it needs and wants to do.

The agencies themselves have a mandate for each of their own different areas. USAID to do development and impact health outcomes. HHS to do disease control. DOD has security and forced health. And the Department of State (inaudible). We looked at these priorities and tried to put what we had learned from what each of the agencies was doing with the strategic priority and put together, for the first time for many of these agencies, a joint goal that is both to impact health and to do your health programming to

impact security, to be thinking about drugs, this health activity we're going to do, build up the Afghan government, does it help build security in the country using coin principles and a nearer set of principles for the health programming itself?

We took the technical areas that the U.S. Government is working in, the basic package of health services, the hospital services, the training that is being done, the data systems, the quality assurance, and looked at who was doing them and then how did they contribute to legitimize in health leadership, to providing services, to real impact, measurable impact on how -- and does it address either the gaps or the growing need.

The real task of whether a new strategic approach makes any difference is does it address the conflict zones and the things that are not going well. And many of you probably realize that the casualties in any conflict zone are not just those who are hit by (inaudible). The real casualties are

the excess mortality. And though we haven't measured it in Afghanistan, we know from other conflicts including Iraq, that the child and maternal deaths, you know, specifically, can be 30 to 60 fold higher in a conflict zone just from disruption in preventive services, lack of clean water, not being able to get to services when you need it.

So the context and the conflict areas is key to whether the strategy will actually work. We looked at who could do what, what is possible, what are the obstacles, and how could the obstacles be overcome in those conflict zones as well as in the development zones, and then the transition in between.

And the transition is important because it sets the stage for going forward. And as you know, different parts of Afghanistan go back and forth between all of these contacts, not a stable situation.

And, in fact, we found that having this new strategical approach and the discussions it raised helped realize that

there are more options than we had realized in the conflict zones. That while initially people had presumed that because it was unstable and insecure, only the military could work. And the our Afghan counter parts and our NGOs would say, we cannot have armed uniform military personnel taking care of Afghan women. They hated the U.S. breaking relationships every time that happened.

So what else do we do in places that aren't secure? And, in fact, we found we could do more than we thought. We could do training. We could identify private sector and informal sector and NGOs who were there and to do that, and there were ways for DOD, for USAID to interface with those existing partners. Not optimal yet, not even piloted for some of this yet, but possible.

So recommendations: the agencies need to know one another. There are great strengths in every single one of them, and they haven't been drawing on each other, and they didn't know where to go or how to connect. That's beginning to change,

pre-field preparation has already changed enormously. They're beginning to put together essentially a primer, who does what, what do they do, how do I know who they are, who do I call on, with tools and checklist and some sharing of latest systems and reporting.

Turnover is huge. One of the most fascinating things was when I talked to the U.S. Department of Agriculture who works on the PRTs. They have 100 times more people applying to work in Afghanistan than they have positions, the only agency that I met that had more people than positions.

So they saw something differently happening. And we need to look at that and see how we can reduce the turnover, keep people on the ground. The procedures to pass on what has been learned in the past and something that we say we want to build Afghan leadership but in each of our own agencies there are senior Afghan leaders that have been working side-by-side with U.S. government personnel, but not necessarily entrusted to lead through transition. There are

opportunities there for us to do much better. And there is clearly a need for a U.S. government coordinating mechanism. There was a planned ikmed which is now apparently not going to go forward as of last week, but hopefully the new ambassadors will designate a person and a place and a lead agency for health specifically was requested by many people.

On the programming, I think even stating very clearly a shared goal that whatever agency you are, if you're involved in health, of course you want to impact health and have health outcomes, but you also need to be thinking, "Am I doing it in such a way that it will also improve the security in the long term for Afghanistan?"

Do we need to have different roles in different context? Well, maybe, maybe not. Maybe we should have the agencies working in their comparative advantage in all the different parts, maybe in a different way, but not lose the comparative advantages.

And DOD is a big player in

Afghanistan. And one of the norms -- and I heard it again this morning -- is preparedness and excellence. DOD does need to decide what will its lien be and prepare the staff. If it's going to do the kinds of things that they've been doing to give them the tools in advance so that they can accomplish in true excellence. And then promoting Afghan ownership and do not create harm or expectation gaps.

In conclusion, the health sector is actually a model in Afghanistan. The Ministry of Health in Afghanistan is a model in and of itself. It works better than any other ministry in the government, but also the U.S. government's response is a model. The different agencies right now are more willing and ready to work together and have begun to do so compared to any other sort of sector within the U.S. government.

This has resulted in really incredible progress, far better and more than I've seen any place else, but if we were to further coordinate, we could have much greater

impact, both on health and on security and that these can be mutually important. And I would like to (inaudible) that given the excess mortality that happens in conflict zones, perhaps the number one mission of DOD to address the conflict itself, and the insecurity would be the greatest contribution to improving health for the people of Afghanistan.

Thank you.

DR. LEDNAR: Dr. Peterson, thank you for sharing your experiences and your insights with us on Afghanistan. We have time for one or two questions from the Board for Dr. Peterson, if there are any at this point.

Captian Naito -- Captain Naito.

CAPT NAITO: Fantastic presentation. All the things you hit upon we're discussing in NAVY medicine right now, but (inaudible). Just I think I can probably get together with you afterwards to talk. I think your most important point was, again, the expectation gap. And, again, we go in a lot of times with, like you said, giving out American

medicines when the Afghans only have a certain level of medication. That really creates a destructive relationship there. So, again, the Afghan national police surgeon and the Army Surgeon General just visited us at that (inaudible). I was lucky enough to listen in and, again, their main plea was for training and support. As you so pointed out so nicely, is that that's a big part, is the support of them and not for us to go out with our western type of expectations and do things, because, again, the secondary indirect harms are very great there.

So I really applied your presentation, it's excellent. I'll be sure to take it back to my leadership as well. Thank you.

DR. LEDNAR: Dr. Halperin.

DR. HALPERIN: I was trying to think of a superlative beyond fantastic. I mean it was really a terrific presentation. And just briefly, you know I think of a phenomenon called yo-yo'ing and it certainly happens in urban America, promised things don't deliver,

people go up and down, and heartache results.

You know in a traditional categorization of primary secondary tertiary prevention, this is in a war environment, so in essence this is like tertiary prevention and the war is already occurring. The question is how much help is this intervention going to be.

In thinking about whether there is even greater prospects for international provision of health care to countries who are in crisis, that would lead more to a primary preventive kind of approach. And the only example I can think of countries who are highly engaged, if you will, in primary prevention of crisis through provision of health services, aside from perhaps the Peace Corps in the United States, would be the Cuban international health care efforts.

And I wonder whether there has been a comparison of what's been accomplished through their provision of nurses and doctors to third world countries all around the world at apparently small expense given economic

issues in Cuba versus the more tertiary prevention health, as wonderful as it is, but could we move to primary prevention as well and maybe even prevent some of these conflicts?

DR. PETERSON: The Cuban health system is a very interesting model and does have some application to all of this, but in the work that USAID has done in health, they've been on the primary prevention from a health perspective for you know their entire development perspective. I think one of the things I see in Afghanistan that doesn't always happen is the very strong engagement of the government of Afghanistan and a very strong Minister. So we have examples here in Afghanistan where, you know, deciding that they actually are going to care about their own people and devise a system that will improve the health of their people is critical.

We saw the same thing in Mozambique after the war, both health and education came up very rapidly in Mozambique because they

had, frankly, their Prime Minister was a doctor and their Minister of Health was a doctor. And they said, "We care about the health of the people." And they focused the government's resources on the primary care and the prevention within it. And there was really spectacular results. The even more primary than that, you know which I alluded to, is the "can we reduce the conflict" or the conflict zones so we have a larger and larger area of the country that is safe and secure so that people can get to the services.

We're looking at distance technology. Can we give and train community health workers in a stable place, send them back to their homes and give them cell phones so they're using telecommunication to respond to the things that are happening? We're going to have to be fairly innovative, but reducing the impact of the conflict in breaking access to services and to health personnel is going to be one of the key things. And Afghanistan is ready and willing to try some of these new things and with lots of money there and lots

of interest to try and do it well.

What we need to do is, you know, to pilot some of these things and then document what's working and what's not working.

DR. LEDNAR: Okay. I'm going to ask that we actually adjourn this issue at this point.

I understand Dr. Peterson, you'll be able to stay with us throughout the day and have dinner with us tonight.

DR. PETERSON: Yes.

DR. LEDNAR: So if there are others that have questions, I'd ask please be sure to grab Dr. Peterson and talk with her. And I think we've seen this morning a very important connection between the update that (Lieutenant) Colonel Coke presented to us and the insights that Dr. Peterson shared with us on a very important part of the world for our military mission.

So, with that, what we're going to do is we're going to do is we're going to take a 15 minute break now and by Commander Feeks clock, we will reconvene at what time?

CDR FEEKS: I got synchronize your watches, the time is now 10:52 on my watch and we will reconvene at 11:07. Thank you.

DR. LEDNAR: Thank you.

(Recess)

DR. LEDNAR: A little adjustment in our agenda. And our next speaker is Lieutenant Colonel Catherine Witkop, the preventive medicine physician and head of the trainee health program at the Air Force Academy here in Colorado Springs.

Lieutenant Colonel Witkop will provide the Board with an overview of an illness known here by the name "Jack's Hack." The presentation slides may be found under tab five of our meeting binders.

Colonel.

Lt Col WITKOP: First I'd like to take the opportunity to thank Dr. Lednar, Dr. Poland, and the entire distinguished Defense Health Board for inviting me to present today. During the brief I'll be discussing Jack's Hack and respiratory illness during basic cadet training at the United States Air Force

Academy.

Initially I'd like to give you all an idea of what a typical summer looks like at USAFA in terms of the number of cadets who come to the clinic complaining of cough, sore throat, or other respiratory symptoms. This is what I'm referring to as respiratory morbidity.

Next, I'll summarize research that we carried out during BCT this past summer and how a large H1N1 outbreak taught us all a number of valuable lessons.

And, finally, I'll highlight opportunities for further understanding of respiratory illness at USAFA and H1N1 via data we collected during the summer.

Basic Cadet Training, or BCT, spans a period of approximately six weeks which puts the basic cadets or 'doolies' under high levels of mental and physical stress. During phase one, the basics march out or undergo academic military and physical training on the main campus. During phase two, the basics march out to Jack's Valley, located north of

the campus, but still on the grounds of USAFA where they participate in intense field training for approximately twelve days.

Jack's Hack is a lay term for a variety of respiratory ailments that typically occur during the field training in Jack's Valley. They usually persist for a few subsequent weeks after BCT. Efforts to clearly describe Jack's Hack or determine its cause in the past have been largely unsuccessful but it's generally recognized that cough and sore throat are typical symptoms and this was found in a survey study that was carried out a few years ago.

This slide is a graphical representation of respiratory illness during BCT in 2007 and 2008, and in fact, in doing the research for this presentation and for my study, I went back as far as 2005 and saw basically the same trend throughout the last four or five years.

The day of BCT is on the X-axis and the number of respiratory visits per day on the Y-axis. As you can see, during the first

17 days of BCT, there is a low level of visits to the cadet clinic for respiratory illness. However, beginning on day 18, when the cadets march out to Jack's Valley, there is a significant increase in the number of respiratory visits per day and almost tripling by the peak of the respiratory illness rate.

On day 31, they march out of Jack's Valley and though a high number of respiratory visits persist for approximately another week after they march out of Jack's Valley but then return by approximately day 37 or so to our baseline level of respiratory illnesses.

This slide provides actual numbers of respiratory visits during BCT. In 2007, 2008 there are approximately 800 visits to the cadet clinic for respiratory complaints, and of these 50% in both years occurred in Jack's Valley, even though Jack's Valley was only about a quarter of the time represented.

So what is causing such a large number of basics to develop respiratory symptoms, and approximately three weeks into their training? One concern that has been

raised is the adenovirus, which as you all know, has recently caused numerous outbreaks at various training facilities throughout the military.

Also tends to peak -- adenovirus outbreaks also tend to peak at about weeks three to five of training. So this summer we (inaudible) whether adenovirus or another infectious etiology might be responsible for Jack's Hack.

In our study entitled "Epidemiology of Infectious Disease During BCT," our objectives were to rule out adenovirus, or other pathogens as a cause of Jack's Hack, and to evaluate possible risk factors for these symptoms. The study ran from June 25th, the day of in processing, through 14 August, which was this past Friday.

Inclusion criteria were being a cadet, age 18 and above, who was a BCT participant, whether as a basic cadet or a cadre, who are the upper class cadets who train the basics. The cadet had to present for care at the cadet clinic or the infirmary

tent at Jack's Valley to be included in the study.

We enrolled a total of 146 cadets and then for analysis they'll be divided into these three groups: group one is the febrile respiratory illness group. To belong to this group the cadet had to present with cough or sore throat and an oral temperature of 100.5 or greater. The second group was the afebrile respiratory illness group, with basically the same symptoms but without a fever. And the third group was a control group. These are cadets who presented with other symptoms, musculoskeletal, skin symptoms, et cetera.

After completing informed consent, each subject filled out a two page questionnaire which included demographic information, basic medical history, smoking history, a list of symptoms in which they filled out which symptoms they currently had and for how many days they've had them, questions regarding perceived stress level, some questions regarding sick contacts, where they were for the two weeks prior to BCT.

Clinical exam was documented and then each subject underwent a throat swab and a nasal wash. The specimens were sent down to the advanced diagnostic laboratory at Lackland Air Force Base. This is a research laboratory that also carries out infectious disease surveillance for the Lackland trainee population.

The specimens were tested with polymerase chain reaction or real time PCR for each subject for each of these pathogens. And this included the ability to subtype for adenovirus, serotype and influenza A subtype, which became significant during the summer.

So now to give you an idea of how our cadets look this summer in terms of respiratory illness, and I apologize, I don't believe the slides came out very well in the book, but you can hopefully see them up here. We have a similar graph to what we saw for 2007, 2008. Here on day 18 when the cadets marched out to Jack's Valley, we saw an increase, a gradual increase in respiratory visits that persisted throughout their time in

Jack's Valley and decreased back to a baseline level when they returned from Jack's Valley.

What is unusual however, is this spike at about day 12 or 13 and did Jack's Hack strike early this year? No, in fact, the culprit was something we're all familiar with, the novel H1N1.

In order to get a better picture of the respiratory illnesses during the Summer of 2009 and whether Jack's Hack even existed, I separated the visits for the respiratory complaints into two. In blue are visits by those who are at some point during the summer diagnosed or placed into isolation as being suspected or confirmed as having H1N1, and in green are those who are not.

And to see this even more clearly, I've divided out the graphs into two and this graph demonstrates a few key points. One, Jack's Hack was still present this summer, as you can see in the green line after the march out to Jack's Valley. So these are patients who are not diagnosed with H1N1.

Also significant was the fact that

after the march out to Jack's Valley, we saw that we did not actually continue to transmit the epidemic of the H1N1 during field training, which was I think a great relief to many.

And despite the large number of cadets with H1N1, we did still persist with our study and were able to enroll the 146 cadets in the study and we're undergoing -- we're doing the analysis kind of as we speak, we're working on them now, but I did have some preliminary results to share with the Board that I thought might be of interest.

Adenovirus was not in fact the etiologic agent in Jack's Hack. In fact, only one specimen was positive for -- on the universal adenovirus screen and was not found to be positive for any of the serotypes that we tested.

Rhinovirus was the most commonly identified agent in the majority of the cadets with respiratory complaints during the period of field training in Jack's Valley. Rhinovirus is an agent most commonly

associated with a common cold, but has also been found in populations to cause more prolonged illness.

Interestingly, we did identify some *Bordetella* species in a number of individuals. These were not pertussis, so this is not the whooping cough; however, this was a finding that we were going to look into further because it was a unusual finding in this kind of population. My colleagues at the advanced diagnostic laboratory at Lackland did not find similar rates of *Bordetella* among their trainee population at Lackland.

Another key finding of our study was that H1N1 was actually identified in several of the early specimens. In fact, better be lucky because these specimens popped up just as we started seeing an increase in respiratory illnesses in the cadet clinic. And prior to the time when we had our clinical lab specimens back that were positive for H1N1, I had received word from my colleagues at the advanced diagnostic laboratory that several of our subjects for the study were

testing for H1N1.

And there were a few subjects identified in the study that were positive for H1N1 that did not in fact meet the CDC criteria for influenza like illness, of having a temperature of 100.0 and greater and cough or sore throat, which indicates to us that there is a broad range of presentation of the illness of H1N1.

Now that I've covered the findings of the study, I wanted to take a few minutes to provide a little more information on the H1N1 outbreak. This slide represents the epi curve. On the X axis is a date (inaudible) and on the Y axis is the number of cases.

Our outbreak period included patients indicating onset of symptoms between and including June 25th to July 25th, 2009. A confirmed case shown in dark blue is a patient presenting during that time who has a nasal wash with H1N1 identified by real time PCR or culture. And a suspect case, in light blue, is a patient with respiratory symptoms, temperature greater than 100.5, and no H1N1

test results.

Our total number of cases during this time was 179. Of these, 144 were confirmed and 35 were suspect cases. Of the confirmed cases 118, or 82% were basic cadets, and we've had a low level of transmission since that time although we've not had a positive H1N1 case among our cadets in the past 10 to 14 days.

Looking at the curve we can see a low level of transmission from early on, from the time the cadets arrive on June 25th. On the 4th of July the basics were kindly given the opportunity to get together in one large group to enjoy a bar-b-que and fireworks. This is where we believe the greatest level of transmission occurred, for two days later is the day that the largest number of cadets reported as their onset of symptoms.

And that day, the 6th of July, is also when the cadet clinic staff started noticing an increase in patients presenting with respiratory complaints. By July 7th, the advanced diagnostic laboratory had notified me

of several patients with influenza A and subtyping was in progress.

So by the afternoon of July 7th, we started testing. We started performing nasal wash on any cadet presenting to the clinic. At that time we were using 100.5, although we subsequently lowered our threshold to 100.0 for the cut-off at which we were testing cadets and placing them in the segregated dorm or the isolation dorm.

And from that evening on, from July 7th on, the cadets were placed into a separate dorm room where they were then required to stay until their seven days from the onset of their symptoms and 24 hours symptom free. And we had a physician doing rounds everyday in that dormroom to check patients, to check their symptoms and release them if they were at that seven day mark and 24 hour symptom, but they were not allowed to be released from the dormroom until that time.

Furthermore, a large education campaign by public health was also put into affect and we believe that these rapid

measures were helpful in quickly containing the outbreak. I did also want to acknowledge that within about three days of the outbreak a team from the United States Air Force School of Aerospace Medicine Epi Consult Service, a team of three individuals led by Major Mark Duffey arrived up here and was really instrumental in helping us really get through this data while we were busy trying to contain the outbreak. And I want to take knowledge of them. They are continuing to help us with analysis of our data.

This is a photograph of the 4th of July mixing bowl. There's not much to say here, a picture says 1,000 words and I would like to thank Colonel Knight for this photograph of the group of basics down there on the balcony who are involved at this bar-b-que and this fireworks event.

It was extremely unfortunate that such a large number of cadets became sick this summer. In addition to the 144 confirmed cases, another 50 or so were also isolated for some period of time during BCT. Many of those

were also likely infected with H1N1, but were not tested.

As I mentioned earlier, however, we have learned a tremendous amount from this outbreak. We have already started sharing lessons learned with leaders from other training settings and other large university settings and we're in the process of standardizing the materials that we'd like to share with other universities and large training settings.

One of our greatest lessons was the importance of communication and (inaudible) from non-medical personnel. As you saw, I recognized this morning Lieutenant Colonel Parish was a great liaison for us in terms of getting the cadet wing to understand the importance and Colonel Williams who joined us here today for this briefing. They were really instrumental in helping us get this dorm, the separate dorm, available for cadets within approximately a six to eight hour period of time from the time that we first thought this is an H1N1 outbreak and we need

to get these cadets separated.

And, you know, without their support and without their response to us and trusting us that we were, you know, providing them with appropriate information, this outbreak probably could not have been contained quite as quickly.

We've already been able to utilize this experience for planning purposes. When the 3,000 plus upper class cadets returned to USAFA on August 1st, we used our knowledge of the symptomology to screen each returning cadet and fortunately we have not experienced the same outbreak that we did when the basics arrived on campus. The cadet dorms, as you've heard before are now stocked with hand sanitizer and public health information is routinely provided. And we have first hand knowledge now what is required for a rapid response if another outbreak were to occur.

But perhaps the most unique opportunity from this outbreak is our ability to analyze some shedding data. During the outbreak we looked at subset of isolated

cadets and performed serial nasal wash sampling. At the time of collection we also documented their temperature and what day they became asymptomatic. These samples were tested again by real time PCR, the standard CDC methodology, and if positive they were grown out on culture. Samples that grew H1N1 on culture told us that there was evidence of viable viral shedding, which could indicate that those individuals were still infectious.

We are currently analyzing these data on the 53 patients who are included in this study and we're looking at shedding duration relative to symptom onset and resolution, how long they were without fever and whether or not they were on Tamiflu for treatment. We believe results from this study will really aid not only our facility here at the Air Force Academy, the Air Force wide, but perhaps even to the level of the, you know, nationwide, how to respond to these outbreaks.

I didn't bring the data because we're still in the process of analyzing them, but preliminary data do indicate that there is

still a viable virus shedding on days five, six and seven after symptom onset. And this is whether or not they are symptomatic at that time. And so these findings will be really interesting where we're working on analyzing them, sharing the information with the CDC, and we're planning on publishing this hopefully as quickly as we can to get this information out nationwide.

In summary, the typical respiratory morbidity during BCT 2009 was confounded by novel H1N1 outbreak. Adenovirus was not an etiologic agent in Jack's Hack, at least for this year. Rhinovirus was the most commonly identified pathogen and this outbreak, both the study and the outbreak have given us just tremendous amounts of data and we're hoping to provide results to the public health and the medical community as quickly as we can. And finally, I'd like to thank Colonel Kenneth Knight who is not only supportive of my research, but was really instrumental in leading the group that responded to this H1N1 outbreak.

Thank you for your time. I'll entertain any questions.

DR. LEDNAR: Thank you, Colonel Witkop. Dr. Silva and then Dr. Oxman.

DR. SILVA: Thank you for a beautiful presentation. If anything is a model that an opportunity strikes, you have to be prepared. And you clearly were.

I think the place to get this thing disseminated is work with the CDC to put it -- and then MMWR. You have a lot of experience here. This is a gold mine. And I'm not going to take a lot of time to ask questions, we can do that later, but even your data on anti virals when you employ them would be exceedingly useful.

And I'm just thinking about general campuses, large universities, what are you going to do if they -- and many of them are set up now to do this kind of screening, but how do you get them into a separate dorm? You have the capability. Or how do you muster additional health care personnel? The average, you know, student health services is

poorly manned, quite frankly, at the universities. And you wanted someone with active disease to go home on a train or a plane from a large university to disseminate it out.

There are a wealth of questions I'm just thinking about. And I want to get a nasal swab from Dr. Parkinson. He can afford it, I'll get his insurance card.

Lt Col WITKOP: Yes, sir.

Interestingly, we had the space for the extra dorm up to July 31st, and that's when we had them in the isolated dorm. Since August 1st, when the returning cadets arrived on campus, we no longer have that luxury either. So the cadets now, from August 1st on, who are identified with H1N1, are now being sent home on what we call "self isolation" per CDC's guidelines for large universities. And we're sending them home with instructions for themselves. We're sending them home with instructions for their roommates, and how to hopefully prevent the transmission, you know, within their room and further abroad.

Yes, thank you, I appreciate that question.

DR. LEDNAR: Dr. Oxman.

DR. OXMAN: Two quick questions. Who got Tamiflu during this outbreak? And the second question is: When they go into the valley, how are they housed?

Lt Col WITKOP: Thank you. So Tamiflu was provided. Anyone who presented and was diagnosed with presumed H1N1, who was within 48 hours of onset of symptoms, was offered Tamiflu treatment. Furthermore, for prophylaxis we offered prophylaxis to our health care providers mainly in the cadet clinic, but also our optometry providers who are screening -- and our dentist, who are screening all of these cadets as they were coming through during this time of this outbreak, as well as several of our cadet wing folks. There are medical cadet cadre who are serving as the medical officers, they were helping escort the cadets, these basics, back and forth and were actually manning the isolation dorm. And so those who were in

direct contact for long periods of time were also offered prophylaxis.

And the second question about Jack's Valley: They're in tents of approximately 12 to 15. And so that was a concern to us too because we were going from a dorm room setting up on the main campus with two or three to a room, to a setting where they would be greater than ten in a tent. So we actually had a mass screening. The day they arrived at Jack's Valley, we did a mass screening. It actually made the front page of our local newspaper -- with Tempa-Dot, the little temperature testers. Every basic cadet, after they arrived down at Jack's Valley were given a period of cooling off time and temperatures were taken. Anyone with a temperature of, I think, 98.6 -- 99.6 based on the Tempa-Dot because of the slight variability, was brought into the tent to be evaluated. And we actually identified a few who were fibrile in that way.

DR. LEDNAR: Thank you. Dr. Shamoo.

DR. SHAMOO: This question just

reflects my lack of knowledge about the cadets. With them getting sick considered one of the failure of physical and mental stress? And second, do we know that our genetic predisposition to getting H1N1 and could you have studied that?

Lt Col WITKOP: I can answer the first one. And this was a question that plagued us pretty much through the entire summer because the basics come in and they are raring to go. And there are all sorts of, you know, stories and urban legends that if they miss a certain amount of training that they will be released. Most of those are not true and it took a lot of education to the basics to say, "Please, if you are sick, you need to come in because this is a really important issue." However, it was, you know, it was a balancing act though because the training that they undergo during BCT is really critical to their development as cadets. And we did not want them to miss more than they had to, but this was where it was really important that we work closely with the cadet wing to emphasize

to them that, you know, we are -- this is a requirement that they be in isolation. This is not a failure.

And, in fact, I really do think that because they were under so much stress, having that seven day period of time was actually, I think, helpful to help them get back up to a level where they can then go back out to training rather than immediately after they were asymptomatic.

The second question, I don't believe I have the expertise to answer. I don't know if anyone else in the group does.

DR. POLAND: I don't think anybody knows at this point. There is a couple of pieces of data though relevant to it. There does appear to be a genetic predisposition to H5N1. And we recently published a paper showing there is a genetic predisposition to low or high response to influenza vaccine, which is a little different, so.

SPEAKER: If I may add a couple of points here. I think the underlying question is why we had such a high attack rate right

off the bat. And we were real concerned about that and that's what drove us to the measure of segregating, which is above and beyond the CDC recommendations.

One of the unique things that Cathy mentioned was that most of these folks were basic cadets. So the cadre, which were interacting with them all the time had a very low attack rate compared to the basic cadet. And that's where I look back at that 4th of July night in which: (a) they're already in that high stressed environment, probably a little immuno compromised, and now they're coughing, breathing, hacking, laughing at each other and that's why we implemented those.

So as we look at the high attack rate right off the bat, it's kind of like the reports that came out of Mexico. Your initial thought are, "Uh oh, we really got to be prepared," and we were, but then looking at how the upper classmen responded, that kind-of gave us the confidence to go back to the self-isolation in the rooms vice having a segregated area after the return of all the

cadets.

The second thing that we're looking at, Major Duffey and company, actually took the opportunity to look at viability of the virus on (inaudible) inanimate objects. And so these cadets that we knew were actually positive before they were on Tamiflu, we had them cough and sneeze on different surfaces and start swiping, you know, immediately, 30 minutes later, two hours later, so all that two to eight hour viability recommendation by the CDC hopefully will actually have some science to back that up.

DR. LEDNAR: Dr. Halperin, last question.

DR. HALPERIN: You know in thinking about the CDC recommendations and thinking about a few weeks from now and thinking about being in a place like Newark with 30 or 40,000 undergraduate students in town, I think one has to come away with the how unusual a situation this is where everybody is tightly controlled and cohorted, et cetera. So the beauty of the field epidemiology is self

evident. You did a wonderful job. I think the difficulty is going to be in writing what the implications are for the general educational community. And I wouldn't be so optimistic. I think that what this is telling us we're just going to have large, big, uncontrolled outbreaks with -- sorry, but that's what we're going to see.

I wonder whether science-wise amongst the people who are not symptomatic unless I missed it, whether a little serosurvey to see how many of the people actually escaped infection or actually seroconverted but were relatively asymptomatic, just to see how far this really went. Maybe it burned itself out because you burned out -- you didn't have more people to be infected, but anyway, it's a nice job.

Lt Col WITKOP: Thank you. That's a very interesting question, certainly something we'll look into.

DR. LEDNAR: Okay. I'm going to have to sort of bring this discussion to a close. Obviously, very, very interesting and

I think really best practices view that we've received. I'm going to ask Dr. Poland if he wouldn't mind saying just a few words and sort of a synopsis for what we've heard so far.

DR. POLAND: First, one quick comment relative to what Bill said because I think what he said is very true. I view this much like how we would take an experiment into a laboratory and try to control as many variable as possible and find the relevant underlying truths, if you will. And then the tough part is always generalizing them outside of the laboratory, but that's what I think the value of this was.

The second thing is (Lieutenant) Colonel Witkop mentioned something very important -- and I'll harken the Board back about a decade when we visited Navy SEAL training camp one after a couple of fatalities and near fatalities from respiratory illnesses. And the issue there was attention she mentioned between the individuals, in this case the cadets, not wanting to drop out or be perceived as weak, or as you said, many of the

legends going around about, you know, "you're going to get your orders to go back home, is where you going," type thing.

And get them to report symptoms and accept treatment makes all the difference in the world. So congratulations on that education effort.

