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HUDSON VALLEY REGIONAL EMERGENCY

MEDICAL ADVISORY COMMITTEE

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MINUTES OF MEETING, held at the offices of Hudson Valley Regional EMS, 103 Executive Drive, New Windsor, New York, on Monday, September 8, 2014, at 9:30 a.m.

Yvette Arnold,

Court Reporter

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A P P E A R A N C E S :

DR. ERIC STUTT, Medical Director

DR. FRANCINE BROOKS,
Evaluation Subcommittee Chair
DR. DAVID STUHLMILLER,
Helicopter Subcommittee Chair

WILLIAM HUGHES, EMT
Executive Director HVREMSCO
JEFFREY CRUTCHER, QI Coordinator

BON SECOURS COMMUNITY HOSPITAL

DR. CRAIG VANROEKENS,
Physician Representative
CATSKILL REGIONAL MEDICAL CENTER
DR. HOLDEN, Director
DR. VOHRA,
Physician Representative

GOOD SAMARITAN HOSPITAL

DR. DENNIS MAO,
Physician Representative
HUDSON VALLEY HOSPITAL
DR. RON NUTOVITS,
Physician Representative

NORTHERN DUTCHESS HOSPITAL

DR. WILSON,
Director
NYACK HOSPITAL
DR. SACHIN SHAH,
Physician Representative

A P P E A R A N C E S : (Continued)

PUTNAM HOSPITAL

DR. BROOKS,
Physician Representative

ST. ANTHONY COMMUNITY HOSPITAL

DR. RONALD ROSHE,
Physician Representative

ST. FRANCIS HOSPITAL

DR. GARY NEIFELD,
Director

SHARON HOSPITAL

DR. RICHARD BENNEK,
Director

WESTCHESTER MEDICAL CENTER

DR. JON BERKOWITZ,
Physician Representative

WESTCHESTER REMAC LIAISON

DR. ERIK LARSEN,
Physician Representative

ALSO PRESENT

DAVE VIOLANTE
ANDY LaMARCA
MIKE BENENATI
MIKE MURPHY
MICHAEL WITKOWSKI, via telephone
RICHARD PARRISH

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DR. STUTT: Good morning, ladies and gentlemen. Good morning. This is the September 8th meeting of the Hudson Valley REMAC.

And our first order of business is to welcome you all back after a good summer. And next order is to do the roll call.

So, Fran Brooks?

DR. BROOKS: Here.

DR. STUTT: David Stuhlmiller?

DR. STUHLMILLER: Here.

DR. STUTT: Craig VanRoekens or representative?

Dr. Holden?

DR. HOLDEN: Here.

DR. STUTT: Dr. Mao?

DR. MAO: Here.

DR. STUTT: Dr. Nutovits or rep?

Dr. Fareed Cohen -- or Alexander Cohen?

Dr. Wilson?

Dr. Papish?

Dr. Santikul or -- Dr. Vorha, is here for Dr. Santikul.

DR. VORHA: Um, um.

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DR. STUTT: Dr. Butterfass -- or Dr. Brooks for Dr. Butterfass.

Dr. Roshe is here for Dr. Dittmeier.

DR. ROSHE: Here.

DR. STUTT: Dr. Neifeld?

Dr. Hill?

Dr. Bennek?

DR. BENNEK: Here.

DR. STUTT: And Dr. Brooks for Vassar. One more page.

Dr. Berkowitz?

DR. BERKOWITZ: Here.

DR. STUTT: And Dr. Larson?

DR. LARSEN: Yes, I'm present.

DR. STUTT: Dr. Shah is here.

DR. SHAH: Here.

DR. STUTT: Review of minutes. I hope everyone had an opportunity to review them, if there is any corrections or comments?

No corrections or comments.

Could we get a motion to approve the minutes as presented?

DR. BENNEK: I'll move it.

DR. VORHA: Second.

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DR. STUTT: We have a second -- move and a second.

All in favor?

All opposed? Unanimous.

Dr. Wilson is now present.

The item number three on the agenda is under old business, the collaborative protocols with BLS. From discussion with Mr. Hughes this morning I know that many of the county EMS coordinators are continuing to update their BLS squads regarding the collaborative protocols.

I don't believe we have a finalization date for that, Bill --

MR. HUGHES: I haven't, no.

DR. STUTT: -- end point so I imagine that will continue until all are updated.

We are going to talk about some MFI training that has been offered back I guess in June. That we decided we were going to provide MFI training to broaden the scope of practice for many of the organizations -- many of the paramedic organizations in the community that would want to participate by

having not only trained persons but also certified persons -- Jeff, do you --

MR. CRUTCHER: No.

DR. STUTT: We had setup the meeting for September 21st, but apparently --

MR. CRUTCHER: Apparently there was no interest from any of the agencies to pursue that particular avenue.

DR. STUTT: What we tried to do is make a central venue here where any agency that wanted to send a trainer, someone to be trained to go back to their own agency to become CFI -- MFI certified or trained they could do it themselves then. I know some of the agencies in the region are doing it through their own advances, making contacts with other trainers -- certified MFI trainers and bringing it right to their agency, but nobody has chosen the region for that. I imagine that date is still available, or is it closed if --

MR. CRUTCHER: The date has been closed.

MR. HUGHES: Right, because of the lack of enrollment.

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DR. STUTT: Lack of participation.

Any comments on that?

Service upgrades. Town of Wallkill Volunteer Ambulance ALS upgrade. This is a somewhat complicated issue and I put together some thoughts to try and clarify it, several members are present who can add to this if necessary and I'm sure there might be good opportunities for that.

During 2012/2013 when we began the transition to the collaborative protocols we recognize that many aspects of our preexisting medical control plan no longer mesh well with our new collaborative protocols. So many people here now were members of the protocol committee who helped to rewrite our medical control plan as well as integrate them into our collaborative protocols.

One of the revisions that we made was to address the way that a BLS agency would become an ALS agency. So bear with me because I'm sort of building a platform here so everybody can understand what has

transpired in the last few months. So we wanted to change how a BLS agency would upgrade to an ALS agency. And specifically the changes that we introduced into the prior medical control plan were that we were going to require a fitness and competency in addition to what was already preexisting requiring a public hearing as part of the process to become ALS agency.

Our first application that came to us after we had revised our medical control plan, the first application for upgrade process back in March of 2014 was when the Town of Wallkill Volunteer Ambulance Corp. in Orange County informed us of their intent to upgrade to ALS. In response our Executive Director Bill Hughes provided TOW VAC with all of the requirements and all of the applications that were necessary to fulfill that requirement to fulfill the application. They completed that documentation and application in July, on July 9th all of that was forwarded to