I also hope that -- we often learn in respiratory, particularly viral, illnesses that -- and we were talking a little bit about it earlier with Dr. Ennis -- when you've seen one outbreak, you've seen one outbreak. And I hope that it will be immortalized as Jack's Hack study, will continue at least another year, because this was obviously an unusual year we think. Wouldn't it be interesting to find out that there is always a harbinger of some influenza followed by rhinovirus or something else. So, again, congratulations on a job well done and I look forward to seeing the data.

Lt Col WITKOP: Thank you.

DR. LEDNAR: One last comment, Dr. Oxman.

DR. OXMAN: I have a comment that might have some significance. The picture you showed about the group meeting outdoors, my understanding is that respiratory transmission is very inefficient out of doors. And hand washing, that may emphasize the importance of hand washing. And while at UCSD and Davis and other -- and in Newark -- there is no hope of having the kind of segregation that you had here. If in fact avoiding large groups indoors and washing hands, effectively, might be the answer. And I wondered if that was worth some -- if not discussion, at least some thinking about whether that picture you showed of the crowd had implications for what was and wasn't going on.

Lt Col WITKOP: Yes. We don't know for sure that that's exactly where the transmission occurred, but that is the one event where all the cadets were in pretty close proximity in a large group and chronologically made sense. Absolutely there is being outside and that was one of the things that was reassuring to us in going down

to Jack's Valley, was despite the fact that if they were in the tents, at least they were out of doors for the most part.

But we have, for our planning purposes for the upcoming weeks and months, one of our recommendations to the cadet wing if this were to occur again, is absolutely to limit large gatherings of ill individuals and I think the CDC also, that's their key recommendation. I'm not sure we'll ever know for sure that the 4th of July event was the culprit, but it certainly -- as you can see in the picture, they were at least close together.

DR. LEDNAR: (Lieutenant) Colonel Witkop, thank you very much for your presentation and your continuing work. Thank you.

Okay. Our next speaker this morning is Sergeant First Class Eric Strand. He was born in Bad Toeltz, Germany, a place I actually had the good fortune to travel to and perform an epidemiologic consultation back not so long after you were born in 1981.

But he grew up here in Colorado Springs until high school, after which he joined the Army as a counter-intelligence agent. Since graduating as a Special Forces Medical Sergeant, he served three tours in Iraq and was most recently the company medic for a Special Forces group.

Sergeant First Class Strand was named the 2008 Medic of the Year by the United States Special Operations Command. That is quite a terrific feat. Congratulations.

SGT. STRAND: Thank you.

DR. LEDNAR: Sergeant Strand will provide us with a brief on combat medicine from a Special Forces medics point of view. And his slides may be found in tab four of the meeting book.

Sergeant Strand.

SGT. STRAND: Thank you so much for your time and I want to thank the Defense Health Board and Commander Feeks for inviting me out here and giving me your time and attention.

I am Sergeant First Class Strand.

I'm from Bravo Company Third Battalion, fifth Special Forces group. This is an information brief and the information will be unclassified.

I'm going to go briefly introduce what Special Force is and what Special Forces does because I know that not everybody here is familiar with what we do. So I'm going to touch briefly on what that is and what it means for me as a Special Forces medic. And I'm going to go through the situation leading up to the casualty event that occurred to us and go through the actions that occurred afterwards and the treatments that I provided. I have a few lessons learned that I walked away from that with and I'll give you the outcomes of all the patients in the long run.

The core element of the Special Forces mission is the Special Forces Operational Detachment Alpha. It's commonly known as the ODA. You'll see that term throughout the slide show. An ODA is a 12-man detachment that operates semi-autonomously in an area to do a wide variety of functions. We

have five core missions. It's direct action, unconventional warfare, foreign internal defense, special reconnaissance and counter terrorism.

More specifically, Operation Iraqi Freedom, operation Enduring Freedom, we train, advise, and assist host nation security forces through a variety of methods.

A Special Forces mMdical Sergeant, or an 18D, is a Special Forces operator that also has 12 months of medical training that covers trauma, basic medical emergencies, some clinical stuff and kind of a whole grab bag, jack of all trades, medical skills for whatever situations we might encounter.

We're responsible for all the traumatic and medical care of the Special Forces detachment and all our host nation counterparts. Usually it also spreads out through travel engagements to the local villages as well.

I'm going to go ahead and frame the situation that we were in. This was 2008, April of 2008, when this occurred. During

2007, 2008, the surge in Baghdad and Bacuba started pushing insurgents out into eastern Diyala Province. They were using eastern Diyala Province as a safe haven to transport themselves up to Mosul to continue to fight. We were out there in eastern Diyala Province trying to halt their progress and try to deny them a support area.

So this was in the same area as we were trying to dismantle one of their support networks, we had a fatal IED about one mile from where this event occurred and we had some significant problems due to the weather and dust. We had a two hour delay in MEDEVAC times. That's significant because in Iraq a lot of people are spoiled with MEDEVAC times and aren't used to having to sit on patients.

So that leads us into where we were here. You know it's still windy, it's still dusty, it's still cool in the morning. It's about 04:00 local time when we arrived on the target. We had the ODA, our 12 man ODA, and 20 Iraqi soldiers to conduct this operation. The enemy forces -- this was the small

village. And I'll show you some pictures so you can get an idea what it looks like, and they were defended by a very good early warning network that could see vehicles coming in from a long way and numerous defensive IEDs, which I told you we already encountered in a previous situation.

Our primary casualty evacuation plan was two UH60s staged out of an FOB with a 15 minute response time, a 30 minute flight. Our secondary CASEVAC plan was for us to drive casualties to the nearest aid station. Understand, too, that our detachment was working in an area that was separated by about an hour drive time from any other US Army unit and we were responsible for maintaining control over about 500 square miles. The mission was simple, to conduct a mission to capture a local insurgent cell leader.

To counter some of the problems that we had with early warning, we started doing a lot of dismounted operations that night, walking up onto the target, laying a cordon, laying an overwatch element to prevent the

enemy from fleeing as we arrived with our assault force. I was on the assault force with five other ODA members and then six ODA members were walking in the cordon.

For those of you that haven't seen a wadee, I have a picture of one. It's basically like one of the big wash out ravines they have here in Colorado. It was a known route of enemy escape in the village that they used before they had cache locations. They had little spider wholes and caves. So we were trying to block that exit as the assault force moved in.

As the cordon element was walking in and moving into position there was a roving guard at the target house. He discovered the patrol as they were walking and immediately started running into the target house to alert all the occupants. One of the ODA members, Staff Sergeant Brown, grabbed three Iraqi soldiers and ran forward to neutralize the guard. As soon as he stepped into the courtyard of the house, they encountered machine gun fire and instantly fell.

The rest of the cordon element rushed forward to the objective house to try to provide aid and get them out of that situation but they were pinned down by machine gun fire, rocket propelled grenades and hand grenades.

As the engagement started, we drove in on the road leading up to the objective house. If everybody understands the graphic there. So that's where we are. As you can see right here, to the east of the village, there is a huge open area with very restrictive terrain that's difficult for vehicles to move through. So you're stuck on the roads if you're going to assault this area with a vehicle. You can also see that the visibility is extremely large.

We did an overwatch mission several months before this where we actually got to watch an assault force move onto the target and we saw the vehicles an hour before they arrived at the target village. The wadee that the cordon element was infiltrating on is the picture on the right. And you can see it's

pretty typical for Iraq and you can see it has a lot of good places for the enemy to hide. So we were trying to block that for them. And then you see as you come up on the village how densely populated it really is. And you have all the tangles of wires and confusing roads and complex houses that make an issue getting into the area.

This picture was actually taken months before the operation in the same location where this occurred. This is our detachment advising Iraqi soldiers on an operation and you can see this is just a typical Iraqi mud hut with the courtyard and the buildings inside. The wadee is off to the left. You're facing south in this picture.

So as we drove in, you can see the locations of the casualties marked by the red circles, the vehicles -- I was in the rear vehicle. I was commanding the rear vehicle as we came in, as the assault element. As soon as we got up onto the objective, we were not able to engage at the house with machine gun fire because we didn't know where Staff

Sergeant Brown was and there were several Iraqi soldiers that were unaccounted for, many of them were injured and some of them had taken cover in a location that was removed from the action.

The first casualty I came across was the Special Forces medic that was assigned to the cordon element. He initiated self-aid and moved to me and began to relay to me that there were other casualties involved. I established a casualty collection point at my vehicle, which was the rear vehicle, radioed up the grid for that and let everybody know that I was setting up there. And then the team began to initiate their full assault onto the house.

As we came up, the enemy forces started engaging us heavily hoping to repel us, but then as they noticed that we were bringing fire power into the situation, they started breaking contact, continuing with the hand grenades and the machine gun fire to get cover for the leaders to leave.

Also this was occurring during hours

of darkness and the Iraqi forces did not have night vision equipment so we ended up illuminating the area with 40 millimeter parachute flares.

As the team initiated the assault, the team members just started radioing to me that there were casualties at the location as they were picking up and moving. Understand this is the right thing to do because neutralizing the threat is the best way to prevent future casualties. I would say that the only thing that they failed to do, and I'll address that in my lessons learned, was mark the casualties with the red Kem-Light because they were very difficult for me to find and I ended up having to expose myself to enemy fire to search for them in the dark.

In total, there were three US soldiers wounded, three Iraqis were wounded, there was one enemy wounded, one US soldier was killed, and three enemies were killed. We ended up -- four of them were serious enough that we had to put onto a helicopter and get out of there, and two of them we discovered

wounds later on that required immediate attention.

Here is another picture of a typical Iraqi mud hut. You see as you're coming in the gate is to the right and it enters into a courtyard. And it's not as when you go into a house and everything is connected. Each one of these rooms is separate from itself, so you can see it's a difficult environment where there is a lot of places where people can hide.

And what they did was they pretty much set up a machine gun in the corner of the courtyard and just pointed it at the gate. And it's a very simple and effective, efficient way to repel anybody that you would want to keep out of your house.

A list of the casualties here, the first one had a gunshot wound to the cerebellum. And I'll elaborate a little bit more on these casualties in later slides. Casualty two was the other medic. He had shrapnel to the right arm, face and chest from a grenade blast about four feet to his right. Casualty

three was an Iraqi soldier who had a gunshot wound to the face. We had another casualty that had a gunshot wound through and through to the neck.

The fifth casualty had a gunshot wound to his lower abdomen and his upper thigh. And the casualty six and seven had shrapnel wounds that I discovered after the assault was over, but they were in the chest area so I decided to go ahead and initiate a MEDEVAC to get them x-rayed and make sure they didn't have any chest wall compromise.

Casualty eight was an enemy and he had multiple gunshot wounds to the pelvis.

Casualty number one was Staff Sergeant Brown, the ODA member who went to neutralize the guard. He had a single gunshot wound to the sternal notch. It had entered in at a 45 degree angle, it pierced the soft part of his body armor and clipped the top of his plate and then dove down into his sternal notch. So by the time I saw him, the ground was completely red with blood and he was already pulseless and apnic. I just

declared him dead to the commander and allowed him to call it up to our company and continued to treat other patients.

A little note about the body armor thing, is that one thing I had to deal with his family about. They were wondering how he got shot in the chest with body armor and they were wondering, you know, do we need bigger body armor, do we need this, that. And I ended up having to explain to them that himself included, that we would all rather be able to accomplish our mission by not being weighed down with unnecessary equipment and we all understand the risks that we take when we go on these operations.

Casualty number two, he sustained -- a grenade landed about four or five feet to his right, so when he came to me he was extremely confused and agitated due to the proximity of the blast. He definitely sustained a concussion from that event. He did manage to apply a tourniquet to his right arm, but he only covered -- the entry wound was lower than his exit wound that went into

his arm pit. So the tourniquet was in between his two wounds. I ended up having to revise the tourniquet, later converted him to a pressure dressing. He got fentanyl lollipops for pain and I applied a splint.

Part of his injuries was that he had pain that was extremely out of proportion to the injuries that I saw, so I suspected at first that he had a fracture. And I remember commenting to him, specifically I said, "Hey, I'm not going to do a crepitus check because I'm just going to splint you anyways." And he appreciated that.

I treated him for hypothermia. That's something you're going to see throughout. I treat all these patients for hypothermia because it was about 65 degrees outside, but after conducting a foot movement, everybody was sweaty and a little bit tired, so it was a concern of mine throughout the whole time.

And I ended up disconnecting him as much from the fight as possible, number one due to his altered mental status and number

two because I had medicated him. So I completely disarmed him and I disconnected his radio so he didn't feel a need to participate in anymore of the activities with this operation.

Casualty number three had a gunshot wound to the face. He had his lower jaw shot completely off. He was alert and oriented and his tongue was intact and I was able to visualize his airway. He came to me as is. We're still fighting that cultural war with the Iraqis about self and buddy aid, but we'll win it one day.

So what I did -- it was a difficult wound to manage the bleeding on. I initially tried a HemCon dressing and tried to leave him in the care of one of his buddies so I could go out and find other patients, but they weren't effective in providing pressure to it. So, I ended up making a little bowl out of kerlucks that was laid across my arm and filled it with Celox powder, and just pressed it up into his wound and maintained pressure on it until the bleeding began to stop.

I applied a nasopharyngeal airway. I decided not to do a surgical airway because we were still being engaged by the enemy and I didn't want to have to worry about any treatments that would be affected by me moving the patient. And then he ended up getting 500 ML of Hextend and we gave him morphine for pain.

Casualty number four had a through and through gun shot wound to the neck. It was a posterior triangle injury. It didn't cross mid line. It didn't cause any problems with his spine or his airway. What he did have, however, was a venous bleed that had soaked completely through both his undershirt and his uniform top, so it was life threatening. I ended up applying a HemCon bandage to the exit wound where the venous bleed was coming from and putting asap around that and under his arm. The entrance wound was treated in a similar manner and he had no airway problems. He ended up getting a liter of lactated ringers because we had a limited amount of Hextend and there was other patients

that were in more serious need of it.

Casualty number five was the most serious casualty. He had a gunshot wound to the lower abdomen. It basically went in beneath his plate and caught him. He was kind of an overweight Iraqi soldier, so it caught him where his pants went over his belt underneath his body armor and he already had a significant amount of pain and rigidity, and I could feel the blood clots forming inside his abdomen. He also had a gunshot wound to the upper thigh, that was the more cut and dry injury. I was able to tourniquet it and stop the bleeding there.

We were not able to get any kind of intravenous access on him, so I had to apply a F.A.S.T.1 intraosseous device and he ended up getting 500 CC of Hextend. I applied a NPA as his condition began to deteriorate. And he was pretty aggressively treated for hypothermia.

Casualty number six and seven, it's actually -- I was watching a brief similar to this at the Special Operations Medical

Association conference in 2004 and they were going over the lessons learned and they were talking about having your whole team file through after everything calms down so you can inspect them and make sure that, you know, if they missed any wounds due to adrenalin rush and they weren't feeling any pain. And, sure enough, I found two guys that did have penetrating injuries to the chest. One went in through the axilla under the arm and the other one went in back where the scapula is in between where his -- the load bearing portion of his vest.

And I did an initial examination. They didn't seem they were having any distress with breathing, so I ended up applying occlusive dressings and they traveled with me as I closely monitored them on their way to the next aid station.

They also received -- they were just hydrated with water and they received combat pill packs. That's the same for casualty number seven.

The enemy casualty received two

gunshot wounds to his pelvis from Staff Sergeant Brown as he entered into the courtyard. Due to the amount of time it took to secure the objective because we did have some unexploded ordinances, we had some suicide vest, and some explosive caches that prevent us from fully clearing the house for a while, he was already on his way out by the time he arrived to me. So there was little I could do for him but just make him comfortable.

We did have some issues with casualty evacuation again. Air assets were red as we went on in this operation, so we had a very, very long delay with any type of air platforms. Initially they told us that we were going to have to conduct our on ground CASEVAC and as we were preparing to pack everybody up into the vehicles, they told us that the birds were one minute out. This was about one hour and 45 minutes after the contact began. So I had been with these patients the entire time.

All the serious casualties were

loaded up into the helicopter and I ended up discovering the other wounds later on. As we were going to the next aid station to drop them off to move them up to Balad it was about an hour drive. We arrived at that aid station and we find out that the dust storm in Balad had become so bad that the aircraft were being diverted back to where we were. So I ended up seeing all these serious casualties again.

Luckily, a friend of mine that was on another team was stationed at that FOB and he ended up relieving me of my tasks and taking over the CASEVAC for the rest of the 90 minutes to Balad. They were transported in strikers with the local infantry unit.

These are some of the significant things that I walked away from this with, you know, when I say here the casualty event is a tactical event and that's something that rings true, you know it basically means that a medic only succeeds when he's surrounded by people that are performing good tactics. So it requires the entire team for him to be successful in providing treatments because

good tactics keep him from being overwhelmed with additional casualties. They keep him safe and the commander supports him in what he's trying to do.

There is also a lot of other decisions that have to go on as far as managing the personnel you have, giving the medic enough people to have a couple extra hands but still be able to conduct the assault or break contact, depending on the tactical situation.

A big multiplier for me was cross-training. That's something that special forces has always been known for, is teaching everybody everybody else's job. And it was a big help for me because I was able to stay back and maintain a big picture assessment of what was going on because as soon as I started having to provide a treatment, I get tunnel vision and I miss all the other patients. So, you know, that's something that's very important, it's a huge multiplier for me.

As we were coming back on our hour return trip from the nearest FOB going back to

our home base, we encountered an IED that was placed for us. This was -- you know, we've already had a difficult day, a long difficult morning, a long night, and we were pretty distracted and tired, but it shows that you can't ever lose your focus and you can't ever stop paying attention to what's going on around you until you take off your kit and after that you can let go, do whatever you want.

So you can't ever let your guard down. The positive note to that was that the Iraqi security forces that were escorting us did discover it and they destroyed it.

The thing about marking the casualties and just all the little nuts and bolts things, we always brief that before we go out, "Hey, you guys, don't forget to do this. Don't forget to do that." And they hear it a lot, but the thing is that the tasks that you do over and over again, physically, are the tasks that you're going to do when the time comes. And that's something that we never actually physically did in our

casualty play, was break the Kem-Light and drop it on them. It seems like a simple thing to do, but if you don't ever go through that muscle memory, that's one of the things that gets dumped first when you're in a stressful situation.

Something that I had to consider about myself and about everybody else too, because this affects everybody metabolically in as far as dehydration and fluid levels and my ability to perform more complex procedures that I may be trained to do, but may not want to do, is that we had already had several long days of patrols and during the day time it was very hot, during the night time it was very cold. We had missed a few meals and we definitely lost a few nights of sleep. So that's a consideration that not everybody is going in, in a good metabolic state. Not everybody is going in fully hydrated. So it's going to affect all the medical treatments that you render. It makes people more susceptible to hypothermia and shock and everything else.

One of the things that made me successful was that myself and the other medic, is that every month we would completely unpack our aid bags and then repack them. It gives you through the visualization of looking at your equipment and knowing how you're going to use a piece of equipment, what injuries you're going to use it for.

As a Special Forces medic, I am rarely a medic. You know, I have a lot of other tasks that I have to conduct. I am a Special Forces operator, so I have to find something that keeps my mind engaged in medical tasks because I don't want to be caught off guard if something happens.

Weather caused delays with CASEVAC, but it also prevented us from getting any type of UAV support or any type of (inaudible) support. So we were stuck with what we had on our bodies and in our vehicles to deal with the overwhelming amount of force that we encountered when we first approached the target house. And we were also never able to develop a full picture. As a result of that,

two of our primary targets did escape when they broke contact. And it's just a balancing act when your planning. You have to think if it's worth doing the mission now or if it's worth waiting. In our case, it was worth doing the mission now and that's -- you know, we're trained to operate without all the high tech toys and that's what we chose to do.

The other medic was seriously wounded. The Special Forces group has a long tradition of medics becoming wounded and killed, especially since the war on terror began, and all the teams know where we are that the entire element need to know how to conduct casualty operations if there is no medic and that requires a lot of training. It requires integrating casualty play into tactical training so that it's always in their mind and it's never an unexpected event.

And in this situation, I used a lot more conservative treatments than I have used in more secure environments or in clinical environments because every time you conduct -- if you conduct a surgical airway, that's

another wound you have to reassess. That's another thing you have to manage. That's something else that has to fail, so I want it to be as portable and streamlined as possible because I have to support the commander in his mission still.

And that goes right into being prepared to move your casualties quickly. We did have an opportunity to get indirect fired called on this village that we were engaging in and you have to be ready -- the casualties are probably going to be the slowest part of moving the element out to a safe distance. So you have to have everybody packaged up at all times. You can't just say, "Oh, a MEDEVAC is coming in 30 minutes, so I can go ahead and leave all my medical stuff laying all over the place," and guys aren't on stretchers strapped down ready to go.

And then finally, you know, where we were stationed at this time, our biggest battle was information. And you know our credibility was our safety. So we have to always win the information war every where we

go. So that means that I don't want to leave any trace that they hurt us at all. We can't let the Iraqi population know that the terrorist won. We can't let the terrorist do any kind of assessment of their techniques and know that they actually did cause casualties.

So I made every effort to leave zero footprint when I left, as far as medical supplies, blood, and any other indications that we had a casualty event.

With the exception of the detach member that was killed, all of our casualties were eventually returned to duty in one capacity or another. The patient with the facial wound -- and this is kind-of one of the reasons that -- one of the things that the 18Ds are trained in, is nursing care. And it's something that we're not always quick to study up on, and brush up on, and stay current with, but a lot of the Iraqi soldiers had surgical interventions performed at Balad but then as soon as they were deemed like they were going to survive, they just sent them back to their home station.

Well, in the area we were, there were no doctors. There was no Iraqi medical support. So I was the guy. So I ended up having to do a lot of wound care, take care of their feeding tubes. And as you see, the guy with the through and through gun shot wound, they actually closed his wound track and it became significantly infected. I had to open that up and debride it later on.

The other Special Forces medic that was injured, he had the pain out of proportion to his finding, I found out later on because he had an underlying nerve injury to the brachial plexus. He ended up losing all use of his right arm for about six months but he's began, through force and will, rehabilitating himself back into an operating status.

And the patients with the shrapnel wounds, did not have any lung compromise, so they were returned to duty several days after arriving in Balad.

I'll go ahead and open this up for any questions that you may have for me.

DR. LEDNAR: Questions for Sergeant

Strand? Dr. Shamoo.

DR. SHAMOO: I have two questions. One of the outcomes, you didn't say what was the outcome of the injured enemies.

SGT STRAND: They were all deceased before we left the target, sir.

DR. SHAMOO: I'm sorry?

SGT STRAND: They all died before we left the target.

DR. SHAMOO: Oh, they all died.

SGT STRAND: Yes, sir.

DR. SHAMOO: And the next question is how do you distinguish between an injured enemy who may hurt you in the process of taking care of them?

SGT STRAND: Well all enemies get zip tied and secured because the security of our (inaudible) is paramount. It's not a cold hearted thing where I don't care about them and I'm never going to treat them, but we have to secure ourselves first. So they're even brought to the casualty collection point and they're zip tied and secured. And we usually have a security element with us to make sure

that nobody gets up and starts doing anything crazy.

DR. LEDNAR: Sergeant Strand this was obviously a very difficult operation and especially with the casualties that you experienced. Do you do any kind of a debrief in the team about the experience? And part of that is how people felt about, you know, their fellow soldiers suffering injuries, one of them died. How do you sort of work through the debrief after the mission?

SGT STRAND: It's kind of an informal task that's assigned to the medic on a Special Forces team that he's also kind of the guy that watches people for the commander. And we didn't sit down and do a wash out session, per se, but I did -- I was asked by the commander to keep an eye on anybody and see if anybody was showing any indication that they might not have been handling everything well.

Everybody does handle things differently as far as that, but I think the most important thing for us was that within

three days after this operation occurred, we went out on a confidence patrol because you have to re-engage yourself and reassert your sense of purpose. And then five days after this occurred, we actually did an operation in the same village, at the same house and ended up having some significant gains because of it.

And I think having that sense of purpose and having kind of a clarity and a compass helps you move on easier than people that may not have been present at the situation.

DR. LEDNAR: Dr. Fogelman.

DR. FOGELMAN: Well, a comment based on what you just said, that that's excellent counter-phobia treatment. Did you receive any training in psychological debriefing for the kinds of things that Dr. Lednar was talking about? I understand what you did, but did you, yourself, get any training as a part of your training?

SGT. STRAND: It's a small portion of our training. And we understand we have a

tremendous amount of skills that we have to learn in a small amount of time, but they do touch on it and do touch on the need to it. A lot of it has to do with recognizing some of the symptoms and how you can refer them and how you can deal with it, with the command, in a way that's not going to alienate people.

I think the biggest thing is being empathetic and not being somebody that people are afraid to come to if they have problems.

CDR FEEKS: Sergeant Strand, I am in awe of you. That was one heck of a morning. I do have a question, you made reference to a cultural issue about self aid and buddy aid among your Iraqi counterparts. And I wondered if you could explain that a little bit.

SGT. STRAND: There is difficulties that you deal with when you're training a host nation force and medical training is something that is very difficult to teach them. And we hadn't had this unit for a long time and weren't able to harp the importance of it on, but there is kind-of a "know-it-all" attitude in some of the security forces we deal with

where they're not willing to listen to us when we're teaching something.

And you have to decide whether you're just going to say "Put a tourniquet on the guy because he needs a tourniquet" because I got into a 30 minute discussion with somebody who was absolutely sure that blood had nothing to do with oxygen.

So a lot of these people are very undereducated, so you have to find ways to teach them how to do things by habit and not by knowing why they're doing it.

DR. SHAMOO: I want to confirm that observation of the Iraqis since I'm an Iraqi instructor. They know it all.

DR. LEDNAR: Dr. Halperin.

DR. HALPERIN: Absolutely without getting personal, could you give us an idea what career path medics have after they've got substantial experience? What might people do after this job?

SGT. STRAND: There is a variety of jobs. I, myself, am planning to take on an instructor job for a couple of years teaching

Special Forces medics in North Carolina. After that, I intend to apply to medical school. A lot of 18Ds do go into the Army PA program, a few of them go to medical school, and a lot of them stay in Special Forces and become team Sergeants and Majors and go completely out of the medical realm into the tactical realm.

DR. LEDNAR: Any other questions for Sergeant Strand? I think as Commander Feeks said, that was one awesome response that you gave to your team and to this mission and it's pretty clear why you were selected as the SOCOM Medic of the Year. So, congratulations, again. Thank you for your time.

Our next discussion will be by Dr. Fogelman. Dr. Fogelman is the Chair of our Board's Psychological Health External Advisory Subcommittee and he's going to share with us the Subcommittees' activities as well as the Subcommittee's draft recommendation pertaining to applied behavioral analysis therapy for autism.

We were provided an overview of that

August 7th, and there as a lot of deliberation on this issue within the Subcommittee and Dr. Fogelman is going to share the recommendations of the Subcommittee for the Board to consider.

And his materials can be found under tab six. Dr. Fogelman.

DR. FOGELMAN: Thank you. As most of you know, I generally begin with a light transition or a joke. Feeling rather small in comparison to the previous person standing at the lecture, and I think I will break with my own tradition and thank the Sergeant and move on directly. Maybe later I'll tell a joke.

These are the things I'm going to go through. Everybody can read. I won't read it for you. You've all seen this slide before, or many of you have, that slide is actually going to change by the next time we meet because some people are leaving and one hopes there will be new appointments, but one can't be sure.

This is what we did at our last meeting. You may recall, and if you go into the supplemental slides, which I won't go

zipping to right here, we've tried to impose a structure on all of our meetings so that certain things are covered and we do it in a reasonable sequence and not leave anything out.

And without telling you which thing fits with which, this was the first meeting we had which actually followed the template in which we really tried to cover everything which we had previously identified as areas of interest.

Just to walk quickly through these things, I always talk to the Subcommittee about what happened here and any conversations I've had in the interim. I'll get to the autism thing later. One of the things we tried to do is get our hands around some hard data every time, so that's what the third item was about.

You've all heard a lot about suicide and everybody is deeply concerned about suicide. There is recently stood up a suicide prevention Task Force, I guess is what it's called. One of the members of our

Subcommittee, one of the members of the Core Board (inaudible), serves on that and he's acting as our liaison to that. And one of the reasons that we are not taking that on ourselves is because of the amount of effort that's going into it otherwise, and because we have liaison with those efforts.

One of the reasons we got a brief on the Exceptional Family Member Program is related to the autism question. In an earlier conversation we had among ourselves, we thought it would be useful to know everything that the services were doing to respond to family members.

Commander Ralph is Director of Mental Health Services at the Naval Hospital and has had quite a variety of experience. So he came in and just talked to us about what life was like on the front line where he was, and also what life was like on the bureaucratic front line, which is where he is now as Walter Reed and Bethesda are being squeezed together.

One of our jobs is to keep track of

the implementation of the Mental Health Task Force Report of a couple of years ago. Mike Parkinson, one of the things, remember, I said to you that we are trying to pay attention to the question of robustness, that is also one of the themes for us in everything that we're doing. So we try to have some presentation on that every time. And these last two cover that.

And, in particular, are General Cornum's activity -- is the one that's most linked to the Philadelphia trip I talked about before.

One of our other jobs is to keep track of what's going on in DCoE and I have been trying to create a relationship with them such that they will report to us in a way that's not burdensome to them and we can be helpful to them. So that's what that was about. That's pretty straight forward.

When we were stood up, these two questions were there waiting for us. The second question is being addressed by an ad hoc joint working group of our committee and

Dr. Bullock's Committee, the Traumatic Brain Injury Subcommittee. There is as yet no report from them and perhaps there is not enough activity from them, but there is a person who is in charge of that ad hoc working group and that group will report back to the two committees and interact with us in the whole.

Now we come to the request for action. We've been --

Dr. Lednar, is there a formal procedure you want me to follow with this thing?

DR. LEDNAR: If you would review the recommendations of your Subcommittee and then we can have discussion about it, and then we'll have a Board vote.

DR. FOGELMAN: Okay. Let me talk -- I'm talking about the autism question, which is -- let me tell you a little bit about how we approached it and how we educated ourselves and how we deliberated about it. (inaudible) actually of a conversation we had in the administrative session this morning, in which

one of the questions we talked about was: how do you vote and how do you deliberate on an area that you don't know about firsthand and which you don't really have expertise?

This was a question we discussed when we first brought up this question because only two people, maybe three, on the subcommittee who have direct experience either clinically or on the research side with autism. And we decided, well, you know, we're a reasonably experienced, reasonably senior, bunch of people and we thought we were skilled enough to read research reports if we read enough research to be able to judge the quality of the research and the conclusions based on the research.

Particularly we looked at, you know, the larger body of work and that even if we didn't know the particulars of one aspect of the question, among us all we had sufficient critical faculty to discuss it and to vote on it. And I think that's a truth for the Board as a whole.

Another thing we did was decide that

the data and not the politics and not the emotion would rule the day. And as a matter of process, we discussed it at two face-to-face meetings and one telephone meeting. We had a great deal of reference material provided to us, much of which came from the enormously competent efforts of the Subcommittee staff, which in this case is Olivera Jovanovic, which is standing back there, who did a spectacular job of creating an E-Vault with something like 150 references for us to access over several months.

Now, I can speak for myself, I didn't read everything. I read all of the summary articles and a sampling of the primary articles. I'm quite confident that among the dozen or so members of the Committee who were active participants in this, everything was read at least once and there was some people who read, I think, everything.

Several of us also had close colleagues, the medical school folks, had close colleagues who were quite active in autism and they consulted with them and

brought those pieces of information to the discussion. By the time we got to our last meeting, we had a draft set of recommendations that we were willing to bring into final shape and vote, and then bring to the Board, which is what brings me to where we are here.

The recommendations I'm going to tell you about, or I'm going to make you and ask you to vote on, were all endorsed unanimously by the Subcommittee. Now, the members of the Board all got, I believe, our complete draft memorandum with the list of references and the like.

Is that correct? Is there anybody on the Core Board who has to vote who didn't get that? Of course we have copies of that to be made available to you if you really need it.

So it's important -- let me just go back for a second. That's kind of an abstract of the way the question goes, but what I want you to note about the question is that fundamentally the question was asked about ABA, which is Applied Behavioral Analysis,

intervention in autism, which is a subset of a slightly larger group of interventions.

We tried to restrict ourselves, as best we could, to answering this set of questions focused on the ABA target, if you will. As a general statement we asserted and we concluded and asserted that treating autism spectrum disorders required the integration of treatments, not simply treatments from one discipline or another or with one practical application, whether it be school or activities of daily living or the like. Reviewing the evidence, ABA is a subset of early intensive behavioral interventions. The research tended to show that those interventions may produce short-term gains and they may produce short-term improvements in adaptive behavior, but not for any of the other impairments that autistic kids and adults experience and certainly not over the long term. That is there were no pieces of research which demonstrated in a convincing way.

And this is sort of the fundamental

finding, there is a lot of evidence if you just add up the numbers of studies and the numbers of assertions and the number of anecdotes, but in point of fact there is an insufficiency of evidence that's of sufficient scientific quality that we are willing to say, hey, you know there's evidence there because it's not what we believe. We couldn't draw a conclusion about the long term efficacy and we couldn't draw a conclusion about the other thing we were asked, which is the relative efficacy, other treatments in comparison to ABA.

What should we do about it because we were asked for some general recommendations specific, if we could do it. The first addresses: how do you know what works? Well, that's sort of the fundamental question and as near as we could tell, there really weren't any good studies comparing one mode of intervention to another. And you probably know -- but some of you may not know -- that there are many competing schools of thought, political movements, advocacy movements, in

the autism world. They're all very vocal and they're all very persuaded about their own rectitude and efficacy.

It's very difficult to have an easy discussion with various representatives present. That's my own personal experience. That's not something that happened with the Committee. Clearly there is not enough known, this is a way of trying to formulate it.

And we talked about: well, how do you go about doing it? Among the things we thought about, is that those who are conducting research should perhaps have a central partnership organization, NIH was an idea. It's just an idea. The idea is that one group or one source of research is not going to get us very much farther along.

Moving from the global to the individual application, this recommendation about individualized case managing strategies really is our way of talking about reasonable variability and treatment resources. It is not our responsibility and it's not our charge and it's not within our capacity to make

recommendations about insurance coverage or to -- at least within the context of this question, to make recommendations about how services should be distributed. But we did feel it was important to say that services are inconsistently distributed.

There are some parts of the country which have a little bit of every kind of intervention. There are some parts of the world in which there is really strong work in one kind of intervention. There are places where there is almost none, which, by the way, is where the Exceptional Family Member Program comes in and allows services members and their family to be on duty in locations where there may in fact be services available.

We just wanted to say that there as nothing -- As things stand now, there isn't -- were we to make a specific recommendation, even if there were data to support it, we would be uncomfortable about that because not everybody has access to various kinds of treatment. So, that's what that one is about.

And those are the recommendations

which we endorsed uniformly and are putting to you for a vote and discussion. So, I will try to listen to what anybody asks and I will try to respond reasonably and completely.

DR. LEDNAR: Dr. Fogelman's Subcommittee spent a lot of focused energy on this topic of great interest, with a lot of research and I think have called it as they see it in terms of what the published evidence would suggest. So, with that, we have sort of the discussion of the high points of the slides. We have the text of the actual recommendation that is in the tab, tab six, behind the slides if you'd like to read it.

But let's now have a few questions for Dr. Fogelman.

Dr. Kaplan.

DR. KAPLAN: When this was sent out, as you recall, I sent a comment back and wanted to know more about the burden of autism as it affects the military and their dependents. And the response that I got was that you were going to present this for us today.

DR. FOGELMAN: Oh, well, let me respond to the particular point. We actually asked some questions about those pieces of data of Captain DeMartino, who was the person who framed the original question and gave us the original briefing. And his certain belief was that the data were not reliable and that the numbers that he would try to -- that anyone might try to present about that would not be sufficiently -- would not be data in which we would have sufficient confidence to make an assertion of the kind or even a statement of the kind that you're asking for.

So the data just aren't there at the moment.

DR. KAPLAN: But do you have any idea about how many involved active duty or the troops themselves and what that is in relationship to the number of -- the burden in dependents and families and so on? Is it more, less, half?

DR. FOGELMAN: Again, the data (inaudible) to have confidence in, but the kind-of anecdotal feeling or the incomplete

conclusion that we've drawn from what data we have are that it's not so terribly different among military families as in the world at large.

DR. KAPLAN: And what about troops?

DR. FOGELMAN: Say again? You mean are there autistic troops serving?

DR. KAPLAN: What about troops?

Yes.

DR. FOGELMAN: I think we have no data about whether there are individuals with autism who are serving on active duty or in other capacities in uniform.

DR. KAPLAN: So the recommendation then deals purely with civilian population or dependents or whatever.

DR. FOGELMAN: That's correct. The recommendation deals --

DR. KAPLAN: Exclusively.

DR. FOGELMAN: -- exclusively with dependents of service members.

DR. LEDNAR: Dr. Shamoo and then Dr. Parkinson.

DR. SHAMOO: Thank you. I just want

to make sure I understand it, currently the practice for military dependants, those who have symptoms of autism and they have actual military doctor prescribes ABA, and it's paid for, currently it's the practice. Not everyone gets ABA, but if it is prescribed, it gets paid.

My understanding is the push -- the groups you mentioned is to make ABA -- it's the preferred, or the only, or preferred mode of treatment lacking evidence that ABA will work with all autism spectrum. This is my understanding, so the Subcommittee -- and I'm not a member of the Subcommittee -- so the Subcommittee's recommendation is saying they have no sufficient evidence, basically, to say ABA is even effective. It may be effective. I have nothing against it. I think it can be effective, but is it effective in all modes, whether it is just a component of all other spectrum of treatment. This is my understanding, so if somebody has a different understanding, and that's really what we're voting for.

But the military assist medicine, to my understanding and this is from the outside DOD, I understood it because I have a relationship with people who treat autism that military medicine actually prescribes ABA, and it is paid for.

DR. FOGELMAN: I think that's correct as far as it goes. One of the things I want to say is that we raised the question with Captain DeMartino and I myself raised it independently with a few others, about whether we should make recommendations that were more concrete and specific about what should and should be employed. And happily, in my view, we were told that all we were supposed to do and all we could reasonably do, was make a statement about the science and it was up to TRICARE Management authority and others to make decisions about what to do with that information. So all we're doing is saying these things, which is in fact all the Board -- is all we're asking the Board to do, is say that, "Yeah, we kind of believe what -- well, we do believe what the Subcommittee said and

we'll endorse it and here's the information and do with it what you will."

If they ask me (inaudible) what I think about it, I'll be happy to tell them.

DR. LEDNAR: Okay. Dr. Parkinson and Dr. Oxman.

DR. PARKINSON: Thank you, Charles, for your report and the Committee. Just to connect the dots a little closer here, if I was two years ago sitting at WellPoint, we did this every week for benefits coverage determination. ECRI at the request of DOD, just like WellPoint could purchase from ECRI a report on a newer emerging technology, what's the evidence to give them some ammunition, frankly, when an employer would say, "How come you don't cover it?"

So DOD has gone forward in advance, or concomitant with this effort, to commission a report from ECRI to look at this type of therapy. We don't have the report. I assume it says pretty much what you say here in their findings.

DR. FOGELMAN: Right. And we didn't

commission it.

DR. PARKINSON: Right.

DR. FOGELMAN: It was commissioned

--

DR. PARKINSON: The Department did.

DR. FOGELMAN: But I believe
everybody on the Committee --

DR. PARKINSON: Concurred in the
assessment by ECRI.

DR. FOGELMAN: And it says the same
thing, yeah.

DR. PARKINSON: So what's happening
here is we're building a sequential evidence
based case, first, from ECRI, a civilian
agency, which is the gold standard that does
this for the five big health plans and self
insured employers. You now have a blue ribbon
panel, Psychological Health Committee of the
DHB, comes down and says insufficient evidence
using medical standards.

While the Committee has now
specifically been told or said that it's their
charge to come up with a coverage policy, this
clearly will be used as ammunition for

coverage policy. It would be inappropriate not to, from my perspective.

Having said that, evidence is a very small piece of coverage policy. So I just wanted to get it all on the table that I think this is a classic case study of perhaps an appropriate use, an appropriate balance between the expanded role of the DHB, an expert Committee that looks at the science, comes up with recommendations about the quality of the evidence, throws over the fence to the broader customer, which is the ASD for Health Affairs, to go in and make perhaps a difficult decision about coverage policy. But that's okay.

The one question that I would have, which we always did, is if I'm sitting at WellPoint, well what does Humana do and what does United do? What does IBM do? So did the Committee do any benchmarking, or was it provided any benchmarking, or was that -- I mean obviously it's not in your charge, but that's what, if I'm sitting back at SkyLine tomorrow afternoon, I get this report -- okay,

well, what does IBM do for their 110,000 employees for this?

And, again, it happens in the real world. Right?

DR. FOGELMAN: Other than to the extent that some of that information was in some of the material we reviewed, no we did not.

DR. LEDNAR: Okay. But I think Mike highlighted a very important sort of line connection of connection. What the Subcommittee did is to review the science, review the evidence. It is others, not ours, to take that evaluation of the science and other inputs that affect decisions that they need to make and they will make. So we are not talking about coverage decisions. That's not in our charge, that's not in our scope. We're talking about the science and the evidence.

DR. OXFORD: Although given that my interpretation of point 15 that the Board endorses the implementation of individualized child adolescent and family focused case

management strategies, but take into account regional variability and treatment resources, suggests that to the extent that the DOD is going to cover any treatment for ASD, then it ought to consider, at this point until proved otherwise by research recommended under 14, that all of it is equal -- has equal merit or should be treated equally.

Whether that means not covering it, or if you're going to cover one form, you probably should cover another one.

DR. FOGELMAN: Perhaps, but I think -- and that's a reasonable reading of this, but really what we're intending is to pay attention to the regional variability and the needs of individuals.

DR. LEDNAR: Dr. Halperin, Dr. Dickey, and then Dr. Shamoo.

Dr. Halperin.

DR. HALPERIN: Two questions. Your meta-analysis is consistent with other meta-analyses that have been done. Correct?

DR. FOGELMAN: Yes.

DR. HALPERIN: Okay. Second

question: based on available evidence early intensive EIBI may produce short-term goals for adaptive behavior. That is a positive statement from your Committee that for some outcomes associated with autism, that this is an affective intervention, period.

DR. FOGELMAN: Note that "may" was the strongest verb we were willing to -- adverb that we were willing to use.

DR. HALPERIN: Okay. Well that's where I'm kind of loose. Sitting on the Mandated Health Benefits Board for the State of New Jersey, which I do, the question is: does this mean meta-analysis, good group of people, that this is an effective therapy and should be covered? And the outcome of short term gains in IQ and adaptive behavior is a very positive outcome. This ought to be covered. And then the other, you know, pay attention to local variation or whatever, I just kind of ignore.

So the real issue is I'm looking for a positive evidence that there is a positive clinically worth while outcome. And you seem

to be giving that. If you're not, if I'm misinterpreting, then you got to help me because I seem to think this is a positive outcome and should, in somebody else's hands, not our responsibility, end up in this being mandated and paid for.

DR. FOGELMAN: Do you want to call on somebody else or should I respond to that?

DR. LEDNAR: Why don't you go ahead and respond to that if you would.

DR. FOGELMAN: Well, I'll make an attempt to respond because I don't remember the details of the discussion we had about this, but because the question was asked to us about one kind of early intervention treatment, we didn't want to say that all early intervention treatments could necessarily show something because there wasn't anything. And we didn't want to say this was the only one.

So in order to not be misleading, even though I understand that the ambiguity seems to you to be misleading, in order not to be misleading about the whole realm of which

ABA is a part, we didn't want to say the whole realm works. And in order not to be narrow, we didn't want to say ABA works as opposed to the others because we don't really know. That's where the conditionality of the statement comes in.

So if you were sitting on the Board that you just described, and you asked me about it, I would say, "This is what we think and probably nobody is going to scream at you if you decide for the next two years that you might want to pay for treatment X, as long as you study it carefully and see what's real."

DR. HALPERIN: But, in fact, our mandated Board doesn't study it carefully, it just basically says EIBI is going -- a specific treatment, if you will -- is going to result in therapeutic effectiveness, hence cover it like we cover all sorts of medical --

DR. FOGELMAN: Yeah, but we're not willing to say that about all EIBI.

DR. HALPERIN: Well, are you willing to say that about some specific identifiable EIBI?

DR. FOGELMAN: No.

DR. LEDNAR: Dr. Shamoo, and then we'll come back to Dr. Dickey.

DR. SHAMOO: I am really concerned of what I heard from my colleague, Dr. Parkinson and you, Wayne, about that we deal only with science. As an editor of a journal called Accountability of Research, I'm all for science and database, but our society functions sometimes -- we cannot get science. It's going to take us another 50 years to get the accurate data and science to make a decision, it's A, B and C.

And I am afraid that we are given a task, very denude from its context, and it's going to have a substantial consequences in healthcare coverage that we are really serving very narrow science, but by omission we're really not being scientific because we did not consider the other variables.

Now, I am not a psychologist, but behavioral modification techniques in general and my understanding of that, some of those means work. The data are not what I would

want when I am doing a physics experiment or six clinical trials with thousands of patients because the state of science is not there. And we need to take that into consideration.

So I don't want this recommendation lacking support means that our behavioral intervention in autistic children is going to be losing all its support. I think that will be a misuse of this recommendation. And I'm very supportive of the recommendation, but at the same time, I do not want this recommendation to have implications beyond its literal reading of it because autistic children deserve intervention and if we are going to wait for another 100 years, or 10 years, or 50 years to get absolute data -- we use (inaudible) to treat cardiac patients for years when we didn't know the mechanism. It took them what? 50 to 60 years to find the mechanism. And even now it's not that certain, close.

But we used it because we have empirical observations and anecdotal -- because that's the state of science. We can't

help it. Thank you.

DR. DICKEY: I recognize our job here is not to talk about coverage decisions, but I'm glad there are some people around the table that deal with those because it seems to me that Dr. Shamoo's comments just now lay out for us an opportunity to make some recommendations, and that is you certainly don't want to tell the families of special needs children that we have nothing to offer them, especially if we have at least anecdotal information, but we might want to begin to tie coverage decisions to participation in the various kinds of studies that hopefully mean we will have better information three years, or ten years, or twenty years down the road.

Part of the reason we are lacking so many areas of good data is because we make coverage decisions based on all sorts of things other than good evidence that something works. So if the best information we've got is that this is the only treatment that even offers anecdotal success, then we should say that but we should also say that if we're

going to include it in coverage, this or others, where we don't have enough information, let's recommend that they get the coverage as long as they're participating in something that's going to generate information so that three years or five years from now a different board can weigh in with a lot more information than we've got today.

DR. FOGELMAN: I think that's a splendid idea.

DR. LEDNAR: Dr. Silva and the Dr. Luepker.

DR. SILVA: Thank you. So I think this is a very important job or responsibility of the Board to answer this question in my own mind. I think your Committee did a hell of a good job.

DR. FOGELMAN: Thank you.

DR. SILVA: I want to direct the Board's attention to what we're really talking about, the two modifiers: early and intensive. Do you employ this therapy in someone who has had autism 15 or 20 years. Okay, no. There is no evidence for that. The intensive -- and

I remember who represented it, they varied, but I think the minimum that I heard was 24 hours to 30 hours per week forever and huge costs.

Now some of those may profit from it, but not across the board. There is no evidence. So I think allowing the local caregiver to make that decision on early intensive is fine, or whatever modality is available, but I think we got to be careful of blessing something where there is no evidence that will go on forever and ever and ever. We're not doing our job.

Thank you.

DR. LEDNAR: Dr. Luepker.

DR. LUEPKER: Well Joe said nicely what I was about to say. My recollection of the presentation from the mother about a year ago, very emotional presentation, was that it wasn't that they weren't paying for ABA, they weren't paying the full costs. So it was a cost issue. But I have to disagree with you a bit here, I think that Wabane or whatever, you know, there are all sorts of historical drugs

that have been used and never tested, but it's 2009 now. And I believe in a number of behavioral interventions, but I also believe they can be scientifically evaluated and to accept them without that kind-of undermines our reason for being I might say.

I think you know experiments can be set up to do this. Do they need to be 25 year experiments? Maybe not, but the Committee seems to cast doubt that even their short-term benefits they're unsure about that. And so if they're unsure about that, we need better science, I think.

DR. SHAMOO: May I respond? If you notice, and the transcript will show it, I never used early intensive. I used the word behavioral intervention. A psychiatrist or a psychologist should have the latitude of some behavioral intervention when there are children with autism and irrational and unreasonable conditions. So I never used the early intensive care, you know, this 25 to 30 hours a week and forever.

DR. O'LEARY: Dennis O'Leary. I'd

like to speak in support of Dr. Dickey's recommendations. I think that's really an important suggestion that we could maybe enhance the recommendations to suggest that you know where this is utilized, that there be structured evaluations of the intervention. I think that's the only way we're going to learn.

We do have more or less (inaudible) population for which it would be possible to learn over time and probably a sufficient patient population to learn from.

DR. LEDNAR: I think what Dr. Dickey and Dr. O'Leary have said is a little bit more precise than the wording in recommendation number fourteen right now, which is a generic advantage of approaching this generally in the world of medicine through clinical trials and evidence base, but -- and your suggestion is really encouraging participation inside DOD in mortalities that are evaluated in a rigorous way.

DR. FOGELMAN: I would be very comfortable saying that our Subcommittee would

endorse that notion.

DR. LEDNAR: Dr. Halperin.

DR. HALPERIN: Just a little caution, I don't think it's just 20 hours or 30 hours. It's 20 hours or 30 hours with a interventionist and then the rest of the time with the parents and at home, night and day. It's a big investment.

If the evidence reached some level of suggestion that it works, I agree with others that one can take the chance on paying for that intervention even in the lack of modern clinical trials.

The problem with the idea of essentially there will be no reimbursement for behavioral intervention unless there is a clinical trial and that's a condition of involvement, somehow includes the idea that you're not going to have -- and that to me is a problem. You're basically going to say, we're going to randomize and some kiddos aren't going to get it, yet there is a level of evidence amongst professionals and (inaudible) bodies that seems to say on the

short run at some level it does work. So I think it may actually be a less of a satisfactory answer than it would appear, unless one is so unsure, unless it really falls in the category of, you know, chelation therapy for autism where there is absolutely no evidence of any kind and you know withdrawing it has no adverse implications.

This, there actually may be an adverse implication and I think we need to grapple with that idea.

DR. LEDNAR: One last comment from Dr. Oxman and then I'm going to make a suggestion for the Board to consider.

Dr. Oxman.

DR. OXMAN: I think recognizing that even the DOD's healthcare is a fixed pie, that if you put vast amounts of money into something that may not work, because if it may work the other side of "may" is "may not" work, I don't think we can afford to do that.

And I think it is reasonable, perhaps to make some kind of a political compromise and require that anything over a

minimum expenditure reimbursement requires participation in a trial. And that in areas where that can't be done, there is some minimum support of intervention.

DR. SHAMOO: I really compelled to speak. There has been several suggestions that we should make coverage conditional on being in a clinical trial. That may violate the voluntary consent in a clinical trial and therefore unethical. I'm not saying it is, but it's bordering to that. There will be a lot of objections.

And I would suggest, if we're going in that direction, I would like to have my Subcommittee to discuss it and have an input from all the Subcommittee members and deliberate on it before we just make that decision here at the Board.

DR. LEDNAR: This is my suggestion: and that is I think we've heard a number of important points. I think we've seen that the Subcommittee has tackled a very difficult question. They've called it as they've seen it in terms of the scientific evidence.

The clear challenge is what others will do with that. I think we've heard some suggestions that perhaps with some minor rewording, could get us the next step. I think we should feel an obligation to be helpful to DOD in giving them some word back coming out of this meeting with a finalized opinion about the recommendation.

I'm getting a sense that there is a little bit of sense that perhaps with some tweaking, a little bit of rewording of one or more of the recommendations that this would be a position that, at this point, given what we know, the Board can put it's impurmoter on. So, my suggestion is that Dr. Fogelman and one or two others who have an interest to sit with him and suggest what you think would be a good way to sort of capture the issues. Do it in a responsible way. We don't want to, I think, start getting into a position where we start creating potential ethical issues. We also have to be cognizant of the fact that military families with these needs don't exist in communities that always can be very responsive

to it. So, we have to be sensitive to that as well.

What I would like, however, is before we adjourn our Board meeting today, that we see a suggested rewording of the recommendations and that we take a vote on that before we adjourn today. That would be my suggestion.

DR. SHAMOO: So whom do I have to --

DR. LEDNAR: By a show of interest, who would like to work with Charlie? Okay, Adil, John, Dennis.

DR. SHAMOO: And when shall we do that?

DR. LEDNAR: I'll leave that to be a self (inaudible). We're going to be adjourning in just a moment for lunch and then we can figure up.

DR. SHAMOO: Well, I've already had three other requests to do things during lunch.

DR. LEDNAR: You're into multi-tasking.

DR. SHAMOO: I'll do my best.

DR. LEDNAR: Yes. I'd put this as a priority.

Neil.

CAPT NAITO: I'd just like to offer one suggestion would be that the Board recommend we revisit this issue because, again, I think it shouldn't be looked upon as an open ended issue and we should revisit it. And I think that provides a modicum of, you know, a safety valve there that we revisit the issue because from my perspective there is a lot talk about it in regards to this issue.

I think the sense of revisiting it somewhere down the line, and so it's not just an open end one time we'll revisit it in a decade, you know, five years or something like that, I think will be very helpful.

DR. LEDNAR: And that kind of wording actually is helpful I think to the Board as a reminder that this is an issue that the Board would like to get updated upon. And I think that's worked well in the past.

Dr. Silva.

DR. SILVA: I want to also propose

that within the military there is psychiatrist that deal -- or psychologist -- with this problem. Could they be consulted as some minimal standards of what's acceptable treatment? They feel comfortable. At what age do you (inaudible) diagnosis and how many treatments for using this technique are advisable. If there are short-term gains in IQ to be recovered, should they be consulted? Well, I don't have the expertise to do it. I don't think anyone here does.

DR. LEDNAR: In fact your thought, Joe, could be incorporated into a recommendation in this document.

DR. FOGELMAN: We actually tried to talk to a few. They're not easy to find and not easy to nail down to talk to. In fact, a lot of the folks who provide the service -- and I don't want to open up too much another can of worms here, but a lot of the folks who provide the service are not uniform people but are contracted people.

And ABA, in particular, which remember was what the question was about, has

a big formalized network about who fits where, who can teach whom, who can supervise whom, who can provide what sort of service, and as you get farther and farther down the line and more and more immediate to the children -- we really are talking about children -- in question, there was, in our Committee, more and more question about, well, who's really doing the training? What's involved in the training and how supervised are these people? How much are they supervised over the course of time in what they are doing?

I don't want to --

DR. SILVA: Thank you for that insight. I expect our audit tentacles here to go down deep. So we got to be cautious as a Board also. This is a politically hot button.

I sent Edmond some material from the State of California where the same approach is being debated with a lot of vigor. So I'll withdraw my suggestion.

DR. HALPERIN: I hate to prolong this, but one can consider a situation in which the standard of reimbursement, if you

will, in a locale, Pennsylvania, New Jersey, whatever, would be for reimbursement for early behavioral intervention and military families in that arena may be getting a different standard of reimbursement.

And I would think that would be a very difficult situation.

SPEAKER: And it's one which exist now.

DR. HALPERIN: Exactly. So, I wonder whether the other approach to this is, you know, a straight forward med analysis, which the Committee has done and obviously spent a lot of time and research with great people doing it, which is the evidence is unclear. It's still equivocal.

Given that this is not a condition associated with the military environment, it has nothing to do with being in the military, it happens to children born to military families. It doesn't arise out of being in the military. The alternative is that the issue of reimbursement for behavioral therapy ought to be consistent with the standards of

reimbursement that are in the locale.

So if in one state it's basically a mandated benefit and the other state it's not a mandated benefit, that that is an alternative approach to this rather than arguing for DOD taking in the recommendations for doing a clinical trial while in fact the much larger society should be coping with the same problem.

DR. LEDNAR: I bet you Dr. Parkinson's got the same thought I do, but he'll say it much more articulately.

Dr. Parkinson.

DR. PARKINSON: No, I don't think so, Wayne, but it's -- in my evolving thinking about this, which is happening, I wonder if the whole Committee approach is overly educational in responding to the question. The question is quite explicit: ABA. It is not about the universe of behavioral therapy. It is not about the universe of other autism related conditions. It is about ABA.

And, Neil, your comment, the more I learn about it is recommendation number -- I

mean number 14 is: there isn't sufficient evidence for ABA, period, end of statement. That's it. You don't have to educate the universe about behavioral therapy, about it's application of broader things, may sufficient of may about the universe. That's confusing the issue. I don't think it's helpful to the Department and I don't think it's scientifically necessary.

DR. LEDNAR: Yes, ma'am.

SPEAKER: Just a couple of comments from the pediatrician in the area. Suggestion: you might want to talk to some uniform developmental pediatricians. There are still a few out there and they probably have a pretty good idea of ABA and the other -- plus, they don't have the monetary vested interest. This is big money that Congress is throwing out right now and it's up at high levels in the Marine Corps. So just asking somebody who doesn't have, you know, monetary interest in it, I think would be helpful.

DR. FOGELMAN: I personally did that. I mean I walked around in a couple of

places I had been and asked the question and didn't find anybody saying anything which was inconsistent with our recommendations.

SPEAKER: And then I'm also hearing numbers as high as one to ten families or --

DR. FOGELMAN: Say again.

SPEAKER: I've heard numbers as high as one to ten families are affected with the autism disorders.

DR. FOGELMAN: You mean one in ten?

SPEAKER: One in ten families, so I guess --

DR. FOGELMAN: I really don't --

SPEAKER: Yeah, it's hard to say.

DR. FOGELMAN: It's not at the top of my head or on the tip of my tongue.

SPEAKER: I've also talked to developmental pediatricians who seem to think that autism and ADD spectrums do run high in the military because of the environment, which is kind of an interesting perspective.

DR. FOGELMAN: Would that I could answer clearly and firmly, but I cannot.

SPEAKER: Right, so just some

interesting add-ons.

DR. FOGELMAN: Okay.

DR. LEDNAR: I'm feeling like King Solomon without a knife. Dr. Silva, last comment and then --

DR. SILVA: Thank you for allowing me that privilege. Why doesn't this ad hoc group just consider going in with recommendations 12 and 13? Restrict it to those two. I think that would help the Department of Defense.

DR. LEDNAR: And as Captain Naito said, having the suggestion that there be a brief back to the Defense Health Board in the future, I think is another way to sort of follow-up that this is an important issue that needs ongoing review of the science as it evolves.

DR. ENNIS: But I find that recommendation -- and I know nothing about this, but if I item 11 is correct as it is, I don't think you can throw it out and go with 13 and 14.

If item 11 is incorrect, then modify

it; but if that's correct, you can't throw it out in favor --

DR. LEDNAR: So what Dr. Ennis has provided is one more input to our ad hoc discussion that Dr. Fogelman will convene and then come back to us with some --

DR. FOGELMAN: Well, actually, I'd like some explicit guidance about the last piece of the conversation. Is it the Board's collective wish that we reduce the number of recommendations and that we prune them to be as narrow and precise as possible? Because this is in fact the debate we had in the Committee, that you see what we came up with.

DR. O'LEARY: If I might, I think all we're really saying is that independent of the number, the recommendations point-by-point must be consistent. If there is an internal inconsistency, that must be addressed.

DR. SHAMOO: The question is -- and he asked a very good question -- is number 11 should be the same strength as the other ones. There are insufficient evidence to support the EIBI, because one, you say there are

sufficient evidence for some. It works in short term. But the other one you say "insufficient."

And what he's saying I think is a very valid point.

DR. LEDNAR: Wait a minute. Twelve is about long term efficacy and 13 is about comparative efficacy. And 11 is only about a particular application. So they really do deal with different realms.

DR. ENNIS: I understood that. Maybe I misunderstood Dr. Silva's recommendation. I thought he meant to remove the other recommendations and just leave 13 and 14 in, to delete 11.

DR. SILVA: So, yes Frank, I did but I'll retract that also. You read me the riot act on this. You can't ignore data selectively. Okay. But I like the way that Charles just framed it, these categories, how they relate to your thinking of your Committee. Maybe some headings need to be added. I don't know.

DR. LEDNAR: And I think what Dr.

Silva is just reinforcing is, as your Subcommittee has spent more time thinking about this in great detail to the extent that a few additional really focusing words might be added, that will make it very much easier for those who receive this report to know what we're saying and consider how to --

DR. FOGELMAN: Can I respond with something explicit then?

DR. LEDNAR: One last response.

DR. FOGELMAN: Five minutes into lunch could the people who are supposed to be talking with me, commandeer a table because I've got to go back to my room for something. So if you all would commandeer a table, I'll be happy to join you as soon as I get back whenever we have lunch.

DR. LEDNAR: And we're going to adjourn for lunch now.

DR. FOGELMAN: Wait, wait, wait. I have one more thing.

DR. LEDNAR: What's the one more thing?

DR. FOGELMAN: Can I do one more

thing? Since I didn't start with a laugh, can I end with a laugh?

DR. LEDNAR: All right.

DR. FOGELMAN: You may recall that I said that -- well, I said that we had a kind of standard template for our meetings. One of the things that I pushed into the template was something about feedback because my own belief, all my own work and everything I do, is in some way shape or form predicated on feedback. I always go around asking people, "What did you think of this? What did you think of that?" And I've done this in this group.

So by way of asking you for feedback to me about the presentation and whatever else you want to talk about over the course of the time we're here, you know, I do want to ask that, but I want to show you how I asked that of the Committee.

This is also in your printed version. The Committee liked anchoring one and seven as retched and transcendent, which is not what I was taught in graduate school,

but -- so, if you want to offer comments to me about how close to retched and how close to transcendent the recommendations and conversation were, I'd be happy to take them in that vantage.

I'd point out that on all of these our own judgment about our meeting was that it was somewhere between five and six. So now that I've done my --

CDR FEEKS: Okay. I think we can break for lunch now. And I ask that Board members, ex-officio members, Service liaisons and Defense Health Board staff participate in a group photo opportunity first, please. So let's gather outside the front of the building right now and then all our other biological needs can be met right after the photo.

I do realize this may affect the expressions in the photograph, but we just -- the photographers have been waiting. So, thank you.

Oh, we will dispense with the administrative session and reconvene at 2:00 p.m.

(Whereupon, at 1:13 p.m., a
luncheon recess was taken.)

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

(2:05 p.m.)

DR. LEDNAR: For our afternoon session, our first speaker this afternoon is Major Michael Fea. He'll provide us an update on the novel influenza A/H1N1 outbreak. Major Fea serves as the Joint Operations Environmental Health Officer within Health Service Support Division J4 Directorate, as well as the Preventive Medicine Officer in support of the Joint Staff Sergeant with a focus on medical health care system strategy capabilities, information management, information technology -- I'm going to guess is what the acronym is for -- and readiness.

Major Fea is also a Joint Staff Liaison to the Homeland Security Council and as security and U.S. Delegate to NATO's Force Health Protection Expert Panel.

His presentation slides may be found under tab eight.

Major Fea.

MAJ FEA: All right. Thank you very much.

DR. LEDNAR: The thing there under tab eight, so I'll ask our DHB staff -- or should we be having something to look at?

MAJ FEA: I handed out a piece of paper and I'll go -- I handed it out to some of you and I'll explain why as we go through the slides.

DR. LEDNAR: Okay. Major Fea.

MAJ FEA: Okay. Thank you very much. Thank you for the opportunity to come and brief you on what DOD is doing for medical mitigation strategy as we have gone through this. And I do apologize, I know Dr. Hachey wanted to be here to present this and he's got other obligations as well as some others that wanted to be here.

I am an engineer by trade, so I'll make that up front, but on the Joint Staff you try to be a jack of all trades and you try to learn as quick as you can. So, without further ado.

This is what we're going to go over. These various areas have been vetted not only through our OSD counterparts, but also the

interagency, in some cases our NATO partners, as well as the various Joint Directorates: J1, which is Personnel, J3 Operations, of course myself in J4, J5 which is Strategy, J7 which is Exercises, and J8 which is your Joint Requirements.

So this is a total team effort, our medical piece in the big pandemic influenza planning and response effort.

Okay. Policies and guidance. The policies and guidance that we have incorporates all of the information that the Centers for Disease Control gives to us. And those are continuously updated as we get new information, we actually do have a product which is in the overarching pandemic influenza clinical and public health guidance.

It's actually on your next slide. I've got a picture on the DOD PI website. But on this, as we get updated information, we continuously update. So we have that common operating picture, if you will, so the folks on the ground and operational level, whatever it is, can get in there and see, "Okay, I need

some information. Here's that one stop shop."

Additionally we have policy and guidance on various areas within the pandemic influenza for vaccines, for antivirals, for limited resources. How do we deal with it when we get overwhelmed? The most recent one was on vaccinations. It just got done being coordinated and this particular one, it was: how do we deal with a limited amount of vaccine and a greater number of personnel?

And in this particular one, in the first draft as it went out for coordination, it was kind of looking at it from the case fatality rate of: do we want to stop it from the transmission standpoint or if that case fatality rate increases as severity increases, do we need to change our thinking and start protecting critical personnel because the mission of DOD must go on.

And so that's kind of those decisions that we're trying to make, trying to facilitate through these policies.

As I was saying, you'll see on here and I've put this up here just so that

everybody has awareness of the DOD PI Watchboard. You'll also know on there, on the bottom left hand side, the flu.gov, the new website if you will, the naming of the website for all the additional information from DHHS, CDC.

Okay. Global surveillance. We have a unique national asset in what we have for our surveillance capability. This is stated in various documents throughout the interagency identified in 2006 with the Global Emerging Infectious Disease and Response System, the Armed Forces Health Surveillance Center, now we've got a great capability.

They are consistently watching everything, and of course their efforts have been looking south. And what do we see? Interesting enough, I was on a telecon Friday, the President and the White House has put out a task to the interagency that select few, to come up with a report both unclass and class to be turned in by the 26th of August.

We have two different agencies that will be contributing to that, and that is the

Armed Forces Health Surveillance Center and the National Center for Medical Intelligence. Because we got to remember also, intelligence is a big key in this, especially at the beginning.

So we have a great asset in that. It provides us a viewing of not only us as the Title 10 folks but also our beneficiaries. So we're able to see across the globe on what's going on with us and with our partners that happen to be out there.

One other item that I put up here is DOD has submitted Emergency Use Authorization for J-bates. This briefing was actually briefed by our Deputy Assistant Secretary of Defense for Force Health Protection already and that's Colonel Don Noah, at an interagency meeting that was headed by the Assistant to the Secretary of Defense for Nute Kimbio.

They, in that meeting, said "You know what? We have got to get more involved on the Nute Kimbio side of this." And this is one of those efforts where they have been very instrumental in helping us out. In order for

us to be able to have a better surveillance capability out there, diagnosis capability, we have put this emergency use authorization out there so we can use the J-bates. So, it's another tool in our kit, if you will.

This is for some of you at the head table, I've given you this; and for others, I put it every other as I had the numbers, but it's the Department of Defense Weekly Global Influenza Surveillance Summary, is what it is. It's found on the DOD PI Watchboard. If you're not aware of this product. I pulled this off right as I was leaving to go TDY on the 4th. I take that back, this past Tuesday. This was the most current that was on the website.

But you'll notice in the top block that they have it set out by Service. You'll notice in the Air Force it says "Outbreak among US Air Force Academy cadets leveled out at 132 cases with no reported hospitalization or deaths." So you see that, but it also says, "Peterson Air Force base in Colorado reported the first fatality from pandemic H1N1

in a civilian employee assigned to NORTHCOM."

So we have information. They're keeping track of this. This is a weekly update that comes out every Tuesday and what I was trying to do was highlight at the bottom the information that goes from our MTFs, that goes up to those Service public health centers, or those hubs, and then reported up to the Armed Forces Health Surveillance Center is being captured and they're taking this information then and putting it back out to the field so that you can make decisions. They're trying to be the eyes on of more than just the trees that are in front of you.

And so you can see they've looked at ILI, an influenza like illness, outpatient visits for the Pacific Military, the medical treatment facilities, as well as visits for incidental pneumonia. So just to highlight again that we're continuing to do surveillance at a heightened stage.

Non-pharmaceutical measures. In our non-pharmaceutical measures, social distancing, infection control is embedded in

our policy and our guidance across the realm there. That's kind of one of those that we've made sure we try to tie all of that in. We have also, from the non-pharmaceutical measures, purchased 1.35 million pandemic influenza preparedness kits.

Now, I know we had a telecon -- I can't remember how long ago it's been -- with this group and Dr. Hachey did explain a little bit about that. But these kits were bought. There is one for every active duty service member. In those kits they have two N95s, four of the surgical masks, some hand sanitizer, as well as some education material. This was meant for the families so that you would have some education. It would help you when you're dealing with family members to try to have some intervention there. So we have those. And we have PPE stock piled at the MTFs that are out there for the providers.

From pharmaceutical measures, this has been kind-of the bigger challenge with the vaccine. With the strategic plan for the pandemic influenza preparedness, we signed up

to purchase enough vaccine for 1.35 million personnel. We did this with H5N1, we did it again with H1N1.

Also in that particular plan, the Department of Health and Human Services was supposed to buy enough vaccine for 20 million personnel. Now I've been involved with this since the 22nd of April and I remember it was about a week after this thing started, we were over at the White House in the situation room and DHHS sat there and said, "Okay, we're not only going to buy enough for 20 million, but we're thinking about buying enough for another 80 million personnel."

If you look at the DHHS plan that's out there, there are five tiers and that's kind of for the entire American population, for the 303 million personnel. So in this particular case, we signed up for the 1.35 million and that's what we're getting. Now, of course, it comes to the challenge, if you've got more people than that. So what are you going to do? And I'll go into some of the thinking and what we're trying to do with

that.

As I discussed earlier, the draft vaccine (inaudible) policy, we've gotten comments from it and I haven't had a chance to talk to Dr. Hachey to see how that is or is not going at this particular time; but the question always comes: what about everybody else?

As I mentioned earlier, we had a Chairman's crisis management exercise at the end of June and we gave the Chairman a scenario where it was a worst case second wave coming through. And some of these questions were very relevant. What are we going to do in this?

Some of the things that we hadn't thought about is what about our OCONUS dependants? DHHS covers, you know, through the state plans, our CONUS dependants although we're not certain at this point how much, because each state and territories -- we've got 56 different plans out there, we may get different amounts depending where you're at. If you look at the tiers, we're not so certain

where our people go in, but with -- I know Dr. Hachey has talked to the folks and it sounds like we're going to get an additional amount of vaccine for a million and a half personnel. It's still ongoing.

We did get an agreement from DHHS to give us enough vaccine for 290,000 OCONUS dependants. Now there is one thing that Colonel Krukar had brought up, and that is: does that just cover sponsored beneficiaries that are over there or does this also cover those folks that may not be sponsored but are with their spouse? So it's another one of those things that we're looking into.

Okay. When this incident broke out on the 22nd of April and when I first became aware of it, the first thing that popped in my mind was the Health Affairs policy that we had on antiviral release. It was guidance on an antiviral release. And it had categories in there.

Unfortunately, these categories: select critical forces, critical, alert, operational, and all other forces, were

kind-of categories that were made up by the medics. We were looking for something that we could say if we didn't have enough no matter what the emerging infectious disease was, you know what kind of category would we give and I have definitions on here -- on the next slide, I believe.

But in this particular case we hadn't been able to get our operational folks to give us who are these people. And so I thought this was the perfect opportunity. I had been planning the pandemic influenza since 2006. I thought, okay, this is the big one and I figured I'd now try to force our aligned counterparts to tell us who are these folks because we may not have enough and it may be that severity does increase and we've got to take care of our critical personnel. And that's all we're going to have.

So with that being said, we were able to get some information. The Joint Staff, J3, was able to send out an action package to the Services, to some of the agencies in the COCOMs, to tell us how much

and what category would they be in.

This is the definition: those select critical forces are those that have to be vaccinated regardless of the amount of vaccine you have. So when the Chairman comes to me and says, "Am I being vaccinated?" "Yes, sir." It may not be me, but it's definitely you. But you have those select. You have those critical forces that have, you know, a higher mission that are supporting strategic operations, whatever it happens to be. This was kind of the medics, "Okay, this is what we think it is." Of course we told them in the action package, "This is what our definition is, but you guys can redefine this based upon your service if you'd like. We're not telling you how it's defined, but this is kind of what we were thinking about."

Those alert forces, those that haven't deployed yet but are on the hook to deploy, we need to make sure we're taking care of them as well as those operational forces that may be fulfilling mission essential tasks. They're the ones who are taking care

of those things, maybe at a tactical level or potentially an operational level.

The responses that we got back were kind of all over the map in some cases when you had the numbers and I thought, wow this is going to be hard. We had some that said everybody is critical. Everybody is critical, not select critical, alert or operational, they're just critical. And I thought, well, that doesn't help us. We had others that said everybody is select critical. And so what we did is there were a whole bunch of them that did give us some good information. They had taken the time, given us some good numbers. And so when I looked at it, I thought, you know, we got to simplify this because these numbers could be all over the place a month from now.

So as I looked at it, I said, well -- and this again is a proposed approach, I still have to talk to Admiral Smith in depth about it, but it looked like these were percentages of their total numbers that came out. And it was almost consistent with what

we got for input.

So, I said, well what if we get a vaccine and we're only given X amount. Well, whatever I can give you -- I know what the end strength is. Now this includes Title 10, so this would be your Active Reserve; it could be your Guard that are on Title 10 status; this would be your civilians; and this would be your critical contractors. Okay. So however the Service or COCOM defines that, whatever we have, 15% if that's all I've got left, then everybody will get 15% of their population and you figure out who it is that you need to give it to.

At the same time with this, I was trying to hook it up MILVAX because I understand the seasonal flu model. I understand how they do business and I'm trying to keep it the same so we minimize the differences. And so in this case instead of necessarily on a seasonal flu saying, "Here's how much I need" putting up the paperwork, it would almost be a push down, "Here's how much I got and here's how much you're going to

receive."

We may still be able to do the paperwork at the bottom. The people would already know how much they're getting and then we could just validate it, but trying to think beyond H1N1 and saying, "Okay, we may have less vaccine for the next one." I don't know. But that was kind of our thinking and it was validated by the numbers we received.

Antivirals. Of course we've got a million antivirals sitting at our medical treatment facilities that are out there. We also have seven million sitting in our stock piles. And, of course, as we go through the slides here there may be a time where we have to decide when do we release our antivirals. Our position is, use them for post-exposure, prophylaxis, or therapeutic. And I said don't be using them for prophylaxis simply because your burn rate is going to be so high and you're not protected afterwards, but again, there may be situations where we have to consider that.

Antibiotics, we have those pre-

positioned at the treatment facilities also for bacterial pneumonia.

Communication: that was brought up this morning. This is huge. We have dealt with this in several different areas when it comes to, you know, the incident like here at the Air Force Academy. When it comes to international health regulations and communications; when it comes to the InterAgency and the Department of State, and trying to get everybody on the same sheet of music so we're all saying the same thing and every body is in harmony. So one of the things that we're doing internal to DOD is we have re- written -- well it was DODD 6200.3, which is Public Health Emergency Officer, that was the title of it, and we changed it to a DODI on 6200.03 Public Health Emergency Management. And it really gives more meat to what do we expect of a public health emergency officer and this new role, a medical emergency manager.

The medical emergency manager is more like your J5, kind of your plans person.

Your PHEO is more along the lines of your J3, the execution, the one that goes out to the public to make sure we've got the local community, we've got the state, the tribe, whatever it happens to be, that we have spoken to these people and we've incorporated that into our plans.

Now, one other thing I need to mention, the medical emergency manager not only would take care of the medical plans, but would also make sure that they tie into the installation plans because we don't want to lose sight that PI is much bigger than medical.

So we have that and, in fact, this past week I was down in Albuquerque with the Defense Medical Readiness Training Institute, DMRTI, and we were talking about what are all the teaching requirements, education requirements now because of this new DODI that's going to be released here soon.

External communications. These public affairs guidelines. We've talked about this. I know OSD Public Affairs has been

intimately involved as well as the Joint Staff Public Affairs and the COCOM Public Affairs, in trying to get the message out: "this is what we're doing."

One of the biggest challenges that we've had so far, and you may be aware of this, was the international health reporting with Kuwait. It came up, we had cases that came in to Kuwait, and we knew about them. We let the Department of State know, and Department of State let the local government know and it was radio silence.

And so we were in a situation where we said, "Well, we know we have to report as soon as practicable" is what the language says. And so we waited and we waited. And we said, well, we don't want to be earmarked at the end of the day like China was with SARS that we're trying to hide something.

Ms. Embrey, Lieutenant General Paxton from the Acting Director of the Joint Staff, myself, Colonel Lamb, went up to see Secretary Lynn, the Deputy Secretary of Defense and we said, "We need to report." And

he nodded and said, "Okay, let's go ahead and report."

And so the Public Affairs guidelines came immediately thereafter to get the message out, "Here's what we're doing." And really, the key was get it to the embassies. Have them engage with the host nations. We're working right now with Ambassador Loftis who works in the Department of State, and he works with the pandemic influenza group. He's in charge of that. Him, Department of Health and Human Services and ourselves, to come up with something that we can give to the embassies and say, "Go talk to your host nations so we don't have another situation like Kuwait happen again." So that they know in advance that if you don't report, we're going to report within whatever it happens to be. It's still a draft product. But to let them know in advance. And we think this will be good for probably 85% of the nations out there.

For those special cases, Department of State, you need to work and figure out what's the agreement just so we know and

everybody is on the same page again, so very, very important.

And I'll end just with a couple of slides on PI operating plans. You know, here we were doing all of our planning in 2006, looking for bird flu. I mean, literally. When you look at the COM plan, 3551, and the various COM plans that were out there, we hooked severity kind of with a lynch pin. And we had anticipated that the severity would be higher. Now, it did have a lot of flexibility in that plan, but we thought it might be a little bit higher and that it would start somewhere else. We said it will start maybe in Indonesia or something like that and make its way eventually to us. But then reality set in, it's here. The first five out of eight cases were identified by the Navy and the Air Force.

And so we had a paradigm shift there. Now what do we do? Well, with the plan we still have the Joint strategic capability plan that says that US NORTHCOM will be the one that's the global synchronizer

for the plans. So between them as the planning synchronizer and our J3 shop, we had a PI synchronization conference this past week. And we talked about how do we make our plans flexible.

We have these COM plans. They put out a planning order and said, "develop your operation plans because we've got to get ready for the second wave this Fall, and within that, try to get as much flexibility as you can." And so that's what we really did and as we were doing this for the COCOM services and agencies as they're now developing these operation plans, we had to start looking at what could we potentially call our phases. We have several phases that we can be in. Right now, DOD is at phase zero. But the way the plan is set up is each geo COCOM can be in a different phase. In fact, they can have different phases even within their COCOM.

And so what we try to do, and this is draft still, is try to make it more resemble with what we're saying in reality, is we've got surveillance throughout every single

phase that's out there, but there are certain key tasks that have to be considered and executed if we go to the next level. Now this next slide will kind of help you understand.

What we did, instead of having just triggers, you have your first case over seas somewhere, then you have your first small cluster overseas. Now you have, you know, larger clusters overseas and it finally hits the homeland and then you finally start doing things. There were kind of those triggers and then I had actions.

What we were trying to do is more of an indicator, if you will. What are some of those things that need to be considered in trying to figure out what phase should you be in and what appropriate action should be done?

And as we looked at this, we were putting our minds together. In some cases the transmissibility and severity is going to be unknown. I mean at the very beginning we weren't quite sure. And I remember just a few days after all this started, we had the national center for medical intelligence say,

"Hey, there is an alert. This could become a pandemic." Well, it wasn't a public health announcement, but our intel guys were telling us, "We're seeing this transmit quick enough here that we could see eventually a WHO pandemic phase six. And sure enough, several months later it happened.

And so kind of taking that into consideration of what do we have here, is it low transmission, but we've got medium to high case fatality rate like our H5N1? Or is it the opposite? Or do we have something else here? But taking that information, running it through what type of medical countermeasures we might have or not have and what do we expect of our personnel rating. When we're talking about this, when we talk about pandemic influenza, we've got to remember it's all about readiness. DOD is readiness.

And so do we think that whatever we've got now we may not have a vaccine? Perhaps now our antivirals don't work and this is what we think could happen to our personnel levels and what phase should we be in, as well

as what are we getting from our community?
What kind of assistance do they need? And
trying to figure out what phase do we need to
be in.

It helps us because as we're dealing
with NORTHCOM right now, depending what phase
you're in, is if we stand up reasonable Joint
Task Forces or elements thereof and trying to
synch the planning and try to determine
requirements with the Department of Homeland
Security and DHHS.

So these are some of the things that
are still draft that we're trying to run
through. You can see the decisions that have
to be made depending what phase you're in and
we're trying to give the COCOMS as much
flexibility as they can to get as much done as
they can, but we know eventually the Secretary
of Defense is going to have to say, "okay,
let's move some people out" or perhaps the
rotation of forces stops for a while until we
can take care of whatever our priority is at
that time.

And that's all I have on that, on

the update. Are there questions?

DR. LEDNAR: Questions for Major Fea? Dr. Oxman.

DR. OXMAN: How extensive in the field is the rapid diagnostic deployment now?

MAJ FEA: The rapid diagnostic?

DR. OXMAN: PCR.

MAJ FEA: The PCR. The RTPCRs?

DR. OXMAN: Yeah.

MAJ FEA: I can tell you right now, we have -- like, again, we put in this Emergency Use Authorization for the JBAIDS, which is an RTPCR technology. When you look for confirmatory labs right now within DOD, you have three. You've got NHRC, Naval Health Research Center, U.S. Air Force School of Aerospace Medicine and recently you have NMRU3 down in Egypt, Naval Medical Research Unit.

They're wanting to put more of them, more of these ABI 7500 as the platform. They want to put more in theater in (inaudible) COM in particular. But once we get this Emergency Use Authorization, that will give us up to a year to be able to use those for confirmatory

testing.

DR. LEDNAR: Other questions for Major Fea? One of the aspects of responding to this is dealing with the fear factor. Different than the biology, just the perception and how that's going to drive certain behaviors and other things. So is this part of the plan that you're putting together? Managing the fear and anxiety that will come?

MAJ FEA: It is and I know I've talked to several -- and it goes back to communication again and how are we going to communicate this if our beneficiaries don't get the vaccine. How do we stop the fear, if you will? But I think at this particular time we're still trying to develop that communication product and it will have to go out here very soon, that says: "here's how things are going to work."

And, by the way, you know we've seen people get this and they've been able to do well with the countermeasures that we have. I mean even her at the U.S. Air Force Academy,

it did a wonderful job.

DR. LEDNAR: As countries have stepped away from laboratory confirmation of sick patients, how are we monitoring emerging Tamiflu resistance of this strand?

MAJ FEA: That's interesting. The European CDC has been watching it significantly and I believe our CDC as well. The last I had heard, we had six cases. And so they are watching it. We get an update usually weekly that says, "Okay, here's what we're seeing across the board."

I'm not sure the specific mechanism of how they're capturing it, because you're right, we're not reporting individual cases, now it's clusters, deaths, absenteeism.

DR. LEDNAR: Dr. Poland and then Dr. Ennis.

DR. POLAND: One question I had, it was triggered by your comment of well of course the Secretary of Defense will get the vaccine and that's fine, but there is another factor in here and that is the epidemiology of the disease. So the fact is that on average

the Secretary is not going to get infected with this. If he is, he's not going to have symptoms. If he does, he's not going to be sick; and if he is, he won't get hospitalized. If by chance that should happen, he's not going to die.

Whereas you have non-critical forces that unique to the epidemiology of a pandemic virus, but this one particularly, where your death rates and your morbidity is going to be in younger individuals. For example, almost as sort of critical accelerants of a pandemic in your recruit training areas, which is what we heard about this morning. And yet they would not be considered -- they are in the 40%, fifth tier that you showed.

MAJ FEA: Let me caveat this because I didn't put it up on this slide. I had it in an earlier version of this slide presentation. And that is there are target groups that we would be pulling vaccine out at the beginning, and that would be whatever -- and this is where we're trying to figure out who makes the decision and who would they be. And it's

based on that epidemiology.

When you're looking at transmission, it would be your new ascensions. It would be those that happen to be here in school. It can also be those that are on the subs and those afloat. It could be your -- you know, it could have an element of the critical nature and that is to make sure that the folks that are deployed to CENTCOM, Horn of Africa, Korea, get it as well.

So we have thought about that, although I didn't have it on the slide.

DR. OXMAN: Thank you.

DR. LEDNAR: Dr. Ennis.

DR. ENNIS: I'll just make a comment and invite you to respond if you think it's appropriate. It seems to me that the DOD -- and it's part of the national plan, and DOD bought into it a few years ago, but the AFED and the DOD rarely controlled what influenza vaccines they wanted to purchase and who they wanted to give it to, and they did that for decades up until recently.

And it seems to me that because of a

result of a decision to go with this national plan and basically be part of the team, which has its benefits, there is a lot of uncertainty in terms of what exactly -- how many doses the DOD is going to contract for by and who's going to get it.

You really have to wait for HHS to kind of give you what's there. And they're responsible people and you're likely to get what you need and use it appropriately, but historically it didn't go that way and it seems to me that there's a downside to that, as well as there may be an upside in terms of the overall good for the nation.

MAJ FEA: Right. I mean you have some very good information there. They did decide and this was on OSD's side, that they would purchase a set amount and between HHS and us we did purchase, you know, enough for 1.35 million.

However, when it comes to the transmission part of it, we probably need to get more input into that side and when we administer it.

DR. LEDNAR: Colonel.

COL KRUKAR: Michael Krukar. Yes, sir, that has been realized. We do want to -- that's why we're trying to influence the fashion in obtaining for the distribution. As Major Fea mentioned, we want this to be more like -- the distribution to be more like seasonal influenza. It is a program that we think works fairly effectively by going through different channels. There is a lot of unknowns. And so we've expressed our concerns to try to help influence the distribution to be more like seasonal influenza.

Now whether or not we're being heard or whether that's going to be decided or not is still unknown but we're trying to influence those.

COL JAFFIN: Colonel Jonathan Jaffin. The comment I wanted to make is actually not a question, but a comment. We've been monitoring the Tamiflu usage through the Army's Pharmacovigilance center. And we've just let the FDA know that we've seen about a 10% error rate between using the prophylactic

dosage rather than the therapeutic dosage when Tamiflu is prescribed for therapy. The trouble is, it's 10 pills either way and whether it's two for five days or one for ten day is the distinction.

And about eight to ten percent of the prescriptions for therapeutic treatment of influenza have been prescribed as the prophylactic dose. So the FDA will probably be sending out a warning. We're going to be putting out a similar warning throughout the Army systems and I think throughout -- and the DOD is sending out a safety message as well. But just to let all of you know about that.

DR. LEDNAR: Dr. Luepker.

DR. LUEPKER: Yes. I'm curious about this handout from the website and the graph there. And this morning, as well, with the cadets. So how many -- you've got clinic visits and they appear to be rising. So how many of these people are coming in because they have respiratory symptoms, but now they've heard there is an epidemic and maybe they ought to get checked out whereas before

they would have said, "I've got a cold. I'm going to take a day off and not go to the doctor."

MAJ FEA: Right, that's very true. I can't give you a specific number on that but I can see your point there. It's well taken. With us not going and doing confirmatory testing in some cases, it's just symptomatic. And so you're right, we're probably getting many more that are coming in that don't necessarily have H1N1.

DR. LEDNAR: Any other last questions or comments for Major Fea?

Dr. Kaplan.

DR. KAPLAN: Could you give a little bit more information about what the time line is for the H1N1?

MAJ FEA: The timeline?

DR. KAPLAN: Vaccine.

MAJ FEA: The last that we've heard is that it's supposed -- let me back up a step. It's in safety. I'm not sure if it's made it to efficacy right now, those trials. And from everything we've heard we'll get at

the end of October to the beginning of November. And it's supposed to be, at this point, a two shot series, 21 days apart. I know I've spoken to Colonel Krukar and he's spoken to the field about making sure seasonal influenza is taken care of early, get it out of the way so that we have the assets and everything ready to go when the next vaccine comes out.

DR. KAPLAN: Thank you.

DR. LEDNAR: Major Fea, thank you for that discussion on H1N1.

MAJ FEA: No problem.

DR. LEDNAR: Major Fea actually has got a pressing engagement back on the east coast he's got to get to, so we're going to take the second item he is going to brief us on, which was scheduled for later in the afternoon, and he's going to give that now.

And let me just introduce that. In the Defense Health Board back in June of 2008, the Defense Health Board issued a report regarding the findings and recommendations pertaining to the health risk assessment

conducted at Balad Air Base, Iraq, for burn pit exposures.

The Board's report was provided at the request of the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness. And based on a review of the revised draft issued by CHPPM and the Air Force Institute for Operational Health, Major Fea is going to actually share some thoughts about a proposal that's being developed for sampling of burn pits and a monitoring plan for perhaps later this Fall.

So, he's going to share some of his ideas and some of his thoughts at this point.

Major Fea.

MAJ FEA: Well, thank you again. Just real quickly, it's more background slides than anything just to refresh your memory on some of the things that have already taken place on the joint based Balad air sampling, some of the things that came of that. And the bottom line up front here, the Air Force and the Army are getting together wanting to potentially do more air sampling,

not only at Balad but some other installations and theater, in the Horn of Africa, Afghanistan and Iraq and what they're doing as they're going through this information and trying to figure out, you know, should we be doing sampling, what should we be sampling for, they want to make sure that the Defense Health Board has an opportunity to review before they press out.

So let me quickly go through my slides. Again, just as a reminder that the burn pits have been used in Iraq since 2003. We've had various levels of plastics and other things that we've had to dispose of and, you know, it's a reality of going to war or just a deployed setting there. And with this, since 2003, there's always been that concern about, okay, is there dioxins out there.

If you have the right conditions and the right type of plastics, you could potentially make dioxins. And so there was always that concern and along with that, you had some of the acute respiratory illnesses that were coming out of the theater, and so

there was concern on that part as well as what we were seeing from Congress as well as our media inquiries.

And I know I've had to answer several congressional inquiries on behalf of the Chairman or some of our leadership in saying here's what kind of sampling we have done.

Also on top of that we, in the past, had a letter that was locally generated that says here are the problems with certain locations and that letter, not being exposure driven type of memorandum but just concerns getting put into the medical records. And so there was a lot of concern there.

The health assessment since 2005 we've been using the military exposure guidelines. And as we have done this we have found that the risk is low, except for particulate matter, which we have found to be moderate, a little bit higher throughout the entire theater.

And so in 2007, as a way of reminder from January to April we had extensive

sampling that was done out there at Balad. The U.S. Army Center for Health Promotion and Preventive Medicine assisted in performing a health risk assessment. So they helped out with the Air Force to come to a combined product.

Now in this they did use the EPA methodology. When you look at that, it's a little bit skewed in the fact that you have compromised people when you're using EPA information instead of just a health risk assessment here's what's going on. And as you can probably remember, back in 2007 when this was all created, there was a mathematical error that made it look like we had a potential long term cancer risk for dioxins.

Of course because of that, we actually did a serum sample of 25 personnel, found that there was nothing there, and also at the same time, this was December of 2007, we found out that there was actually an error in the calculation. Actually it was the beginning, I guess, January of 2008.

So Ms. Embrey, as the Deputy at that

particular time, the Deputy Assistant Secretary of Defense, had actually written a letter to the Defense Health Board asking for comments on the general risk assessment process and the findings that came out in what the Army and the Air Force put together, so just had asked that there be some suggestions on quality control measures for the combat environment as well as offering and recommendations for future assessments. And I know that that's what had actually been addressed.

The results of the Defense Health Board review said let's make sure that we don't call this a comprehensive risk assessment. It's a screening risk assessment. And that was because of some of the limitations we had. We didn't have enough analytes that we had sampled for. We didn't have locations. And many of the samples that we did -- we had 24 hour sampling. And so we weren't quite sure what was the highest point and shifting meteorological conditions. So we couldn't pinpoint in that 24 hours, okay, this

was the high point or this wasn't the high point.

And so after looking at this, the Defense Health Board came back and concurred with the conclusion based on the information that no dioxin associated short or long term health risk were there based upon everything we had done.

There was more, and that was the recommendations. And this was the bottom line that we've tried to incorporate and that was to minimize the use of the burn pits. We've been working extensively with our engineers to get those taken care of, so we minimize the use as soon as probable. And if we do have to use them, where is the best place to place them so we minimize exposure.

Continue exposure assessments. And this is what the Air Force and the Army is trying to do, is to say, "Okay, we understand we've got some more incinerators out in theater and we have some other sights that need to be sampled, so we want to do that."

Recommend appropriate control

measures be put in place with regards to future risk assessment, particularly in austere combat environments. And that's exactly what the folks in SIMCOM are doing right now. And this is probably -- the last paragraph that you gave us in that Defense Health Board memo, said the Board plans to engage to determine risk assessment best practices which can be effectively employed in austere and hostile environments.

And so that's what we're hoping for, is to help us as we go through this, when we look at the environmental health site assessments, environmental baseline surveys, knowledge that's from the ground, just different looks at this. I'm trying to figure out what should we be sampling for, from an environmental standpoint. Should we be looking at the Serum Repository? Should we be looking at pulmonary function test? What, in the whole gambit of things, what should we be looking at? And that's what we're hoping we can get some help with.

So this is the current status in

theater, and that is we've got 27 incinerators in theater right now, four at Balad. And so almost -- and I was talking to the guys yesterday because I was actually down in Albuquerque with the Joint Environmental Surveillance Working Group and they said they think just about all of the solid waste now is being taken care of in the incinerators.

So the question was should we go ahead and do more sampling out there because we have various sampling at the beginning of 2007, later in 2007, some in 2008, 2009 time frame. Should we go ahead and do more sampling out there? As well as, like I had mentioned earlier, some of those sights that are in Afghanistan, Horn of Africa, and some other sites that are in Iraq. And so the request is that the DHB review the proposed (inaudible) sampling plan and risk assessment methodology. We want to make sure at the very beginning that we are using best practices, that what we want to do is actually worth what we're trying to get to.

And so that's my request on behalf

of the Chairperson for the Joint Environmental Surveillance Working Group.

DR. LEDNAR: Okay. I was just asking Commander Feeks if this interest was going to be conveyed to the Defense Health Board in sort of a written request form. I think that would be helpful --

MAJ FEA: Okay.

DR. LEDNAR: -- just to be sure that we're clear on the question, clear on the scope, and make it easier to be sure that we answer the mail. And Commander Feeks can advise you on how best to do that.

MAJ FEA: That's not a problem.

DR. LEDNAR: I might ask Dr. Halperin, because he was obviously central to the work that we've done on the Board up until now about Balad, if you've got any other questions or comments that you'd like to position with Major FEA as he's going forward.

DR. HALPERIN: I think we should request that the request to us be specific as to whether it's generic. That is, is the process of risk assessment appropriate versus

specific. That is this is a risk assessment of a very different place. This is no longer burn pits, this is now replaced largely with incinerators. So is this -- are we going to be reviewing a generic approach towards risk assessment of various episodes or are we being asked to review a protocol for risk assessment of Balad as it is now, which I understand is largely incinerators.

Either way, we can do it if it's specific it adds to our experience. This would have been the third risk assessment, if you will, the first being Balad 1, the second one being Cromate and the third one would be Balad 2. So, if it's specific, we can do that and we're gaining experience, if you will, learning how the military does this. If it's generic, that's an alternative request, but we can approach it from a generic point of view as well.

But I think it'd be nice if we had a specific -- we knew specifically what it is that we were being asked to do when we were asked to do it. There are other members of

the Committee and they have different opinion.

MAJ FEA: Okay. And that's very useful information because when you think about it, Balad is just an environmental health risk assessment, whereas some of the other areas may still be more geared towards that burn pit. You're right, it's kind of -- I'll have to find out what exactly they're wanting and we can put that in writing.

DR. LEDNAR: Thank you. Dr. Parkinson.

DR. PARKINSON: Excuse me. To extend Dr. Halperin's comments a little more, if you think back to the overview briefing at the beginning of all of the operations going on around the globe, and we think broadly of the DHB charge, which is health, the growing awareness of this term something like it called environmental equity, if DOD goes into a country and DOD is there for one, two, three, five years, what is the footprint that we leave environmentally when we move out? Is there an overarching doctrine in existence in DOD that talks about the principles of

environmental equity or environmental sustainability pre, during and post a DOD operation?

It may not be there, but I think politically, and I think scientifically, ethically, that we're on the verge of having a concept like that. So I'd like to know if there is anything like that out there already.

DR. LEDNAR: Is there anyone who can answer Dr. Parkinson's question?

Major Fea.

MAJ FEA: We do have, in many nations out there, the overseas environment baseline guidance documents that helps us to understand what is it above and beyond our requirements that we have to meet for the host nations, but it gets a little tricky when you go into combat operations because then you have to figure out what applies, what doesn't. Hence, there are many countries out there that don't have anything.

But, it's a good question. I could bring it back to our engineers and get you an answer to see what do we have out there.

DR. LEDNAR: What's clearly a challenge is that the sampling technologies is outpacing our ability to interpret what it means. We can measure certain analytes down into the parts per trillion in concentration and clearly, you know, the environmentally footprint that's left behind is an important one, but we shouldn't forget that many times what raises the real concern is, "Will that make me sick?"

Is there a health aspect to this environmental contamination? So it's important that we, you know, stay close to that.

Let's see, Dr. Halperin and then there was a question -- Dr. Mason.

DR. HALPERIN: Just another brief comment for the benefit of everybody around the table: you know we can address these generic issues as have just been described by Mike and yourself, myself, but you know when you look back at this three year experience, when we've actually been involved, probably the most useful thing we did was not generic,

it was actually playing the role of pure reviewers on the specific risk assessment. And, you know, these are two different tasks.

On the one hand, are we going to review every risk assessment done by DOD? That would be an immense undertaking. On the other hand, insuring that somebody's doing kind of peer review of them would avoid a lot of false alarms. I shouldn't say a lot of false alarms. Could avoid a false alarm, if it were to occur from a math error or something.

So, I think we've got to decide what our role is here. Generic is fine, but we can do generic and still a false alarm can come out because we're not reviewing a specific. Or we could do specifics and get way over our head with a volume of work if nobody else is going to be doing that.

So I think those issues have to be brought into what the best result is here.

DR. LEDNAR: It would be fair to say that it is not the role of the Defense Health Board to be a high volume service delivery

mechanism for the Department. We are an independent source of advice, for example on approach and criteria, but we're not here to crank out pure review of hundreds of risk assessments for the Department of Defense on an ongoing basis.

DR. HALPERIN: Although that's how we have been useful in a couple of these episodes.

DR. LEDNAR: But some of our learnings have come from the specific --

DR. HALPERIN: Case studies.

DR. LEDNAR: -- understandings. And from that comes some very, you know, good foundational recommendations.

Dr. Mason.

DR. MASON: Having had the good fortune to work with Dr. Halperin throughout this issue, one of the things that's troublesome to us is we're late in the game with regards to being provided information. You refer in your brief to extensive sampling in 2007. It's 2009.

You refer to the Serum Repository.

We took exception, and still take exception, to the way in which those 25 individuals who are selected, and the way in which the data were over-interpreted. Okay?

So it would seem to me that we are more than happy -- I and other members of the Subcommittee -- we are more than happy to be on the receiving end of some very specific questions. We are more than happy to address, if you will, a general template and general recommendations with regards to how does one go about -- as an environmental epidemiologist, you know as well as I the Achilles' heel is exposure assessment. Exposed to what? To what extent? For what period?

And you know better than most, as an engineer in the Air Force, the Air Force engineers that wrote the memo that we're not specifically mentioning today in terms of the number of incinerators and in terms of why weren't they already in place. So we are many years behind the curve with regard to ways in which to provide information prospectively.

So we've got to deal with that particular reality.

And so I would suggest, sir, that as soon as is practicable, that we do indeed hear from you formally, in writing, what is it you're asking us to do?

MAJ FEA: Okay.

DR. HALPERIN: So that we can then say, "This is what we can and cannot do." We can then provide the Department with appropriate, if you will, advice and counsel.

MAJ FEA: Will do. I appreciate that, sir.

DR. LEDNAR: Nicely said. Thank you. Any other questions or comments for Major Fea? Okay, if not, Major Fea thank you for both of your briefs.

MAJ FEA: Yes, sir.

DR. LEDNAR: Safe travels winging your way back presumably to Washington D.C. and thank you.

Okay. Not to go more than 30 minutes away from H1N1, let's return to the topic with Dr. Poland.

I think everyone knows Dr. Poland, but let's see, let me get the right script in terms of what he is going to do.

The pandemic influenza preparedness subpanel is a activity within the Defense Health Board.

DR. POLAND: Did Major Fea leave yet? Is this your watch, sir?

DR. LEDNAR: And in addition to returning Major Fea's watch, and Dr. Poland always being on watch for the latest in pandemic influenza, he's going to present the findings and proposed recommendations of the Pandemic Influenza Preparedness Subpanel of the Infectious Disease Control Subcommittee regarding the Department's preparedness and response to the novel A/H1N1 outbreak.

The Core Board was provided with a draft on the 31st of July for review in preparation for today's discussion and after the presentation and discussion, we will have a vote, as a Board, on the Subpanel's recommendations.

So, with that, Dr. Poland.

DR. POLAND: Thank you, Wayne.
Perhaps after my brief you may feel the need
to circulate the Purell[®], but we'll see.
Okay.

The purpose here was to give you
some brief background on our work, review,
some of the PI preparedness work that we've
done, and the specific recommendations we'll
look at today and then get your approval for
them.

DR. LEDNAR: And Dr. Poland's
material is in tab nine, if you're looking for
it.

DR. POLAND: These are the Workgroup
members and individuals who participated in
many of the deliberations that we had and the
ongoing work of the Panel. I might just
digress a bit to give some background.
Remember that this started as a Select
Subcommittee established by Dr. Winkenwerder
in 2005 related as the previous speaker
mentioned to avian influenza concerns.

And the rules of engagement are
listed up there, was to assist DOD in pandemic

influenza planning and response. And there were specific issues of concern, epidemiology response, vaccine, antivirals, personal protective equipment and surveillance.

It was to be DOD specific. There are lots of civilian issues that we weren't going to consider unless they were relevant to DOD. They had to focus on areas within DOD's sphere of influence. We can't control what DHHS does for example. Focused on both immediate and future recommendation and on what's feasible.

I won't go through all of these, but these are just a list of some of the various recommendations and documents that the Committee has produced over time, starting back in January of '06 and proceeding up through May of '09.

Now, one issue I think sometimes for our now Panel is that the members of this Panel are highly engaged nationally and internationally on these issues. And as new information comes up, I think I always fear sometimes they get a little frustrated with

me. They would like to engage sooner or more often. And I have sort of resisted some of that with the idea that, again, our role is an advisory role here to DOD. They need to receive the same information that we're hearing, digest it, move it around and mold it to what they can do and what they can't do within DOD and what they plan to do, and then us add to that or comment on it or raise new issues.

We are going to be putting together, it's not exactly clear how yet, but Mark Miller, myself, and Commander Feeks are working on what will be some sort of relatively secured almost like blog, I guess, where we can trade information, house documents, et cetera. And I think we'll be able to achieve what some members of the Panel might want to have in terms of rapid access to information, et cetera.

So I'm going to look at these specific issues today. They sort of cover the waterfront of pandemic influenza preparedness. And I'll go through them in sort of

telegraphic form to fit the amount of time that we have today. We had several teleconferences, much in the way of email back and forth. We had a face-to-face meeting on 8 May. We had representatives from all the DOD branches, NIH, CDC, GEISS, Health Affairs, DHHS, the National Vaccine Program Office, and others, and it was to update the current situation in regards to H1N1, review our prior recommendations. And this resulted in about 20 additional recommendations.

Now I'm proud of the fact that this Panel has very carefully crafted the recommendations that we bring to you today and our past recommendations. And the evidence that I would submit to support that is that when you look back on our products going back to '06, there really isn't any substantive change we would make in those, even though we didn't know what novel H1N1 was or would become, et cetera. They're meant to be generic enough to be useful and yet precise enough to be useful in a specific situation.

So to go through our specific

recommendations, one -- and many of these are things that DOD is already doing. It's not like we were telling them something new. We were reiterating things that we thought were important and they too agreed were important.

One was for heightened active surveillance, primarily looking for changes in severity of cases as Fall would come upon us, changes in the epidemiology of cases, changes in the antiviral sensitivity and expanded surveillance in Mexico and Central America in particular. Originally we had Africa on that list and there's been a lot more work now in Africa. But part of this relates to the fact that all the experts knew that Central America and Mexico was never the issue. Well, they were wrong of course, at least in this case.

The antiviral sensitivity issue is an important one. There are, I think, six confirmed, a couple of unconfirmed cases of oseltamivir resistant novel H1N1. One in somebody who had not been on prophylactic treatment, nor been ill, so it was apparently transmitted to her, which is of considerable

concern. But they have been low in numbers as far as anybody knows and certainly not the situation that we saw with the adamantanes and seasonal H1N1 a few years ago.

The second concern, the area of antivirals. Again, we reiterated the importance of following CDC guidance, but just as the previous speaker said, we also recognize there were special situations where DOD rightfully should and should be willing to sort of step forward and do things that CDC wouldn't take into account necessarily. And those included some shipboard, Special Ops, deployed forces and what we call congregated forces. So, you know, you got 16,000 future leaders in the four Service Academies. I didn't know how to count up all the recruit training at any given time, but those are a lot of individuals that don't necessarily fit into, you know, critical forces for example, but nonetheless, could be critical accelerants of a pandemic in terms of DOD.

We raised -- and in fact I had written -- and I think it was just a few weeks

ago published in JID -- an editorial about concerns with the one drug approach to prophylaxing and treating influenza. We wouldn't do that with any other -- and don't do that -- with any other RNA virus, but we sort of persist in that mental frame of thinking with influenza. And in that editorial we pointed out how that repeatedly gets us in trouble.

Interestingly enough now some of the biotech companies are developing triple combination drugs in one pill, sort of like what we would do with HIV and are field testing those this Fall.

And then just the caveat of being sure that there is a mechanism to replenish supplies as they got used. So nothing new that DOD wasn't already doing, but just reiterating.

There were some special populations that we thought, based on new information, should enter into the thinking and planning scenarios. And these were children, as it became apparent that the morbidity and

mortality was primarily occurring in the U.S. a median age of about 14 to 16 years old, something in that neighborhood. And some concerns with morbid obesity although at least one additional look at that concern has suggested that there wasn't a special risk associated with that, but nonetheless, things to potentially think about.

In the realm of research, we thought that DOD was positioned to materially assist with the advancing the science in ways that would not be possible or unlikely to be possible on the civilian side. You've heard of one in terms of fomites and transmission, duration of shedding, et cetera, that are being done here at USAFA, antiviral efficacy and resistance and drift.

Now that last bullet that may induce a bit of sensitivity -- and this was the idea of encouraging senior DOD leadership, if you will, to actively fund and support research in this area. The strong feeling -- excuse me -- of our Panel that particularly the research aspect, not so much the practice or clinical

or educational aspects, but the research aspect of respiratory illness has sort of morphed into something different than it was in the past and is not -- DOD wouldn't really be viewed nationally as the leader or necessarily a leader in respiratory, particularly viral respiratory illness. And that was not true in the past. DOD often was very much the leader in those sorts of issues.

Now having said that, it's also true that it's our DOD who I identified the first couple of cases of -- actually I think four cases of H1N1. So, they certainly do have a platform and a role there.

Active surveillance. I mentioned a little bit about this. And in particular this third bullet there of identifying resources for focused southern hemisphere and equatorial surveillance becoming a priority since that's not a traditional area where those sorts of surveillance activities did happen. Now there is a NAMRU and Lima. Right?

SPEAKER: Yes.

DR. POLAND: And we also noted that

DOD GEISS funding is a concern in terms of timely surveillance and response. Again, there have been some morphing of those agencies and how they're being positioned.

Interagency interactions. We just commented that NORTHCOM, Canadian Command, and Mexican Command interactions should be encouraged and strengthened since there was very obviously the need to maintain the sorts of relationships where there was a lot of cooperation where we could get access to samples, et cetera.

In terms of diagnostics, you've heard a little bit about that just a minute ago, and that's part of expanding the ability to diagnose novel H1N1 to more locations to insure continued throughput capabilities, particularly looking forward to this Fall when we may have co-existent seasonal influenza and H1N1. A lot of fear and concern, a lot of testing being done. And how are you going to sort of prioritize that? What algorithms are you going to develop to determine who you're going to test, how you're going to test them

and in with what speed or (inaudible). And then anticipating confusion with these issues and approval of alternative diagnostic platforms. And you heard about that just a moment ago.

To come back a bit to the idea of respiratory disease research, we really felt and have commented consistently, I believe, since 2006 and actually a little bit before that of this idea that there really should be a respiratory disease research sort of DOD internal team that had long term funding associated with it. Now the clinical research vaccine trial part, I think, has been well handled and is well positioned within MILVAX and other areas, but the research aspect of it, if you will, some of the basic research I think is of more concern.

And that's a capability that we have felt strongly DOD dare not give short shrift to because historically along with diarrhea and other infectious diseases, it is what compromises operational readiness.

Vaccine trials. We commented on our

hope that DOD would materially assist in clinical trials of a H1N1 vaccines. There was a mechanism that was proposed in that regard and a big cognizant of enhancing collaborations within NIH and BARDA.

We reiterated our October 2007 recommendations where we reviewed -- would like to review the new plan. Major Fea just commented that it's just now being sort of coordinated, but we would like to review that plan for use of vaccine. Consider the possibility of difference in implementing one versus two dose schedules. For those that may not know, through the NIH there are a variety of vaccine treatment and evaluation units. They just started their safety studies and immunogenicity studies of this vaccine.

So, if everything went perfectly, it will be some 40 to 60 days before there is sort of a go with this vaccine. And then there'll be time devoted to distribution, et cetera.

One of the things that will occur in here is to determine is it possible for

probably the age 50, or 60, or older age group to potentially give one dose. Now think of the confusion here.

Everybody will get one dose of seasonal vaccine, except for very young kids getting it for the first time, where they'll get two. Most everybody, if not everybody, will get two doses of H1N1 vaccine separated by a minimum of 21 days, and potentially there will be some carved populations that might only get one. That's a record keeping nightmare in managing that and in educating people about that. So what's the plan going to be to do that?

Insure active safety surveillance capabilities. I need not remind probably anybody in this room about the concerns that exist in that regard, mostly related to the swine flu vaccine of '76/'77 and how would those surveillance capabilities be enhanced. How is the electronic data transfer going to occur? What are the reporting mechanisms going to be, et cetera?

It's certainly a lower priority but

again brought up the topic of convalescent plasma, reiterated our May 2008 recommendations in this regard, and again suggested collaborations that might enhance that while recognizing this is unlikely to be something that DOD is going to, you know, manage, but it's something DOD could be supportive of in terms of either biotech, pharma or FDA, or other NIH or other places that might be interested primarily because DOD has access to a young healthy population whose going to get infected and recover from it and has excellent blood collection and plasma collection capabilities. And this could be a real resource. You know in some of the talks that we've had, we introduced the concept, somewhat more privately, not publicly, that there are individuals and assets that must survive.

And as a last scenario sort of measure, having plasma available to provide passive immunization and treatment, could be a part of that plan.

We also talked about pneumococcal

vaccine. At this point it doesn't appear -- we need more data, but it doesn't appear that it's bacterial pneumonia that is causing the mortality in relation to novel H1N1. It appears to be primary viral pneumonia and a hemorrhagic ARDS like picture. It's really a nasty one, but nonetheless, that could change if we had a wider transmission or a change in the virus this Fall. So it was sort of a "just remember, let's keep reviewing and updating prioritization and administration and stockpiling plans for pneumococcal vaccine." And mention that conjugate pneumococcal vaccines are in phase three trials.

The implication of that is outside of the normal CDC recommendations, we don't want to rush in and give polysaccharide vaccine because at least the initial data shows that conjugate vaccine given after a polysaccharide vaccine may not be as immunogenic as the other -- even as the other way around.

So it was sort of be ready in case we need pneumococcal vaccine, but don't rush

in and give it unless it's clear that it's needed.

We also talked about surge capacity and insuring availability of essential resources. This is an area that DOD is expert in those sorts of logistics, but we were just sort of reiterating that and I think also praising them for the work they had done in that area.

Communication and education needs. It's less clear to us exactly how much of this has been done to providers of all levels, active duty, guard and reserve components, beneficiaries and retirees. And also taking the opportunity to try to evaluate the effectiveness of those different strategies. And as I said, it potentially will get very, very confusing this Fall with all the different schedules and types of vaccines out there.

So that is sort of a brief summary of the many recommendations that we had and I'd be happy to answer any questions or elaborate on anything.

DR. LEDNAR: Dr. Oxman.

DR. OXMAN: Hi, Mike Oxman. There are two things I would like to comment on. The first is that as we're spreading the PCR platforms for diagnosis of H1N1, it would be a small addition to be able to rapidly diagnose mutations that yield oseltamivir resistance. And I think that should be put there on the front burner. It's a minor addition both in costs and in science, but it could --

DR. POLAND: And it sort of fits into that what are the algorithms going to be for what testing, what kind of testing --

DR. OXMAN: Right.

DR. POLAND: -- who gets tested and so forth.

DR. OXMAN: But when you have outbreaks, which is one of the things that will be tested, it would be very important to add that ability to check for oseltamivir resistance. And if you have the platform there, it's a relatively easy and cheap thing to do.

The other thing is a little bit more

perhaps controversial. And that is I've been concerned since we're supposed to be increasingly in real time providing useful advice to the DOD. One of the things that I felt is that I felt inadequately informed about what the DOD is doing today. And so I'd like to have a better dialogue between our Subcommittee or whatever we're called, our Panel, and Wayne Hachey and others like him who are in fact right at the moment implementing the current plans because it would help us to understand what those are and if we had something to add or subtract to at least make it known.

DR. POLAND: It's a good point, Mike, and it's sort of this tension between -- the people in DOD that are working on this are literally working 18 hour days --

DR. OXMAN: I understand that.

DR. POLAND: -- seven days a week.

And so how do you, you know, how do you interrupt what they must be about doing to say, "Well, wait tell us what you're doing so we can comment on it." And I think in part,

other than our face-to-face meetings, that that will be facilitated by this -- what's the word for it? It's not a blog. Mark suggested a word for it.

CDR FEEKS: This is Commander Feeks. It's an e-room that we're going to set up for you.

DR. POLAND: An e-room, thank you. Yeah. An e-room where we can see perhaps those documents early on --

SPEAKER: Right. A copy on the e-room wouldn't cost any time at all, and I'm sure Wayne, from talking with him, would be willing to do that.

DR. POLAND: So we're working on that.

DR. LEDNAR: Dr. Clements.

DR. CLEMENTS: The only thing I would be concerned about it is that we don't get target fixated here. Whatever the probability was a year and a half ago or two years ago, that H5 would come across the landscape, is the same today as it was then. And so we're all fascinated with H1N1 right

now, which may turn out just to be a nuisance at the end of the day. I would not drop our preparedness for pandemic flu that may in fact arrive in a different form. And if it happens to come this year, we're going to have a major issue on our hands.

So, I think we need to just continue

--

DR. POLAND: Excellent point.

DR. CLEMENTS: -- to remember that there is another landscape out there that we need to keep our eye on.

DR. POLAND: Thank you.

DR. LEDNAR: Just to reinforce Dr. Clements point, from a corporation preparedness and communication point of view, a lot of preparation over the last several years has been around the H5N1 as the threat. And in April when H1N1 clearly began to emerge as the pathogen, there was a tremendous amount of rework of communications materials, but I think building a framework of mindset that these are two, but not the only two, that could potentially become a pandemic in the

future.

So maintaining some generic functional capability where you have a plug and play for whatever the pathogen turns out to be.

DR. POLAND: You know, I mean we have a small outbreak of -- well, not so small outbreak of H7 among turkeys and some of their caretakers in central Minnesota.

And so what we endeavor to do is provide some information and guidance that would be, as I said, generic enough to be useful for any of those pandemics scenarios, but at the same time specific enough to attend to whatever the unique epidemiology and morbidity and mortality may be for a given strand. And no Minnesota and turkey jokes now.

DR. LEDNAR: Other questions for Dr. Poland and the panel before we solicit a vote on the recommendations which he's reviewed with us?

Okay. I'm not sure how best to do this. Who'd like to advise on how we call the

question?

Okay. Taking the advice of our Roberts' Rules expert, we have received a set of recommendations for the Board. All those in favor say aye.

SPEAKER: Aye.

DR. LEDNAR: Any opposed? It passes as unanimous. Thanks to the Panel for all of your effort.

DR. POLAND: Thank you.

DR. LEDNAR: We're going to do one more topic before we take a break. We, in fact, will be hearing from Colonel Rentas on fresh whole blood safety.

Colonel Rentas serves as the Director of the Armed Services Blood Program within the Office of the Surgeon General of the Army. He's a member of the FDA's Blood Products Advisory Committee and the American Association of Blood Banks Standards Programs Committee.

Colonel Rentas will brief the Board on safety issues regarding fresh whole blood transfusion. His presentation slides may be

found under tab 10.

Colonel Rentas.

COL RENTAS: Thank you, sir, for having me here today. I think this all started back in September of 2006 when my predecessor Commander Mike Levi actually briefed this Committee on the current status of collection and transfusions in theater at that time.

As a result of that, back in June 2008, the DHB made some recommendations to Dr. Cassels and my intent today is to address those recommendations and at the same time provide you with a current status for blood operations in theater and all the things that we have done during the last year to increase the safety of the blood supply on anything that is collected in theater.

For the last year or so I have been working very close with (inaudible) Smith, which is the Joint Staff Sergeant, (inaudible) and Mike Fea, as well as another 10 or 12 people to try to address these recommendations. And, in fact, one of them is

here today, Dr. Jeremy Perkins is here today.

Jeremy, if you could please stand.

Jeremy is the Chief of Blood Research at the Walter Reed Army Institute of Research, has deployed twice, has donated whole blood in theater, has actually used platelets in whole blood, he's the clinician. In some of those clinical questions that I may not be able to answer, he may be able to do so.

So thanks, Jeremy, for being here today. This is my agenda here. The purpose: I pretty much already stated what the purpose is. The benefits of transfusing, non-FDA compliant blood products.

Some background information on whole blood data, as well as platelet.

Blood product availability. Our current policy and guidance for HIV, Hepatitis B, and Hepatitis C. Some of the countermeasures that we have in place now to decrease transmission.

The current status. The issues that were raised by this Committee or Panel. And then some conclusions. Again, I already

stated what my purpose is here today, to show you what the current status is and to try to address the recommendations that were made last year.

So what are some of the benefits of transfusing non-FDA compliant blood products. And for those of you in the Committee that may not be aware, what I mean by non-FDA compliant is blood products that are collected in theater that are not fully tested according to FDA guidelines, because they're pretty much collected on an emergency basis.

The physician practice of collecting and transfusing fresh whole blood platelets supports those techniques and resuscitation techniques that they have out there to control bleeding. This is normally a clinical decision that is made in the middle of a mass casualty.

Retrospective studies. And let me highlight that, retrospective studies because you all know some of the caveats involved anytime you do retrospective studies. Examining the efficacy of whole blood and

blood (inaudible) we have shown that whole blood versus red cells alone has an increased survival in massively transfused patients.

When you compare whole blood to RBCs, red blood cells, and plasma, there is a slight increase survival. However, when you compare whole blood with all the components, there doesn't seem to be a statistical significant difference.

In addition to that, retrospective studies performed in theater suggest a significant survival benefit for the massively transfused casualty when both platelets and a one-to-one ratio of plasma and red cells is used. Well whole blood provides all of that. It provides the red cells, it provides the plasma, and it provides the platelets. And there have been at least two or three publications regarding (inaudible). Some of the background on whole blood. Whole blood has been used extensively to resuscitate casualties all the way back to World War I. As of 31 December, 2008, 3,571 whole blood units have been transfused in theater to 497

U.S. patients. As of today, they have been one documented transfusion transmitted disease and this was the Hepatitis C virus transmission in 2005 in which the unit up on collection was not tested at all with rapid testing.

Seventy-six percent of the whole blood transfusions are taking place at level two facilities as expected because they do not have all the blood components that the level three facilities will have. The percentage of whole blood transfused (inaudible) RBCs down to 3.8 in 2009 as compared to 7.3 from 2006 to 2008. And it's also down from 3.6 to 2.3% when you compare whole blood to all the other blood components transfused.

At the present time we collect a sample from every donation and we send that back to the States so that all the FDA license testing can be accomplished.

The current Joint Theater (inaudible) System Clinical Practice Guidelines on whole blood were just updated last year, about seven months ago in November

2008 and the bottom line is listed here: whole blood is neither intended nor indicated for routine use and it's only to be used when nothing else is available or when we are unable to deliver an acceptable rate to sustain the resuscitation of an actively bleeding patient.

As you can see, whole blood collections are way down from the level that we had in 2006 and 2007. If I could add that 2009 is looking pretty close to 2008, with about 133 whole blood transfusions from January through May. That includes all OIF and OEF.

Whole blood transfusions from 2006 to 2008 on OIF. This is just to show you, as I mentioned before, that most of these transfusions are going to levels to facilities because again they do not have all the blood components that level three facilities have.

OEF, again, 60% at level two and 40% at level three. You're probably wondering why the leveling OIF is 40% as opposed to 25% in OEF. The reason for that is because we did

not start collecting platelets in Afghanistan until 2007, even at level three facilities.

The background for platelets. It was first used in OIF in 2004 and OEF in 2007. As of 31 December 2008, 1,857 platelet units have been transfused in theater to 744 U.S. patients. Collections for platelets are much more controlled than whole blood. The bottom line on this is that we do not allow anyone to donate platelets in either Iraq or Afghanistan unless we have a complete battery of FDA license tests already on file. Platelets are good for five days. We keep them for five, sometimes seven days if we send them out to Level Two facilities and all products are tested for bacterial contamination, just like they are back here in the States.

In addition, samples are tested with rapid testing for HIV, Hepatitis C, Hepatitis B, and as I mentioned before every time someone donates, a sample is collected -- or samples are collected for retrospective testing and that testing is sent back to the

States.

Platelet transfusions are down 46.5% and 32.2% from 2007 and 2006. However, platelet use as compared to whole blood has gone up by 17% in 2009 when compared to 2007 and 2008. And the current Joint Theater Trauma System on damage control resuscitation addresses the use of platelets. Again, this was updated in November of 2008.

Basically, what is says is the platelets should be used as part of damage control resuscitation because, as I mentioned before, retrospective studies have shown that there is an increasing survival whenever platelets are used.

This is the platelet use from 2003 to 2004 to 2008. You're probably wondering where those platelets are coming from 2004 and 2005. Some of those platelets were actually either brought in from Germany untested or they were provided by the locals at that time. It wasn't -- I'm sorry. I'm sorry. Disregard the comment that I just made.

This is OIF and OEF combined. So,

as you can see, we started 2004 on OIF and 2007 we started an OEF as well and that's what that number goes up to 1879. As casualties go down in 2008, in 2009 platelet usage has gone down as well.

Again, platelet transfusions. In OIF, level three 85%. Only level three facilities collect platelets. That's a procedure that takes about two and a half hours and it has to be done by specific people. And OIF level two, there is a 15% transfusions.

When you come to OEF, it's pretty much the same thing.

Blood product availability. This is something that we have done substantial improvement here in the last year, year and a half or so. It used to be that Level Three facilities will have all the blood components out there. It's gotten to the point now that Level Two (inaudible) what we call our forward surgical teams, just about all of them have plasma and some of them have platelets as well. I truly believe that that's the reason

why some of the whole blood collections are down, because we're making components available to level two facilities that they didn't have before.

Platelets are still very limited. Of course they're only good for five days and are collected at Level Three facilities. And of course all these places will collect fresh whole blood if the surgeons feel like that there is a need to do so.

Level One battalion aid stations, there is no blood products at this time.

This is the current policy and guidelines for HIV, Hepatitis B and HCV. For HIV, 90 days before you deploy. For HBV, requires that all deploying military personnel should be vaccinated against both Hepatitis A and Hepatitis B. At this time there is no current policy or guidelines for screening prior to deployment for Hepatitis C. This issue was discussed at the SIMCOM's surgeon's conference back in November and again in May of this year and it was decided that based on the risk, the (inaudible) risk, with all the

countermeasures that we're using right now it did not justify the cost to test everyone for Hepatitis C virus before they deployed.

These are some of the transmission countermeasures that we have right now. Four screen for HIV every two years. Ninety days before they go into theater. Vaccine is not available for HIV or Hepatitis C; however, it's required by all the surfaces for Hepatitis B.

Free screening, these are people that will come in and say, "If I need it, I will like to donate." So we'll go ahead and take some samples from those guys, take it back to theater and now we know whether they're positive for anything before they actually donate.

Retrospective testing. I mentioned this a couple of times. At the time they donate, we take a sample, we take it back to the States and we do all the FDA license tests back in the States.

And this is a key here. We have a much more improved rapid testing for HIV,

Hepatitis C, and Hepatitis B, and we're making this available to level two facilities as well.

The current status: a Health Affairs policy has been drafted and it has been approved by the Surgeon Generals of all the Services. Right now it's in Ms. Embrey's office for signature and it addresses rapid testing, free screening, retrospective testing and follow-up of recipients.

As I mentioned before, whole blood transfusions are down, platelet transfusions are down, the new improved rapid testing is available at level two facilities, increased availability of blood components at level two facilities, free screen, retrospective testing -- and when you look at the current or the clinical practice guidelines, they're addressing both whole blood and platelets.

Something that I have not mentioned before is frozen blood. We have an inventory of frozen blood in both Iraq and Afghanistan right now. This is an FDA licensed blood product. We have made the equipment available

to Level Three facilities in both Iraq and Afghanistan for use. The first transfusion took place in November of 2008 and as of today, we have over 100 transfusions of the glycerite blood in Iraq and Afghanistan.

And as we speak, the equipment is getting into Kandahar since we're taking over that facility out there to collect platelets in Kandahar as well.

If I may, I'm going to go fairly quick through the issues that were raised by this Committee. The first one was to limit the employment of emergency blood transfusion to instances where nothing else is available. I believe because of what I have already stated, you can tell that that's pretty much where we are right now. Transfusions are way down. Clinical practice guidelines are on (inaudible) and collections and transfusions of whole blood are way down from the levels that we had in 2006 and 2007.

A comprehensive risk benefit analysis of Hepatitis C. As you will see, on the next page, we have done that. Basically

what we have done, we went back and we pulled the test results of 17,387 samples. This goes all the way back to 2004 and 2005 from anyone that tried to donate in theater, either tried to donate or donated in theater. And no HIV cases were identified.

There were nine positive cases of Hepatitis B -- I'm sorry, Hepatitis C that were identified and six positive cases of Hepatitis B. This will give us a risk for Hepatitis C of 1 to 1,932; and for Hepatitis B of 1,298. When you look at the middle column there, if you include the rapid testing and you use the sensitivity that (inaudible) has, for Hepatitis C, the (inaudible) risk estimate will be 1 to 40,000; for Hepatitis B will be 1 to just over 18,000.

The Department should support facilities and facility industry efforts to improve and gain FDA license of rapid testing. The bottom line here is that there is not a market here back in the states to do the rapid testing to license market rapid testing that is FDA licensed specifically for whole blood

collections, or donor collections. FDA has approved a diagnostics test for HIV 1 and 2, and that's what we're using theater. We're working with the agencies right now and manufacturers to see if we can get a Hepatitis C virus and a Hepatitis B that at least will be FDA licensed for diagnostic purposes out there, we have no idea how long we can go with that because, again, there doesn't seem to be a market out there.

At the present time, known FDA compliant collections are screened using the three kits that we're using right now. As I mentioned, the HIV is FDA licensed for diagnostic purposes. The Hepatitis C, the Hepatitis B, they're not FDA licensed at all.

One is probably about a year away from getting FDA licensed for diagnostic purposes and that's the Hepatitis C -- I'm sorry, the Hepatitis B. The Hepatitis C, we have no idea where that stands.

Before we put those test kits in theater, we completed extensive validation of all three of them at the Walter Reed Army

Institute of Research by the retrobiology people and infectious disease people out there. And we peak and then select the best test kits that are available right now for these markers. And that's what we have in theater at the present time.

You told us that we needed to get moving and it was taking too long to get brought into theater and that's exactly what we have done. If you look at the green here, and you look back at 2008, the green means the number of units that was getting into theater within seven days of collection. If you go back to 2008, starting with January there, only 31, 147. When you start looking at November and all the way through June 2009, you can see how the green has increased to the point that in June we had over 2,000 units that got to theater that were received in theater, within seven days of collection. That is a big improvement in that.

The key has been the fact that now we have two flights to theater every week instead of just one, and the fact that the

facilities out there, Army, Navy and Air Force, have actually looked at the way they were doing things and they're much more efficient now than they were a year ago.

The Board recommended that we take a look at maybe the establishment of a blood donor collection and testing facility in theater. Bottom line here it's expansive and it really wouldn't change anything because those units, even if we have an establishment out there, will still be non-FDA licensed.

FDA license testing is very comprehensive. It takes time. Whenever you collect whole blood, you want to collect those and you want to transfuse immediately. In fact, we only keep those for 24 hours and if they're not transfused they're discarded. So we recommend that no blood testing or collection facility be available in theater.

The HIV internal testing policy of every two years, you asked us to take a look at that and as I mentioned before SIMCOM has changed their policy and it now requires that you get tested within 90 days of deployment.

You asked us to look at the Hepatitis C virus seroprevalence. And I already mentioned some of that the residual risk estimate studies that were done. However, the Walter Reed Army Institute of Research Infectious Disease Department has designed strategies to conduct seroprevalence and sero incidence studies of recently deployed personnel. They will define the epidemiology of HBV and HCV in deployed forces. This is spending approval at Fort Dix as we speak.

And, as I mentioned before, the retrospective testing of over 17,000 samples yielded a seroprevalence of 1 to 1,932.

In conclusion, the current infectious disease transfusion countermeasures that we have in theater right now are much better than what they were a year, even two years ago. And, in my view, they provide a good level of assurance against transfusion transmitted infections.

The collection and transfusion of whole blood and platelets according to

established, and I want to stress that, according to established CPGs, it's saving lives and should continue. And increased availability of blood components at level two facilities likely has played a role in the reduction of whole blood transfusions.

I'll be happy to answer any questions that you may have.

DR. LEDNAR: Colonel Rentas, thank you for that information brief and feedback to the Board on a topic that clearly has been of interest over time by the Defense Health Board.

Questions for Colonel Rentas. Dr. Poland and then Dr. Kaplan.

DR. POLAND: Yes. Thank you for that report. It's particularly welcome because I remember back some years ago when this was first brought up, one of the answers we got is, "Well, there really isn't much that can be done. This is just, you know, the way it is." I'm delighted that that was not true.

And it harkens to a point that Mike Parkinson has brought up a few times in the

past, and that is this idea of sort of engineering out the human or other factors that limit the sorts of things that we want to do. You mentioned that there are two flights instead of one, but what were the other things that contributed to the reduction and the use of this, the increase in the ability to collect, et cetera. Is it just lower numbers of casualties and so it's easier to do or were there some fundamental -- I'm using engineering in a generic sense -- reengineering of the system to make it possible?

COL RENTAS: Well, the second flight helped. That was a key. Now of course we can double the output out there and we can see exactly what happens whenever a flight is delayed, either because of weather issues or maintenance problems. And we look at that every week.

The other thing that we did was the Services blood program directors send their quality assurance directors to all these facilities out there that are responsible for

supplying blood to theater. And they spent about three or four days with them and they look at their entire process. Why is it that it's taking so long for you guys to collect tests and get this blood to McGuire Air Force base? Why is it taking so long? It should not take that long.

And when they look at the entire process, there were so many inefficiencies within that process that that (inaudible) now to get blood to McGuire instead of day seven, day two, day three and day four. It's only there for about 24 hours, 48 hours or so, and then we can make it to theater by day seven.

As far as whole blood transfusions going down, the fact that casualties are down I'm sure has something to do with it, but if you look at the slide that I put, what I tried to normalize that by looking that on a percent basis, what was the percent of all blood components that were being transfused in 2006 and 2008 versus whole blood, as compared to 2009. You can actually see a decrease with that.

So the other thing here is the Surgeons have come on board. They have updated the clinical practice guidelines and communication, to be honest with you, is much better now. Predeployment training of physicians going into theater is much better right now than it was in 2006 and 2007. There is at least two or three courses that we're offering to those physicians predeploying that may have never dealt with blood before. They get to theater, they have no idea. "What am I going to do with this?" All right, let's go ahead and set up a walking blood bank. So, in that respect I think we're doing a much better job informing and educating the physicians before they deploy.

So when you put all of this together, I think that's the reason what you see -- why you see this here.

DR. KAPLAN: I'm sorry, I missed the numbers. What did you say the seroprevalence of HVC (sic) was? HCV, I mean, was? Did you say 1 for approximately 2,000?

COL RENTAS: Yes, sir. That's based

on the over 17,000 samples that were tested within the last five years. This is from people, it's random, because you don't know whose going to come at your door in OIF and OEF and try to donate. And so in that sense, it's a really good thing because we have no idea who we're going to get. Went back, took a look at that, put all of that on a spreadsheet and that's what that number is based on.

DR. KAPLAN: And those are civilian?

COL RENTAS: No. Those are mostly military people.

DR. KAPLAN: Those are military. How does that -- I'm trying to remember how that compares with civilian prevalence numbers.

COL RENTAS: If I'm not mistaken, we're a little safer than the civilian population out there. I don't have the numbers for you. I can get those for you, but if I recall from the last article that I read, I think the military population is a little safer on all these markers than the civilian

population is.

DR. KAPLAN: I'd be interested in seeing that.

COL RENTAS: Yes, sir.

DR. KAPLAN: Thank you.

DR. LEDNAR: Dr. Luepker.

DR. LUEPKER: Yeah, I just want to compliment Colonel Rentas and his colleagues. Having served on that Committee and seeing you come back here with our recommendations and what I would see as very creative responses to changing the situation, it's very impressive and you and your colleagues should be congratulated.

COL RENTAS: Thank you. I appreciate that.

DR. LEDNAR: Any other questions for Colonel Rentas?

Yes, sir.

DR. BULLOCK: What's the proportion of utilization of that blood on Iraqi soldiers versus U.S. Soldiers?

COL RENTAS: Of whole blood?

DR. BULLOCK: Yeah.

COL RENTAS: Okay. Whole blood is about 50/50. We tend to call them U.S. versus non-U.S. Because there's more than the Iraqi people out there in Afghanistan. We got all sorts of countries out there that we're dealing with, which adds to the problems as to how we're going to handle blood out there. As you all know, we got the Canadians, we got the British, I mean it's just about that the entire United Nations is in Afghanistan out there.

But to answer your question directly, whole blood is about 50/50, 50% U.S., 50% non-U.S. And that has been pretty much the way it has been for the last four or five years.

DR. LEDNAR: Other comments or questions for Colonel Rentas? If not, again, Colonel Rentas thank you to you and your colleagues for the work you've brought to us. Thank you.

COL RENTAS: Thank you, sir.

DR. LEDNAR: Okay. Commander Feeks is going to give us our instructions about our

break, which we're going to begin now and then what we'll do afterwards.

Commander Feeks.

CDR FEEKS: Okay. In deference to Dr. Bullock, I'm not going to ape a crown dialect again, but I will say that I've got about two minutes to four and if we could reconvene at 13 minutes past four. There are refreshments in the next room and we want to try our best to stay on what's left of our schedule so that we don't find ourselves late departing for the restaurant because I know people would like a little break between our adjournment and departure for the restaurant tonight.

SPEAKER: (inaudible)

CDR FEEKS: 6:00 o'clock. Let's just leave at 6:00 o'clock from the front of Rampart Lodge.

DR. LEDNAR: So the bus to take us to dinner will leave at 6:00 p.m. Our goal will be to adjourn out of this room at 5:30 so that everyone gets a break. We'll only be able to do that if everyone comes back when

Mickey's big hand is on the 13.

So, please, we are adjourned for the next 15 minutes.

(Recess)

DR. LEDNAR: Here's Dr. Charles Wade. Dr. Wade is senior scientist at the Institute for Surgical Research at Fort Sam Houston, Texas. Dr. Wade has been a contributor to the health and well being of victims of traumatic injury for over 25 years. His past research includes a focus on intensive care unit, acute care and reconstruction of major vascular system structures.

Prior to his current position, Dr. Wade worked for NASA providing oversight on acute care programs for patients with traumatic injuries and oversaw the development of novel fluids for resuscitation of patients with major hemorrhage at the Letterman Army Institute of Research.

His presentation will focus today on fresh whole blood transfusion outcome and his slides and material may be found at tab 11.

Dr. Wade.

DR. WADE: Thank you. I just want to start with a little history. In 2006, I think it was probably in response to some of the questions that this Committee raised. I have appeared in front of a Congressional Committee that asked us to start tracking transfusions in theater. So part of the work I'll be presenting today, there are 615 patients who are retrospective and then there was a prospective observational study done looking at performance improvement, just to clarify that issue.

There is a lot of people who have been involved in this, most of them have been deployed numerous times, including Dr. Perkins. The problem that we see is that -- I'm looking here at potentially survivable deaths. What do we mean by that? Most individuals that die, about 80% of them are obliterated. They cannot be resuscitated, they cannot be -- there is little chances that they will survive. That leaves 20% of those patients that could have an intervention, and

that is the data that's looked at here.

What did they die of? And you can see that 85% of those that are potentially preventable die of hemorrhage. And that's broken into two areas. One of them is those that are compressible, right here, and you heard a lot on the right side. Those are pre-hospital targets. Sergeant Strand identified the products that are being used for that. We have field tourniquets, HemCon bandages, a variety of other products that we can help somebody that has a compressible hemorrhage.

The other group is the non-compressible group. These people require -- many of them are coagulopathic. They require certain types of interventions, and in the end they need blood and blood products.

So the use of whole blood in the absence of adequate blood components has been the U.S. Military's policy -- and I put policy in parentheses there, it appears in the Emergency War Surgery book, it was used extensively in World War II and somewhat in World War I, it's been used as a standing

source of blood products for over 60 years. And there is accumulating evidence that suggest it's practice is both safe and effective.

So we kind of have a policy called the walking blood bank. Basically this is when standard blood components are not available, we can use whole blood. And what do we mean by whole blood? That's an individual that we -- one of the people that is pre- approved in the cash and I'll go into a little more detail here.

We can draw blood off that individual either at a Level Two or Level Three, and use that for transfusing the individual. You saw where most of the blood is used. We now have a clinical practice guideline that we put in place in 2006. We revised it. It was mentioned in the earlier talk that it was technically put back into theater in November 2008 and it was signed off on fully in January in of `09.

So the decision that must be made a physician who has full knowledge of both the

clinical situation and the availability of blood components. In short, we're tasking somebody to look not only at the care of the individual, but what is the resources that are available to them at that time.

So it should be limited to casualties who are anticipated to require a massive transfusion. That's 10 or more units of red cells. Okay? So technically replacing the whole blood volume of an individual with red cells. So, if optimal component therapy is unavailable or in limited supply, or they're not responding to stored product. Now that's a different area that I want to make sure that everybody understands.

There are patients that you start to give them the standard components and they do not respond. They continue to be coagulopathic and a lot of the individuals that we see from theater have numerous wounds. They may be small wounds, but you get enough of those wounds, they start to (inaudible) and they end up with what I refer to as kool-aid syndrome and they do coagulate. So we have to

give them product that is fresh and available that has those coagulation factors at their peak, and that includes platelets.

A decision is made to initiate the fresh whole blood drive. It should be made in consultation with authorities in the caches or the level two. That is you check with the blood bank, you check with the commander of the facility. The donor person must be an ABO type specific match with the casualty and the decision has not been completely screened for infectious agents. That's made clear to all the physicians that's it part of the CPG, so they understand the risk.

This is a guideline. Okay. It is a guideline. It is not a substitute for clinical judgment. It is not a policy. So if somebody decides not to do this, they cannot be penalized for it. If they want to do it, they can't be penalized for doing that either because they're using their best clinical judgment.

So what is whole blood? It's the walking blood bank. These are prescreened

donors. Okay? Active duty, reserve -- there have been talks about that we're using internationals to participate in these, that the answer is to my knowledge there have been no internationals involved in the donation of blood for fresh whole blood use.

Recently laboratory confirmation of blood group and type, no evidence of transfusions or transmittable diseases, and retrospective testing, which you heard a lot about in the previous talk is conducted. That is not only is the blood product tested that was administered to the individual, the individuals, at least in the U.S. military, are also followed out over a one year period numerous times.

So the study approach, which I'm going to talk about today, is defined which patients have been getting fresh whole blood. That's number one. Number two is to determine it's effectiveness. I want to make this clear. This is not an efficacy study. The question here is with everything that we do to the patient, is it effective? It is as good

as component therapy. Okay?

We've looked at death and complications. The complications are listed below. It's the standard ones that you would expect in somebody who has severe trauma.

Okay?

As I mentioned, there was 615 patients who collected retrospectively of this 2,104 military casualties. I'm only talking about U.S. military casualties. And these products were over the five years from 2003 into October of 2008.

I mentioned the end points that were used versus those of blood components only, use of a multivariate logistic regression and propensity scoring. I'll go into a little more information about that. And differences were determined at the .05 level.

Seventeen percent of those that were transfused received fresh whole blood. Okay? As mentioned earlier, a majority of those individuals received it at a level two. It is a life threatening situation. Now, if you think about it, I want to make sure everybody

in the room understands this, Level Twos usually had 10 units of pack cells. Okay. Meaning they had the ability to transfuse one individual for a massive transfusion. And often with an IED they're handling about three casualties at at a time at a level two facility, and usually two of those would require some form of blood and blood products. Okay?

Patients who receive the fresh whole blood are more severely injured based on physiology, GCS and ICF, ISS. That's the Glasgow Coma Scale which is a mental evaluation of injury severity score is a standardized score used in trauma to assess various levels of severity of injury. Okay?

Overall population is shown here. You can see there is significant differences between the two groups in the injury severity score. And while the mean value for the Glasgow Coma Score in the median is the same, there were significant differences due to the large numbers. So clinically, I wouldn't even look at that, but the little star is there.

The other one here is I want you to look at the difference between the two populations, 1,753 got no fresh whole blood; 351 got the fresh whole blood. Note that they had greater injuries to the chest and abdomen. Okay? Greater number of injuries or severity of injury to the chest and the abdomen, that is the area for non-compressible hemorrhage. We cannot -- right now we have no means outside of direct packing and pressure bandages to control bleeding in the body cavities. So they are the sicker group here.

Number two is they came in hypotensive, they have tachycardia, they were hypothermic, they have an increased base deficit, they have their slight lower hemoglobin levels and they have they're coagulopathic. Even though 1.5 is on the clinical edge, even now some people say that a 1.2 INR in a trauma patient should be considered coagulopathic, they are more severely coagulopathic, the people who receive fresh whole blood.

They receive more blood products.

If you notice here, if you look at the sum of the amount of RBCs, if we include the fresh whole blood in that, three times, almost three times as much for the fresh whole blood group, they get more FFP, more (inaudible), a tendency for more platelets and they get a massive transfusion 84% of the time. They have their full blood volume replaced 84% of the time. And they also get more factor seven use.

So this is the sickest of the sick. So, in summary -- and also, when we look at them, there is no difference in mortality; however, they have a greater complication rate.

So who gets fresh whole blood? It's the sickest patients based on severity of injury and emission of physiology. Patients with truncal injuries, as I mentioned before, have greater severity to the thorax and to the abdomen, and patients who require massive transfusions. The right patients are getting fresh whole blood.

So then comes the thing about how do

we look at these outcomes. How do we balance that? We want to compare the two populations. We know one is sicker. We got to do some type of weighting scale. What we've done here is we do a multifactorial regression looking at the factors that contribute to that which is our primary end point that we wanted to look at.

And we see there is a variety of factors that come into play here, many of these are (inaudible) values, the base deficit, the INR and the hemoglobin level. Factor seven is a treatment regime. However, a lot of these values -- whoops, sorry. A lot of these values, specifically the psychological variables at the onset are not taken and obtained upon admission. The majority of the patients do not have those values.

So we decided to isolate on the GCS and the ISS in our first analysis to match. So we did a propensity score based on factors associated with ISS and GCS. That means that basically we went into the pool of patients,

we picked out a person who had a fresh whole blood, and we matched them to somebody who did not based on a scoring system that weighs those two components outcome.

They had to not die before 43 minutes. The reason I use 43 minutes here, was that's the first patient that died who received fresh whole blood. He received four units of fresh whole blood, but he died at -- so it says that I'm skewing, I'm not putting in a factor that people that died real early couldn't get fresh whole blood. So if somebody died in ten minutes, there is no possibility they could have gotten fresh whole blood.

So we know the people who get that and some earlier work that we did with Jeremy, the patients got fresh whole blood within 25 minutes of injury. So we know that 43 minutes is a pretty good cut off point.

We were able to match 85% of the patient population using ISS and GCS. You can see there's no difference now between those two. You can see that the chest drops out,

the abdomen is still more severe. Some of the physiologic -- even using these criteria, the physiological variables are still different in the fresh whole blood group and they still got more blood, more blood products, more (inaudible) transfusions.

So we had not done a very good job using this for matching and there's still no difference in mortality and the complication rates were significantly greater.

So we went to a propensity analysis again. This time we included the sum of the RBCs, PBRCs, that they received. So, again, we used the 43 minute cut-off. We were able to match 75% of the population. So, 263 patients were matched. Now we see that we've got pretty good matching in all the parameters here. These are the basic ones at the beginning. The only one that was different here was temperature in the physiological parameters.

The usage of blood products was still different because of PBRCs, but they received six units of fresh whole blood. The

total sums are not significantly different. There is a tendency for them to get a little less FFP, but you have to remember there is some FFP in that fresh whole blood. Cryo was not a significant difference. Patients were not (inaudible). And now the massive transfusions are matched, 81% in both groups. Okay?

Factor seven use in the massive transfusion patients -- I mean the fresh whole blood patients, was still slightly elevated.

So we have a pretty good matching. So what did we see? We show that mortality -- this is mortality over the whole course of their care. Okay? Complications, once again, over the whole course of their care. I want you to remember think about this, you've got to be alive to have a complication. Okay? Because most of these patients die in the acute phase. They die within the first 24 hours. In fact, they die within the first six hours.

And you can see here that at 24 hours there is a significant difference in

survival where we had expected these blood products to have their greatest affect. Over 30 days there is still a significant difference in overall. This should be median time to death. That should be mean time to death. The median is down there in the 109 versus 550. In short, they lived longer so they could get some care.

And also they did have some issues in relationship to complications. So, we have a higher complication rate, we have reduced mortality. The question then is, okay, what is the relationship to that? Is the use of fresh whole blood causing the complications? Okay.

So what we looked at here is we looked at those people that survived 24 hours and we looked at the complication rates adjusted for those patients that had died within the first 24 hours. We no longer saw a difference in complications after the first 24 hours and the mortality rate was the same between the two groups, adjusting the complication rate that occurred after the fact

was not contributing to mortality. Most of those things in the complications, we can treat nowadays. Okay? We're pretty good at handling them.

So in summary, patients who get fresh whole blood are severely injured and I mean severely injured. When you look at a civilian population, you rarely see a single institution that has anybody who looks like what we see in theater. Okay?

Patients receiving fresh whole blood demonstrated improved survival compared to those who received blood components alone. Improved survival is associated with an increase in complication rate that appears unrelated to mortality.

There are a number of problems associated with this study. This is a prospective observational performance improvement study. I want to make sure that people understand this is a performance improvement activity. We are now looking at our CPTs and tracking everything we're doing in theater.

A possibility there could have been a limitation of treatment in the fresh whole blood group due to other factors besides having a transfusion, i.e. nobody wanted to donate it, some people had donated before, et cetera, so they may have not been able to get fresh whole blood.

So, in conclusion, there is an association with reduced mortality with fresh whole blood use. You've got to remember most of them don't get fresh whole blood in the theater. If they didn't get it, they would not get anything. Continuation of its use is warranted in the absence of adequate component therapy. I want to sure that has always been what the rules have said, is that we do not use it when component therapy is still available.

Now I want to go back to the earlier talk. One of the big components that was missing -- and as you said, it was missing in Afghanistan up until 2007, is platelets. Okay. So we've used it to replace the standard components in theater. Okay? And so

in the severely injured and the massively transfused patients, fresh whole blood is saving lives and not contributing to increased complications.

Thank you.

DR. LEDNAR: Thank you, Dr. Wade.
Questions for Dr. Wade? Dr. Shamoo.

DR. SHAMOO: I just want to make sure I understand what you meant by this is a performance study. Does that mean you're considering this not clinical trial?

DR. WADE: It is not a clinical trial. It's a performance study in that a clinical trial I would submit it to the IRB.

DR. SHAMOO: Yeah.

DR. WADE: This was not submitted to prospectively to an IRB.

DR. SHAMOO: That is very interesting (inaudible) issue.

DR. WADE: That's why it's performance improvement. It's to look at our standard of care.

DR. SHAMOO: It is interesting and I think maybe the Board or the Medical Ethics

Subcommittee should look into it and maybe that is correct, but I am not willing now to say, yeah, that is what it is at this stage. And I don't know. I need more data and evidence to -- and other people to think it through.

DR. WADE: Okay. The data was collected for performance improvement. It was subsequently reviewed for presentations, et cetera, by an IRB when we went through looking at it for research purposes.

DR. LEDNAR: Dr. Luepker.

DR. LUEPKER: You know, I'm very glad to see this because I probably would agree that it's equivalent, but having said that I think we need to be reminded this is not a randomized clinical trial of two therapies. And while I admire your use of propensity scores and that approach, studies like this are amenable to lots of confounding.

DR. WADE: I agree, sir, but earlier we heard that will we ever do this in a civilian environment. No, sir. We tried. It can be noted by a number in the room here,

I've had a proposal in front of the IRB for two years.

DR. LUEPKER: No, I understand. I understand that and I can see why you would have problems getting it approved.

DR. LEDNAR: Other questions, comments for Dr. Wade?

Dr. Poland.

DR. POLAND: Maybe the question of what's next, what's the next step. I agree with Russ that, you know, the (inaudible) of medical history are littered with studies that seem to suggest -- even a preponderance of studies -- that seem to suggest one route of treatment that on randomized prospective trials don't hold up. And those may not be possible to do. I don't know, but it's why I ask the question: What's the next step? Or what would you like to do next?

DR. WADE: Okay. Within the Army, we have no instituted multi-center trial groups for a wide range of topics: TBI, both TBI acute care, and rehabilitation resuscitation, burn acute care, and

rehabilitation. And last week we just led a \$15 million dollar contract with John Hopkins for orthopedic injuries of which has two separate components to it, one of them is acute care and the other one is long term rehab.

We were looking both at the acute issues of survival and the long-term issues of function underneath all these things. As I said, we have tried to do -- we've had two blood banks involved from two individual centers that are willing to provide blood that's fully FDA approved, but it's 24 hours old. Okay.

The IRB objects because it's 24 hours old. It is not an hour old like -- so we're really not comparing what we would normally do.

So they don't feel that it's appropriate to test this in civilians when it doesn't answer the question of how the military uses the product.

DR. LUEPKER: So what would you like to do next?

DR. WADE: On this one?

DR. LUEPKER: Yeah.

DR. WADE: I would really like to do the 24 hour study using fresh whole blood to replace component therapy in the ED.

DR. SHAMOO: I think having risk (inaudible) IRBs is no reason not to propose a study. I think we all benefit from education and training, and a proper education and training, and explaining the situation and I don't guarantee success but I think it's better than first not doing the study; and second playing word-smithing games with ethical issues because I think that's dangerous grounds for the media and/or other personnel. Let's put it this way. So, I think we need to have transparency, openness and forthrightness. It will serve us in the long run much, much better. (inaudible) I will go as much as I say (inaudible) of some IRBs shouldn't be the deterrent. And IRBs are getting more and more educated in these issues. This is too important just to leave it.

DR. LEDNAR: Dr. Oxman.

DR. OXMAN: I think given the very stringent criteria for the use of fresh whole blood that you've had in the battle field situation. I can't imagine the possibility of doing a controlled trial. And I'd like to congratulate you on the careful looking you're doing. I can't digest this in a quick presentation like this. I have to take hours to look over the tables, but from what I can see it's hard to imagine doing a better job without compromising your appropriately strict criteria for the use of fresh whole blood and I'd like to congratulate you and suggest that you think about how you can, you know, make it a little bit more stringent.

Obviously if people live longer with massive wounds, they're going to have lots of complications than people who die in 24 hours won't have. So that's something that doesn't deter me at all.

So, I'd just like to congratulate. I don't completely agree that this, while it's open to potential bias, I still think it's

about the best I can imagine you doing in the field situation.

DR. WADE: Thank you. I'd like to raise that point again about, you know, how we have to track what we do in theater. You heard the Sergeant talk about a lot of the products that he is using, right. We are tracking them. We are not doing -- we're doing it for safety and effectiveness. Does it really work? Should he even be carrying it if doesn't work? Number one. And number two is that there is a safety issue that we're responsible for looking at. That includes the use of tourniquets, the use of Hextend, intraosseous infusion of fluids, HemCon, now we've got combat gauze. We've got a lot of products that we have pushed out as the military that are never going to be used in the civilian environment.

DR. PARKINSON: I'd like to second all the comments made, but on this issue of how much is enough and when do we let sleeping dogs lie, so to speak, I'd like to back off for a minutes and say how we got in this

situation from perspective.

The advances that we have in military doctrine moving care forward, personal protective equipment that allowed soldiers to survive injuries that would have killed them in the last war, unfortunately everything we needed to support life sustaining in the full component of care didn't move equally forward at the same time.

Blood and blood products was a clear area that did not. It came to the Board and the Board said, "Whoa, hold on a minute here. What's going on with this fresh whole blood?"

And you cited correctly 60 years or 100 years. When I was in the service it was like that's why we had HIV, because we had to have walking blood banks. So we had to have a HIV screening program and it better be every month because we got to use that walking -- it was just in the mantra.

Now you've come back and your team has come back and said, you know what, 85 and 90% of the time it was a logistic resource problem. We got the three services together

who basically had very disparate blood banking practices, did a classic quality improvement exercise and you eliminated variation and delivered a better product, safer, more accepted by the medical community, more accepted by Congress just because of the way it is.

So I don't know that we collectively or even want to encourage, if we're on the right track to go back to a fresh whole blood is it really useful or not absent a clear piece of new medical or scientific information that something in fresh whole blood is compellingly better than component therapy which I don't think is out there beyond some very difficult methodological permutation of propensity analysis, which I'd have to go look that up somewhere and see how you basically risk adjust what you think are scores beyond 43 hours. Very difficult I would think to justify as to why I want to go forward with something more aggressive to study fresh whole blood.

So my personal thing is, you've done

a great job, cease and desist, let's get on with solving the last 15% of logistic problems and somewhere way in the back of our minds, yeah, it's reasonable, someone's dying and I've got nothing else in front of me and I got to get some blood in the guy, I'm going to roll up my sleeve, but beyond that I don't think it deserves much more.

DR. LEDNAR: Dr. Halperin.

DR. HALPERIN: Sometimes it's nice to see kind of the development using traditional means of analysis before you see a jump to presentation of the most modern means of analysis. So you have -- I don't know what it is, 2,000 people who are either transfused with red blood products or had to be given something and the only thing that was available was whole blood because the blood products weren't available if that's what I understand.

And then when you looked at those two groups, they were different, but I don't think you present the univaried analysis and then the traditional logistic regression

before you go onto the propensity scores. And it might just be, in ruminating about the results, it might be interesting to understand what those results are, so you know when we're on the higher plateau of the most modern epidemiology that we feel the confidence that it's a robust analysis because --

DR. WADE: I didn't lay out the full (inaudible) discussion.

DR. HALPERIN: I understand. And we all do that when we have a limited amount of time, but it might be interesting to pull the univariate and the normal logistic together and show us what those results are as well as the highest level, which you did. Yeah, I mean, I'd like to see those, see how they compare.

DR. BULLOCK: I think that you should be congratulated on putting these together. I think that these data on massive blood transfusion compare pretty well with comparable civilian series.

And when you consider this is being done in an austere environment, I think these

date are great and you know just as Dr. Parkinson said, this is a niche thing and you know I think that nobody's advocating this as being better than component therapy but it's there and it vindicates the use of it in special circumstances.

DR. WADE: Thank you.

DR. LEDNAR: Dr. Wade, I think you've received some good comment and feedback for you and your group.

Any other comments or suggestions?
Again, thank you for putting this --

DR. WADE: Dr. Jaffin has a comment.

DR. JAFFIN: Jonathan Jaffin again. Just a very quick comment. We've talked about extending blood products and a couple of the things that the military is working on, freeze dried plasma, frozen platelets and then even off the shelf platelets and things like that. So we're actively pursuing ways to avoid having to use whole blood because we would be able to get component therapy off the shelf no matter where.

So those are just some very active

research areas for us.

SPEAKER: I want to say, we've already prepositioned the study groups in order to take those challenges on when the products come down the line.

DR. LEDNAR: I think this whole discussion illustrates how the Department of Defense has always been trying to push trauma care in the most challenging of environments to the very best clinical outcomes, to use what you've got and to look at your experience and understand it. And for that we really appreciate the efforts of you and your team.

DR. WADE: Thank you.

DR. LEDNAR: One last comment from Dr. Kaplan.

DR. KAPLAN: This may be a naive question but is there a compilation of the research, not just blood transfusions, but the research that can be directly tied to the last seven or eight years in terms of combat medical research? Does the DOD keep this kind of information? I mean is there a place one can look to see about this or any other

subject?

DR. WADE: All of our prospective trials are on clinicaltrials.gov. That's one. Number two is that all this is put before the IRBs, so there is the record within the IRBs and HERO, which is our big IRB, has a full listing of all the projects that have been undertaken.

DR. KAPLAN: On this and other topics?

DR. WADE: On all of our activities both in theater and back here in the United States.

DR. KAPLAN: And can you maybe make that website available to us, please?

DR. WADE: That's up to Dr. Jaffin here.

DR. KAPLAN: Or whoever, somebody.

DR. WADE: Yes, it is.

DR. KAPLAN: Thank you.

DR. JAFFIN: We'll make sure we get it to you.

DR. KAPLAN: Okay. Thank you.

DR. LEDNAR: Okay. Thank you very

much, Dr. Wade.

DR. WADE: Thank you.

DR. LEDNAR: Thank you. Okay, our next speaker is Ms. Anne Moessner.

Anne, in addition to serving as Chair of the Congressionally-mandated TBI Family Caregivers Panel, Ms. Moessner serves as an Assistant Professor of Nursing at the Mayo Clinic College of Medicine, TBI Clinical Care Nurse Specialist in the Department of Nursing, as well as Project Coordinator for the Mayo TBI Model System of Research within the Department of Psychiatry and Psychology at Mayo.

Ms. Moessner will provide an update regarding the activities of the Panel and progress from the developments of the TBI Family Caregiver curriculum as requested by Congress.

And her presentation slides may be found under tab 12.

Ms. Moessner.

MS. MOESSNER: Great, thank you so much. I'll hope to get done in about 15 or 20

minutes, so I don't delay people getting off to dinner this evening.

As mentioned, I'm going to talk about the TBI Family Caregiver Panel that's been meeting for roughly 18 months. So some presentation objectives: review and update you all on how things have gone since we last reported, which was back in Key West in March, I believe. And we'll review the timeline that we're currently under and outline the agenda for our final Panel meeting, which is coming up in October.

Just as a reminder, this was a Congressionally-mandated Panel. This information is in your handout, but the mandate was to pull together a 15-member panel to develop a curriculum for family caregivers of the soldiers returning with traumatic brain injury.

The Panel is a diverse Panel. The law stipulated that, again, a diverse membership of people who had sustained injury, family caregivers, civilian experts, representatives from the various branches of

Service, from the VA, and so forth.

As a quick aside, we were -- our appointments were just renewed this past summer, so those are good for one more year.

Basically, we've been very delighted to be working with DVBIC as a partner on this project and I'll acknowledge Cathy Helmick, who is here today and who may be able to field some questions as she's been fairly involved in the project and her staff has been really an invaluable asset to myself as the Panel Chair, but to the entire Panel Committee.

Again, our tasks were to review the current literature to make sure that the educational curriculum that we put together is evidence based to develop a consistent curriculum to be used by DOD and VA sites because there had not been anything that was consistently being used up until now. And then also that we address dissemination of the curriculum.

We did, at one of the early Panel meetings come up with a definition of family caregiver, which again I won't go over at the

moment. And, again, you can see in your handout the proposed or the intended benefits of the curriculum.

A brief review, most of you have seen this before, but just a brief review of the format of the curriculum and that was to pull together a series of modules. Module 1 being an introduction to traumatic brain injury. Module 2 being a fairly in depth review of the common affects of traumatic brain injury raising from physical to cognitive, emotional, behavioral and so forth. Module 3 on how do you become a family caregiver, that process, that journey. And then Module 4 would be trying to help family caregivers navigate the systems that they will encounter during their caregiving journey.

Our last face-to-face meeting was back in January in Washington D.C. and we had been functioning in module workgroups up until that point in time. At the January meeting, because the content had been fairly pulled together by then, we reshuffled ourselves into new groups, working groups, to look at design

and editing, multi media, the qualitative process review, the dissemination aspects of the curriculum.

And at that point in time, there had been discussion up until that meeting, but at that point in time, there was reconfirmation to not only develop and finalize and disseminate this curriculum for people that had experienced relatively severe traumatic brain injury, but that the Panel felt very strongly about continuing to work towards developing a smaller piece addressing mild traumatic brain injury on all the complexities that go with those who sustain a complicated mild injury.

So I'll be giving today some updates from the newly-formed workgroups and what have we been doing from January until today.

The design and editing group, which I was the most involved with, really finished out all the final edits of the content. We looked at lay-out, design. We worked with the Henry Jackson foundation on packaging.

And, by the way, I brought one copy.

It's large enough that I could only fit one in my carry-on suitcase, but that's going around the table now just so you can see what at least the draft curriculum looks like. It will be tweaked a little bit based on feedback, but it's fairly extensive. But the Henry Jackson Foundation very helpful in terms of packaging and putting together this module product.

We completed some acknowledgments. We also -- the writers that we hired to work with us interviewed several family caregivers so that vignettes could be woven throughout the curriculum. So we finished out the acknowledgments to those people who were kind enough to share their stories with us and with the future readers of the curriculum.

There was consensus. There was much discussion on reading level and literacy for this curriculum and we decided to stick with an eight grade reading level and I'll let you know how that turned out in the focus group review.

There was strong feelings about

making it, the curriculum, usable, user friendly, but also including some piece which could be a handbook for the caregivers that are caregiving for individuals with traumatic brain injury, a workbook type tool so that they could keep track of appointments, medications, their team members, those sorts of things. So that was included in the final draft curriculum.

And then we worked to photocopy or to -- excuse me -- to package, and copy, and create about 100 copies of the curriculum for roll-out to focus groups, so that before this curriculum was finalized and put into use across the country, that we had to go before focus groups to get feedback.

Again, the actual document is going around, but just a couple of slides to show you what the layout looks like based on the Henry Jackson experts in graphic design, layout, working with the writers and with our design and edit group. There are a lot of graphics. We used a lot of bullet points. Each module has a little different design to

it, but there's some similarities from one module to the next.

So, as you can see, these are the cover pages for the four different modules that were put together. We are continuing to work with CEM, which is the Center for Excellence in Multimedia, and the military, and Lieutenant Colonel Randy Moffrey who works for the Air Force and is the leader of the CEM unit.

We have worked very carefully with him and have been really delighted at their response to working with us on this. They had already started work on a TBI website out of the CEM and were able to put a caregiver button onto their homepage. And I'll show you a couple of slides about how we've been able to work together.

First, just a little bit on the mild TBI piece. So, again, we were pulled together to be a family education, caregiver education panel and we will be working on the mild piece. That continues in process. It's been hard for us to figure out what already exist

in the VA and the DOD in terms of print materials or online materials for caregivers or for families, maybe they're not a direct care provider, but they're certainly involved in the injured parties life and, you know, usually are in need of some kind of education and support. So the goal is still to create about a 20 page, much smaller, document or booklet so that the families can have something in writing and online about mild traumatic brain injury and the complexities. So we're working with Dr. Fred Flynn, who is at Madagan and he's the head of the neurobehavioral practice team there, on finalizing the content and getting that reviewed by other people. So this is the basic layout of the mild TBI content.

Colonel Moffrey and the CEM group already has some information on mild TBI out on their website. So here's a multimedia face page. Again, they gave us our own button so that future users can easily find our information. The modules will all be posted as PDFs on the CEM website. The actual

website link is available in your handouts.

And of course this portion of the CEM website will continue to evolve as we finalize our curriculum and roll it out. Again, Lieutenant Colonel Moffrey has done a really nice job of putting out graphics. There is video streams. Again, it's a true multimedia accessible website for family caregivers, complete with an interactive brain, so people can actually very easily learn about the different parts of the brain, how do they work, what happens when they're injured.

Again, video streaming of experts, also from other family caregivers so that there can be some connection from current family caregivers to ones who have been at this a while and have some experiences that they could share.

So moving on from design and editing, the other workgroup that was formed had to do with getting this information before future end users and getting some feedback before we roll it out. So this group -- there

was a bidding process that occurred. We worked with the Alan Newman Research Group based in Richmond, Virginia, to hold a series of focus groups. They found -- we used four sites in Tampa, Fort Bragg, Walter Reed, and San Diego. And they really looked for a representative group of about 50 currently family caregivers who had a range of experience in terms of how long they had been caregivers, what Services they were associated with, urban versus rural individuals, a variety of cultural backgrounds, that sort of thing, active duty, retired guard, that sort of thing.

So there was strong interest in making sure that the groups that were reviewing were representative and diverse.

We were originally scheduled to run the focus groups the last two weeks of July, but I will share with you that a complaint was actually filed, submitted to TriCare TMA that maybe this needed to go through human subjects review, was this a research type activity. And we didn't think so as a panel, but a

complaint was filed and the staff at DBVIC put together a response and we did get a word back from -- after a short review process that from the deputy office of research protection saying that they did not feel this was a research activity and that it was really just trying to get feedback from future end users.

And so that created perhaps a one to two week delay, but we did go ahead and hold the groups the end of July, first week in August. And I was able to get a report, which I'll share with you, at least a brief oral report from the Alan Newman Research Group about what the groups thought about the curriculum so far.

So, bear with me, it'll take just a couple of minutes to review at least a few high points. We will be getting a very detailed written report in about the next two weeks and the Panel will review the written report and revise the curriculum based on the feedback gotten.

But what we heard so far was an extremely positive review of the curriculum,

95% of the people that were in the focus groups rated the curriculum a four or a five on a one to five point Likert Scale. Many comments, "I wish I would have had a guide like this when I became a family caregiver."

Even the most experienced family caregivers felt like they learned something new. They were all relatively surprised at the size of the curriculum but after further review, because it's extensive and there was a lot of discussion on the panel about trying not to overwhelm family caregivers, but after some discussion and looking through the entire curriculum and talking with the facilitator, the focus groups, they decided there was nothing they would have wanted left out. So though it was large, they appreciated that it was comprehensive and that it had the information that they really felt like they needed.

A couple of the criticisms, again, related to the size of the document or the curriculum. A little bit of wasted space. A little bit of repetition of information from

module to module, maybe too many vignettes woven throughout the curriculum. So there was some discussion about maybe taking a look at that in order to downsize a little bit, which we will certainly do.

Most found that it was extremely easy to navigate, which we were happy about because we spent quite a bit of time talking about color coding and tabs and trying to make this modular and easy for people to find the information they were interested in finding. People liked the layout, the color, the design, the bullets.

There was positive response to the tone relatively hopeful tone, but also a factual tone. And they also thought it was about right in terms of health literacy. They appreciated that it wasn't dumbed down. That was a quote from several of the caregivers, but that it also wasn't overly complex. So we seemed to hit about the right mark, at least according to the feedback that we received.

Other comments, we tried to weave in some forms throughout the module that could be

useful forms as in again lists of medications, questions I want to ask my provider next time we have an appointment. So, some of those practical forms were woven throughout the curriculum. A nice positive response to that sort of workable tool.

In the front of the booklet that's going around, we did include this companion's guide to caregiving, which again would be something that the person could use and take with them as they go on their visits or continue on this caregiving journey. They would like that reduced down a little bit so that it would be more portable and easy to take out with them.

Mr. Hoff from the Alan Newman Research Group said the homerun that he felt like the group hit, the Panel hit, on putting this together was the caregiver's companion, this very useful tool that they could take around with them.

We also got very positive response from the pictures of the brain, the basic anatomy lesson that was provided in Module 1.

They really liked Module 3 on becoming a family caregiver. There were several comments about this felt like the first time that was really acknowledged and addressed for many of the family caregivers.

They also very much appreciated Module 4, which was trying to navigate the system. Kudos to the writers that we've been working with because the first time we tried to explain the systems of care from insurance to return to work to acronyms that I certainly don't understand and programs that are very difficult to comprehend, it was about 200 pages and it was at a health literacy level of grade 17. So we got that reduced way down and down to an eighth grade reading level and down to a module that's still fairly lengthy, but it was really designed to be a reference module for family caregivers versus something they needed to read, you know, page-by-page. And so that was much appreciated that that was something that seemed to be useful for them.

We also included definitions, terminology, military rank, all of that

information within that module as well, which they thought was helpful.

In terms of an online copy, over 75% of the focus group members said we really do want a hard copy, but we -- about 75% also said they would go online. They particularly like them as a primary caregiver to have a paper copy, a hard copy. They thought the online version would be extremely helpful for extended family, the other members in their circles of support. So they were strongly in favor of having many versions of the curriculum available, including a companion DVD, which will be available as well.

In terms of dissemination, the feedback they gave us was they would like this handed out in person by someone who's intimately involved in their care so the Dissemination Committee will be tackling that in the coming weeks before our next Panel.

Most said they probably would like it all at once, the curriculum handed to them all at once, but with some considerable explanation about they don't need to read the

whole thing, they may want to focus on certain areas as they're starting their journey, but that they would really like it early in the caregiving process and not later down the road.

We though their comments were very insightful. Again, we're expecting a lengthy typed written report and we will, as a panel -- it will start with the editing workgroup, but then the entire panel will have access to the comments and we will certainly tweak the curriculum based on the feedback.

Okay. So dissemination again, that group has been hanging back a little bit, but they are actively meeting again and I will be joining them on their future meetings over the coming weeks to figure out how are we going to disseminate. These were some recommendations that were made several months ago and these will be tweaked.

Our next Panel meeting is in October in the D.C. area. We're looking to have final approval of all the curriculum modules by Panel members. We hope to have the mild TBI

piece far enough along for the group to react to that and make a plan for that.

The marketing distribution plan we're hoping to approve. And then also we will be putting our heads together about who and how the curriculum will be maintained. And we have discussed that with all of you in the past a couple of times.

Again, the basic timeline we're projecting is -- the first several I've already spoken to. Our Panel will meet in October. We're hoping that at the November meeting of the DHB that we can seek your final approval of the curriculum and so one of the questions I'll have when we get to Q & A is: how might that happen? Can you give me some guidance on does every member of the DHB want a copy of the curriculum mailed to them? Do they want perhaps the TBI subcommittee or the psychological health subcommittee to work with us to have a look at it before it comes out to the whole Board?

So, if you could think about that and have any comments for me, that would be

greatly appreciated.

And I'll go ahead and entertain questions at this time.

DR. LEDNAR: Thank you for that. I think we can all see from Anne's report that the Panel has been very, very busy in developing a material and being very thoughtful about getting reactions to end users and accommodating that. And I think when Congress sees this final work product they are going to be very, very pleased.

Questions or comments for Anne? Dr. Poland.

DR. POLAND: My first comment is: wow. My second comment is: wow.

MS. MOESSNER: It was a bit of work.

DR. POLAND: My third comment is: wow. I just had a couple of thoughts and well done from -- I've obviously been following this.

Does the website or the interactive part have any sort of social networking aspect to it for these variety of families that, you know, will be scattered all over the world

potentially?

MS. MOESSNER: You know, that's been discussed. I don't know if Cathy -- I don't think it has at this point in time. I can't say I've gone out on the CEM website extensively. I know it's been discussed. So I'll definitely put that on the agenda for our next Panel meeting to think about. I know a lot of the family caregivers -- the clinical staff say they do tend to refer the family caregivers to brainline.org, which is also DVBIC is heavily involved in and that's funded by the DOD as best I understand, and that has vast capacity for social networking.

DR. POLAND: My second is really sort of a comment, and that is this would seem to me to be a model for a type -- a way of educating that could be generalized across a whole lot of things. I mean, for example, we were just talking about how do we educate everybody about H1N1 and about the vaccine or about side-effects you might experience, you know, et cetera, et cetera. And I wonder if there is some mechanism or way to think about

infusing this concept through the multiple things we do because it's enduring. And that's where we often, you know, we do something and then it gets lost over time.

This is enduring and particularly if it were online, it wouldn't necessarily have to cost very much.

MS. MOESSNER: Right. Yes, thank you for the comment.

DR. LEDNAR: General Myers, I think Parkinson, and then Dr. Fogelman.

Gen (Ret) Myers: Anne, great presentation and I didn't pick it up in there, maybe I missed it, but -- or maybe you didn't cover this particular aspect, but how much has this been socialized with the medical providers, the physicians that are going to be working --

MS. MOESSNER: Actually, that will be part of the -- when we did the focus groups, there was definitely contact with clinical staff at the sites where the focus group was held. And you know they were pleased with the product. We didn't do formal

review with them, but certainly as part of the dissemination plan, which is forthcoming, it needs to be a massive marketing campaign throughout the DOD sites, the VA, you know the very large and complex VA system.

So that is really the next challenge that we are facing is, you know, how do you get all the way down to the clinical care staff. We have several staff on the panel who work in clinical type positions and have contact with family caregivers who have some ideas, but I'll tell you that it's still -- that is still being worked on.

Gen (Ret) MYERS: I guess I wouldn't underestimate the difficulty in getting, you know, widespread buy-in throughout the community and if you don't then it seems to be the product would not be as useful because you know, you'll hear all these negative things about the product.

MS. MOESSNER: Right. Yeah, we'll be mindful of that. And, again, the Panel fortunately has consisted of representatives from the areas that I think will, you know,

receive the product and you know they're going to be sort of champions of the cause and be out there on our behalf.

DR. LEDNAR: Dr. Parkinson, Dr. Fogelman and Dr. Mason.

DR. PARKINSON: Also, kudos. I mean just phenomenal, Anne, very good. I'd like to be a little more proactive along both Dr. Poland and General Myers' comments. I think absent social networking, absent linkage to the clinical process, this will have 20% value. Five years out it will be very difficult to even find it.

I mean the history of curriculum efforts unfortunately does not bode well absent making them organic and built into the process. So I hope between now and November that we can maybe see a proactive plan --

MS. MOESSNER: Okay.

DR. PARKINSON: -- in the areas of building it into existing social networking processes, because people are hungry for this. That's why these sites are taking off. That's why large health systems are saying, "How do

we leverage people to people power in care management in chronic disease management?"

It's got to be there.

Similarly, when we have a IT system, personal health record, EMR, EHR, we should see a plan for either integration or linkage of this curriculum into the PHR process. So if I'm seeing a patient at Langley Air Force Base whose got this condition, I should be able to click and link or put out a prescription for competency for the family caregiver, lifestyle and behavior change, it's all about medicalizing the behavior change prescription. I could see a prescription for this curriculum that is given to the family member, this is your homework.

Two final points. I would push back on eliminating or cutting down on vignettes. To my read, there is not enough.

MS. MOESSNER: Okay.

DR. PARKINSON: And furthermore, the vignettes don't have pictures. If you could get any of those people to put their pictures next to their quote -- as it is, it's just

more verbiage and it's very text rich. I would go with more pictures, less text.

MS. MOESSNER: Okay. I can't remember if that was discussed, but --

DR. PARKINSON: And not cut back on the vignettes. But just, again, my impression of our own marketing efforts in my own company where we were.

And then the final thing is: consider issuing -- two other things. I don't see something right up front that says, "If you complete this curriculum, here is what you will obtain." In other words, what are the competencies in simple clear statements? You will be able to do the following things for your loved one: 1, 2, 3, 4, 5.

In other words, why bother? Because it is daunting when you lift it up and look at it. It's like, "Oh my God. It's too complicated." And it may actually create -- these are people who are already experienced to family caregiving, but to the new family caregiver, it's like, "Oh my gosh, I knew I needed to be -- you know, just offload this to

a medical provider."

And so a crisp statement of what you can do when you do this, it would be very compelling.

And then the last thing is: people love stars and certificates. You should issue a certificate as a family caregiver. It doesn't have to be NCQA, but it's something that -- this is a lot of work. If I go through this book, I mean -- and then they should -- and that becomes a club that people belong to. "I'm a caregiver. I go to my social networking site. I get periodically updated because now I've got a process where I got to make sure a year from now if there is new evidence or science, it's in the curriculum."

So now you've got an organic process. Really, really great work.

MS. MOESSNER: Thank you, very good suggestions.

DR. LEDNAR: Dr. Fogelman and then Dr. Mason.

DR. FOGELMAN: Well, I too think it

was wonderful. I haven't been able to think of another adjective which will exceed that, so I'll leave it at that.

But I want to agree with and add on one dimension to the last three comments. You don't know if it works until you evaluate it in some systematic way. Greg talked about, "Well this is so good we ought to apply it in other realms." There are other comments about what does the provider community think, you know, how do we make sure that the people use it.

Well the way to know about that and to know whether it's useful and whether it's transferrable, is to create however, and however larger or however small, a way some kind of systematic evaluation of the product when it goes out over it's first year of life. And then we can say things like, "Hey, this is really good and we ought to, you know, reproduce it or spread it around" or "This is the piece of it which works, this is the piece of it that doesn't work."

MS. MOESSNER: Absolutely. Actually

I failed to mention that, but that will be part of the maintenance. You know, as soon as we hammer out the details of, you know, who actually would be maintaining the curriculum, updating it, making sure the content is still accurate, but we will have an evaluative process built in. So I'm hoping to have all those details available at the next meeting.

DR. FOGELMAN: That is evaluating the impact and utility for the families?

MS. MOESSNER: Right. Yes, sir.
Thank you.

CAPT NAITO: Again, just one comment. Probably the most important target audience to get disseminated would be the case managers. We've all hired hundreds of them throughout the military. And also the military ones who (inaudible) the Marine Corps for life programs, things like that.

And the other consideration is making it mandatory, you know, that it's handed out. So, again, if you just leave it out there as something that's a provision, it has a risk of losing it's dissemination over

the long term. So, again, this is something we care enough about that we had you spend all this time and I think it should be made mandatory.

So, some sort of consideration for a mandatory giving out to patients.

MS. MOESSNER: Excellent. Yeah, they're having discussions about at what site is given out, how does the next site understand that it was already given out and not tucked away in a backpack somewhere or lost in the shuffle, but there needs to be some way of communicating that it's been given out and that people are continuing to review it and checking with the clinical staff on their understanding of this massive amount of material from acute care to post acute, to you know several years post injury.

DR. LEDNAR: Last comment, Dr. Mason.

DR. MASON: My sincerest compliments. In Germany we would say, (inaudible).

MS. MOESSNER: Thank you.

DR. MASON: And what I would like to offer for your consideration very simply, is it's fine to have print copy, but it's like our preparedness plans, once they're printed they're way the hell out of date.

MS. MOESSNER: Yeah.

DR. MASON: It's fine to have. It gives somebody something to hold onto. What you have outlined very simply is something that is going to live and the only way it's going to live is if it's going to be modified with some regularity.

So I would love to volunteer the James A Haley VA, which has the largest patient base of veterans in the United States, since we happen to be one of your acute and mild traumatic brain injury sites, and volunteer my clinical colleagues in both psychology and in clinical medicine, to stand up as spokespersons for the utility and to select a few families in the Tampa/St. Petersburg area to basically promulgate.

We have a massive program. I have to be parochial. We have a massive program in

social marketing. This is what it is.

MS. MOESSNER: Yeah.

DR. MASON: And what you want because you don't have time on your side. This is a drop dead unbelievable killing agenda that you've been living with. If you're going to get any sort of evaluation in two months, you better bring in some people right now who are right there in the front lines to gather some information that you can then utilize because the report itself is outstanding. The learning objective is stuff we all do in academic medicine. You're going to take this -- what's the take home? What will your competencies be? What are our learning objectives that we're attempting to import to you?

But congratulations and I feel very confident that my colleagues in Tampa would be more than receptive of your phone call.

MS. MOESSNER: And is this Arisa and Rodney?

DR. MASON: Yes.

MS. MOESSNER: Is Dr. Richardson and

Dr. Vandequil?

DR. MASON: And Scott and Audrey
Nelson.

MS. MOESSNER: And Scott and --

DR. MASON: And everybody that we
work with in Tampa.

MS. MOESSNER: And actually I know
all four of them. Actually I have them on my
list.

DR. MASON: Well call them.

MS. MOESSNER: I'll do that
promptly. Thank you. Thank you for that
offer.

DR. LEDNAR: Okay. I have to cut it
at this point, but I think you feel real
enthusiasm, Anne. Please convey that to the
Panel and our appreciation for the hard work
that you're doing.

MS. MOESSNER: And we did extend
great thanks to the focus group members as
well because they had to read the entire
curriculum and sit with a facilitator for some
amount of time. So know that we did extend
particular thanks to the focus group members

as well.

Thank you.

DR. LEDNAR: Okay. We have three remaining items: one is a short update as feedback to the Board and two votes of the Board.

So we're going to start. Commander Feeks has agreed to give us, the Board, some feedback to a recommendation that the Board made and was delivered to the Department of Defense regarding the Warren Air Force Base Serum Repository.

So, Commander Feeks if you'd share with us what you can about what discussions or decisions or steps have been taken by DOD in response to this recommendation.

CDR FEEKS: It's Commander Feeks.
Thanks, Dr. Lednar.

You may remember that at our last meeting the Board accepted the recommendation in regard to the Warren Serum Repository, that this recommendation was formulated into a memorandum that was signed out by Dr. Wilensky and Dr. Poland, and dated July 8th of 2009.

It was given to Ms. Embrey and she assigned it to be worked. It is being worked. Progress is being made and that's the status of that and I think it's a good thing.

And that's all I had.

DR. LEDNAR: Okay. I think what I would just add to that from my view is that the recommendation was received, it was thoughtfully considered, it's on a path to have the current steward of the Repository, Dr. Kaplan and the University of Minnesota, transfer this DOD asset to DOD to have adequate support to it in terms of funding and oversight, that because what this is, is really a package of sera and accompanying medical record information about those Servicemen who are in the Repository. That's maintained by Dr. Rick Erdtman at the Medical Follow-Up Agency, so the solution that is being developed is really putting the whole package together.

So when there is more to report, we certainly look forward as a Board to hear that. And from all of us on the Board, we owe

a big debt of gratitude to Dr. Kaplan for his decades, literally, of looking after and making sure that this vital resource for DOD is well attended to.

So, Dr. Kaplan, thank you. Okay.

First of the two votes: the Health Care Delivery Subcommittee has been actively working. In tab seven there is a draft memorandum, which I'll just say a few comments in highlight.

And this is a discussion that was first in a live meeting in July, July 15th, and then a follow-up telephone conference call on the 13th of August, around Centers of Excellence in the Department of Defense.

And this was started by a briefing by Dr. Jack Smith, who's the Acting Deputy Assistant Secretary of Defense for Clinical and Program Policy, and Dr. Gary Matteson, whose the Acting Director for Clinical and Program Policy Integration.

And really the were asking the Defense Health Board, the Health Care Delivery Subcommittee for some thought guidance around

Centers of Excellence. And in the draft memorandum -- and I'll just sort of lead you to -- we are being asked to vote as a Board on this communication. So this is a initial memorandum, an initial written communication back to Dr. Smith, in a quick way to help him as he is putting some thoughts together, but there will be more deliberation to follow.

But what struck me about the Centers of Excellence as a concept where a number of questions and charges have been placed -- I don't mean legal charges, I mean requests to establish Centers of Excellence on such clinical issues as hearing loss in auditory system injuries -- and all these, by the way, are outlined in your memo -- treatment and rehabilitation of traumatic extremity injuries and amputations -- by the way, each of these are separated COEs, so what I think you'll see is there is a portfolio of topics -- that the diagnosis mitigation treatment rehabilitation of traumatic brain injury, post traumatic stress disorder, other mental health conditions, this applies to both the DOD and

VA. So this is not just a DOD concept in terms of Centers of Excellence.

It's also to include thoughts on partnerships between the government and private and academic institutions. So this is not a sort of an internal solution, or at least that's not what's being thought through.

Implementing comprehensive patient tracking registered by the COEs. Access to promote and assist in research efforts coming out of the COE activities.

You're going to say, gee this sounds like, you know, soup to nuts. And, in fact, it is.

Coordinating care and rehabilitation for separated and retired military personnel. So it's not just active duty.

So with all of that said, the Health Care Delivery Subcommittee came up with several initial recommendations in this written memorandum which we are asking the Board to approve. And the highlights are that the Department consider developing strategic plans that clearly define the mission of each

center, COE; that these missions are consistent with actionable goals and objectives which are militarily relevant; be mindful of DOD's ultimate need to focus on Force Health Protection and Readiness. And I think at this point I'm going to ask Mr. Middleton, whose looked at these, who also has a thought to add I think that will strengthen this recommendation.

MR. MIDDLETON: Sure. Obviously the principle mission of the Centers of Excellence is their research. And in June of 2008 the Secretary of Defense drafted a memorandum to the Deputy Secretary of Defense, at that time Mr. England, directing a series of things, one of which was to -- given all of the dollars that we spent on research to focus the effort or some of that effort, anyway, certainly on military relevant medical research issues.

As you know, we are funded for things like prostate cancer, breast cancer, cervical cancer, for research as well, which are necessarily unique military issues, but certainly there are some that are relevant.

And so what I had suggested to Dr. Lednar was -- only for your consideration -- is that the end of that Section 16A, perhaps to consider adding something after readiness, something that would read "need to focus on force health protection and readiness and unique military medical research" or something along those lines.

I think that would be -- I think that's important for the Board to state that because I think that's really what we want to have some focus on those military issues. So I offer that for your consideration.

DR. LEDNAR: DOD if they are autonomous and that there be metrics to measure their success as they operate.

And, lastly, that there be a strategy to maintain critical capabilities in the COE over time. One of the examples of that point that we have been hearing is in the area of amputation and limb loss. The good news is that there are fewer of these injuries returning from Iraq and Afghanistan. The challenge to maintain clinical capability in

the face of declining patient volume, is how do you do that. And how do you maintain that capability in a way that if it's ever needed again in the future, we don't have to start from ground zero all over again?

So what would follow this written memorandum, if approved today by the Board, would be additional discussion on governance. And while that topic was raised in the two meetings of the Health Care Delivery Subcommittee, it was also an important one that we didn't want to have an artificially accelerated and superficial discussion. So there will be more work by the Board Subcommittee on governance.

I might just ask Dr. Shamoo, for one, who has been part of this discussion, are there any other comments that you would like to --

DR. SHAMOO: No, all I want to add is Mr. Middleton's suggestion really was discussed, to be really honest, and there were sort of a consensus that that should be the case, it just didn't make it to the final

write-up.

DR. LEDNAR: We can incorporate those words.

DR. SHAMOO: So I would suggest that we vote on it as amended and move on.

DR. LEDNAR: Dr. Clements.

DR. CLEMENTS: Was there any discussion about periodic re-evaluation of the purpose and whether or not they're meeting their objectives? I mean we establish Centers all the time with no sun-setting provision. So to have some consideration of periodic re-evaluation to make sure that they're staying with their mission or that they're accomplishing their objectives. Some indices of success or phasing them out.

DR. LEDNAR: Well this written memorandum includes the recommendation that metrics for COE's success be included. I think, John, what you're getting at really will fit naturally into the governance discussion to come. And part of that is the COE accomplishing what it was set out to do, is there a continuing need? Who makes those

decisions?

So, I think that will come naturally in part two, the next step.

Dr. Silva.

DR. SILVA: This is a very important document. I can tell you at the University of California we struggle with this problem. All these things become self-sustaining and sort of disappear. We have a rule that at the fifth year of existence, before any additional funding, there is a full review and generally there is a review committee who measures success, et cetera.

And the expectation is that these Centers should not exist more than 15 years because they do have a way to just gobble up resources, space, et cetera. You want to make certain they can sustain a viable mission.

DR. LEDNAR: That's really helpful input that we'll take back to the Health Care Delivery Subcommittee.

Dr. Oxman.

DR. OXMAN: Just a question. As I read it, the two Duncan Hunter-sponsored laws

funded the eye and the hearing, but not the other Centers of Excellence. Is that correct?

MR. MIDDLETON: That's correct that they funded the other -- the Center of Excellence for TBI and PH, was separately funded in the '07-'08 supplemental and then further funded. And then some of the Centers, like prostate and cervical and breast cancer, are actually funded by Congressional ads each year. They're not funded in the base budget.

DR. OXMAN: Thank you.

MR. MIDDLETON: Yes, sir.

DR. LEDNAR: Dr. Luepker.

DR. LUEPKER: Yes, you know, I both participated in the July 15th meeting and the conference call last week. Mr. Middleton's comment about research, I certainly would endorse, but there were people in the room that read the law as making these clinical centers of specialization rather than research centers. And I think there is some confusion over that. I'd be glad to put research back in.

DR. LEDNAR: Thank you. I don't

know that that necessarily affects these recommendations about COE in general for the DOD and VA.

Okay. Can I then ask, given the --
Dr. Halperin.

DR. HALPERIN: So the research is about issues that obviously pertain to veterans, but also pertain to military preparedness?

MR. MIDDLETON: The lessons that would come in the research in the evaluation of the center would both to improve the quality of care provided for those issues by the Centers and where they could to inform future decision-making about force protection and readiness.

DR. HALPERIN: Okay. I get it. So second question: this would all be new funding that would be available to the VA or would be a redistribution? It wouldn't be to the VA?

MR. MIDDLETON: My sense is that these would not be Joint DOD/VA Centers of Excellence unless they were specified by law to be Joint DOD/VA Centers of Excellence.

These would be -- because the Defense Health Board would pertain to the ones that were overseen by the Department of Defense, not the Veterans Administration. Not that they couldn't work hand-in-glove, but I think these recommendations would be principle to the ones managed by the Defense Health Program.

DR. LEDNAR: And the principles, I think, outlined in this memo, would logically extend to a well-run COE, no matter who would operate it, including the VA. I think some of the COE's have been established as Joint DOD/VA Centers of Excellence and these recommendations would apply to them. The DOD would have special ability to use these principles in those COE's that it operated.

Dr. Dickey.

DR. DICKEY: Well I think it's incorporating the question, but we got diverted to the VA, is this new money or is this DOD money that currently exist that might somehow then go to Centers of Excellence?

MR. MIDDLETON: Some of this is new money in a sense of new appropriation by

Congress. Some of this will be funded from the base of the Defense Health Program and we were asked to put money in our FY10 program and beyond to support, for example, the Vision Center of Excellence. So we found the money within the program and added it. It wasn't a substantial amount of money, but enough to get them going and started.

DR. DICKEY: And can I clarify before we -- because you want to get onto the vote, but I had to concur with the comments that have been made about the review at a set time. And you said it will be conditioned on the -- or it will be part of the governance discussion. Will we see this back? Or if we feel strongly we want that there, do we somehow need to amend the current recommendation?

DR. LEDNAR: The governance discussion will follow and the points about sort of a time limit establishment of a Center and review, and there will be a Review Panel, I think all comments incorporated into the Health Care Deliveries Subcommittee's upcoming

discussions. The Board will see a draft memorandum before a descent back to the DOD about governance. That discussion may, in fact, inform some other aspects of principle.

My sense, and I certainly look to others who are part of the discussion, that it was going to be helpful and much appreciated by Dr. Jack Smith if we could get this document approved by the Board and back to him even though we had not yet had the governance discussion.

Russ, would you sort of characterize it that way?

So, we'll get more licks at this to be sure. Dr. Fogelman.

DR. FOGELMAN: I got confused here about the question of research and clinical, and clinical applicability. The way this is going to go is (inaudible) back to the law and make the recommendation consistent with what the law is? Because, you know, since my Committee has this charge of dealing with the psychological health and TBI (inaudible), and so does Russ' committee, the question of

research, clinical, clinical research, or some other thing is not irrelevant.

And if these are going to be recommendations for all DCoEs either we are going to have a little bit more conversation about it, or I'm certainly willing to defer to putting the language of the various laws in and making it conform with that.

DR. LEDNAR: Well not being an attorney, and I'm thankful for that, but the laws that establish some existing COE's obviously had something in mind. This document describes principles in the discussion of the Subcommittee of a well-run COE. Whether or not those who wrote enabling legislation were enlightened or not, so I think this could in fact prompt more discussion back around the operation of existing COEs. Clearly they have to work within the constraints of enabling legislation. It would be very helpful to COE's as they stand up and haven't gotten going yet, it may in fact start building in to existing COEs strengths which weren't

initially anticipated by Congress,
potentially.

DR. FOGELMAN: Well, I'm still
uncertain here. So suppose you have a Center
of Excellence which is active in three
different arenas: clinical and research and
some third arena which will make up
(inaudible) arena, but that's not -- those are
not necessarily all covered in this
recommendation. If this recommendation in
fact does include the research phrase, does
that mean that this DCoE, which is dealing
with blue stuff has to find a way to get away
from the blue stuff and just go to the
research stuff?

I mean that's really the question
I'm trying to understand. What's the burden
to be placed on the existing and developing
Centers of Excellence?

DR. LEDNAR: I'll just take a first
crack at trying to answer that. The
activities of existing Centers of Excellence
that are consistent with the enabling
legislation are important to do, and to do

well. COEs that stand up in the future, this is a more complete inventory of dimensions.

I don't know that we really have any authority -- we don't have authority, we recommend, we don't have authority, that activities that we think would reflect a really solid Center of Excellence concept be considered in their construction.

One of the point that -- a little bit practical, but it was brought up by the Subcommittee in its discussion was the Center of Excellence does not necessarily require bricks and mortar. So the concept of a Center of Excellence could in fact be independent of a building. And that was a point that really should be kept in mind.

SPEAKER: (off mike)

DR. LEDNAR: Right. It may in fact be a more complete use of existing facilities, which is in fact one of the recommendations in this report.

Bill.

DR. LUEPKER: Is this silent on the issue of facilitating interchange with

academic institutions? Or does it encourage it or --

DR. LEDNAR: No, it is not silent. It is in fact explicit in recommending it.

Let me see if I can find the right sub-bullet in the recommendations.

DR. SHAMOO: Wayne, I think we're going beyond. This is purely to put our input now at the preliminary level. This is at a preliminary level and then all these issues will be discussed in the Subcommittee and a new written recommendation to the Board will come for your deliberation.

This is purely a preliminary quick view. We did not want them to move forward because they're going to move forward without our at least input and they were interested in our input.

I think this -- all these questions are wonderful and they should be discussed and deliberated upon, but I think it has nothing to do with this preliminary recommendation.

DR. LEDNAR: Paragraph B and D, I think, Bill, address the.

SPEAKER: (inaudible).

DR. LEDNAR: Yeah, 16B and 16D address that question that you have asked.

So as Dr. Shamoo has said, this is a preliminary communication by the Board back to DOD and Dr. Smith, in particular, which they feel would really be very helpful to the department's efforts in moving down this journey around Centers of Excellence.

So, at this point, I'm going to call for a vote which includes Mr. Middleton's additional words in paragraph A, at the end of A. And all those in favor say aye.

SPEAKER: Aye.

DR. LEDNAR: Any opposed? Okay, this memorandum is approved by the Board and will be finalized with Mr. Middleton's additional words and sent post-haste to Dr. Smith. And I'm sure from him he says thank you to the Board.

Okay. We have one last item and I'm watching the clock. And this is to just follow back. We had an earlier discussion. Dr. Fogelman suggested rewording his -- he in

fact very efficiently organized some thoughts together and has reword to suggest to us.

Dr. Fogelman.

DR. FOGELMAN: Well, it wasn't that efficient because the other folks on the talking group didn't save me a seat at the table so we only had three minutes before the start of the meeting this afternoon. So to incorporate the things which you are getting in writing and which I guess I'm going to show you here, but there is one thing that we left out, we left out the point that Dr. Dickey brought up, so I'm just going to tell you that something which is not written here, which I do want to include which will read like this: "These recommendations should be reviewed no less than two, no more than three years from now" or "from their adoption," whatever the language needs to be for that, because there seems to be a consensus about that, and we certainly would agree.

Okay. I'm going to find them here, Beth? No. I'm not going to find them here. I went past them? Really? I'll be darn, they

look just like the old ones. Oh, wait a minute, now come on, I didn't do that. No, no, no, I didn't turn it off. Did I turn it off? I didn't press anything other than backward and forward. All right.

Happily you have it in front of you to look at anyway. Too far. There we are.

Let me highlight the changes and if you'll follow along in your written copies in the numbers. In numbers 11, 12 and 13 what we did -- and thank you the folks who want to raise their hands and say that they volunteered and helped, thank you -- in order to make it parallel with and reflective of the questions which were asked, we put in introductory statements for 11, 12, and 13 so that the fact that they were referring to different pieces of the questions put to us would be clear.

So the first one -- otherwise, there is very little change. The first one is about short term affects and we just wanted to be sure that ABA was included because it's one of the EIBI group. The second one is regarding

long term affects (inaudible) comparative effectiveness. So that, we thought made clear what the difference among those things were and reduced the ambiguity. And we added in -- okay, that's the previous one which was there and we added this one.

SPEAKER: If I might, that actually does address, you know, Dr. Dickey's issue.

DR. FOGELMAN: Well, no, I understood Dr. Dickey to say that our recommendations for the Board are things that we the Board should look at again in a couple of years, rather than endorse it as open ended.

Is that not right Nancy?

DR. DICKEY: Well actually you addressed my issue by putting in the study. Somebody else said we should look back at this at some point in the future.

DR. FOGELMAN: Oh, sorry.

DR. DICKEY: That's all right, you got mine.

DR. FOGELMAN: Okay. Sorry. Well then whoever it was that I was accommodating,

I'm glad to have accommodated you and I'm glad also to have accommodated Dr. Dickey.

So those are our changes and it's late in the day, so if you all will vote to approve it, we'd be all happy.

DR. PARKINSON: We will approve.

DR. O'LEARY: No, no, the first slide, seriously.

DR. FOGELMAN: Which thing do you want me to review?

DR. O'LEARY: The ABA, it's about two slides --

DR. LEDNAR: I think it's paragraph 11 that Charlie --

DR. FOGELMAN: There?

DR. O'LEARY: Yeah.

DR. FOGELMAN: Okay.

DR. O'LEARY: (inaudible)

DR. LEDNAR: I think this is exactly the wrong direction. I don't think it reflects what the Committee talked about. It actually strengthens the statement that ABA is part of a sufficient --

DR. O'LEARY: That used to say may

exist. Is that right or am I wrong?

DR. FOGELMAN: That's correct. Yes.

DR. O'LEARY: It used to say "may exist" and it went from "may exist" to now "sufficient evidence exist."

DR. FOGELMAN: Oh, no, that's not correct. Thank you for pointing that out. It should be "insufficient evidence exist."

DR. O'LEARY: Big difference.

DR. FOGELMAN: No, no, I take it back again. Let me rewrite it. No, it's right the way it is. It's late in the day. I'm dying here, you know.

DR. O'LEARY: So what does it say?

DR. FOGELMAN: Well the "may" is still there, thank you. The "may" is still there and we had a little conversation about it, so -- and I think Dennis wants to say something about it.

DR. ENNIS: Why don't you just leave out "sufficient" and say "evidence?" Sufficient makes it sound very strong.

DR. FOGELMAN: I wouldn't mind leaving out "sufficient" at this point.

SPEAKER: This may not reflect your views, but as I understood it, the problem with "may" was it implied more evidence than really exists. So my suggestion would be since you already said that you meant to say "insufficient" rather than saying --

DR. FOGELMAN: No, I didn't. That was -- no, no, I withdrew that immediately.

SPEAKER: Okay. Well, I don't think that 11 now reflects "may." It reflects that there is conclusive evidence and I am not sure that what you told us earlier supports that. And I wouldn't vote for it with 11 as it is.

DR. ENNIS: You know this wording is not different from what you saw before, except the introductory language to focus attention on what it is, it was about short-term therapy. All the other words are the same words that were in there before.

SPEAKER: But I think the word "sufficient" is a very strong statement and it kind of is conflicted by "may produce." And so if the experts think there is evidence and they don't chose to leave in the word

"sufficient" I think it's less conflicting.

SPEAKER: I don't see any problem with taking out the word "sufficient."

DR. FOGELMAN: Robert, what do you think? You were there.

DR. CERTAIN: It seems to me that the word "sufficient" in that bullet would be better left out. And then the "may" follows from that. The question about 11 and 13 being conflicting, as it seems -- 13 has to do with a comparison between ABA and other forms of EIBI. Correct?

DR. FOGELMAN: Uh huh.

DR. CERTAIN: There is no data to support that one is better than the other.

DR. FOGELMAN: That's correct.

DR. CERTAIN: So there is some benefits, but there is no way to compare.

DR. FOGELMAN: That's correct.

DR. CERTAIN: Right? Thank you.

DR. FOGELMAN: Okay. So with that concurrence from a member of the Committee, I'm happy to drop "sufficient" because it's certainly still --

SPEAKER: (off mike)

SPEAKER: Put your hand over
"sufficient." There you go.

SPEAKER: (off mike)

DR. FOGELMAN: Okay. Is it
sufficient to drop that word? Thank you.

DR. LEDNAR: And let the record
reflect that there was one vote -- one nay.
Okay.

Was there two? All right. One nay
and two abstentions.

Okay. We're going to have just a
couple of administrative helping us through
this evening and tomorrow and then Mr.
Middleton is going to help me conclude this
session, official.

So, Commander Feeks.

CDR FEEKS: Okay. First of all,
with regard to the material in your binders,
we want to try something new at this meeting.
If you look in the inside front cover of your
binder there is manilla envelope. If you
would like to keep the materials in your
binder, I offer you this manilla envelope. If

you just put your binder materials in the envelope, it's now in a convenient package to lay in your suitcase and take home with you.

If that's inconvenient, we can send it to you when we get home. It is expensive, so we're trying to avoid things like that, but I just offer that as an alternative.

Now for Board members, ex-officio members, service liaisons, speakers and invited guests, we have scheduled several activities for tomorrow morning. Breakfast and refreshments will be served at 6:00 a.m. And that will be starting at 6:00 in the lobby of the Rampart Lodge, after which everybody is kindly requested to board buses between 6:45 and 7:00 to ride down to Cheyenne Mountain for the tour.

Now, the attire: business casual I would say. I will be in Class Charlies, which is an open collar khaki shirt. It will be chilly, so I'll also be wearing an Eisenhower jacket. Too much information, right?

Okay. At any rate --

SPEAKER: (off mike)

CDR FEEKS: Well, thank you in advance. We will leave Cheyenne Mountain at 11:00 o'clock and drop attendees off at Mitchell Hall at 11:40 a.m. That's the cadets' mess hall, where each attendee will be paired with a cadet and be escorted to a lunch table. The cost of lunch will be prepaid for each confirmed attendee and will be deducted from your per diem.

With the conclusion of lunch at 12:20 -- they don't dine, they eat -- with the conclusion of lunch at 12:20, a tour of several Academy facilities will be offered. This tour is currently scheduled from 12:30 until 2:00 p.m.

Now, transportation will be available to return attendees to Rampart Lodge at approximately 12:30, after lunch, for those planning to leave before the conclusion of the tour, and another bus back at 2:00 p.m. for the remainder of the attendees.

And, as you know, we've made provision for some people to chase us in their rental cars down to Cheyenne Mountain for

those who want to go straight from the mountain to the airport.

All right, now, if possible, please pack and place your luggage in your rental cars prior to leaving for the tour tomorrow morning. If you do not have a rental car, you can store your luggage in a secured area at the Rampart Lodge. Check out time is 11:00 a.m. and although the Lodge had indicated they may be able to grant a few late check-outs, they cannot grant them for all attendees.

All right. For those of you o joining us for the dinner tonight, which we're going to have -- we're not going to have it here, but we almost did, didn't we? Please convene in the lobby of the Rampart Lodge. We've adjusted it to 6:15. I think it's probably going to slide to about 6:25, but let's try to get to the lobby as soon as we can. The bus is scheduled to leave for the Sunbird Restaurant where we will be having dinner.

If you didn't RSVP for this dinner, please come anyway, but let Jen Klevenow know

on your way out the door so she can adjust the headcount.

Now, as for lunch tomorrow with the cadets, if you haven't RSVP'd with Jen please do so tonight on your way out because she has to give them a headcount and it has to be paid for in advance.

All right. Again, the dress is casual tonight at the restaurant. Weather will be cool. I want to thank, one more time, my staff because we won't gather again and have a chance to thank them, Beth, Olivera, and Jen Klevenow. And I especially want to thank the manager of the Falcon Club here, Kathleen Turmell whose done such a nice job with this venue, which turned out to be great, and the food which has been so good.

All right. That concludes my remarks. Dr. Lednar.

DR. LEDNAR: Okay. My thanks to everybody who stayed with this all day long. We covered a lot today and we have only one more thing to do and that's to look to Mr. Middleton to lead us in our adjournment.

MR. MIDDLETON: Thank you all for attending. As always we in the Department appreciate your time and energy to come and participate in these very important boards. This meeting of the Defense Health Board is adjourned.

(Whereupon, at 5:59 p.m., the PROCEEDINGS were adjourned.)

* * * * *

CERTIFICATE OF NOTARY PUBLIC

I, Carleton J. Anderson, III do hereby certify that the forgoing electronic file when originally transmitted was reduced to text at my direction; that said transcript is a true record of the proceedings therein referenced; that I am neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were taken; and, furthermore, that I am neither 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.

/s/Carleton J. Anderson, III

Notary Public in and for the

Commonwealth of Virginia

Commission No. 351998

Expires:

November 30, 2012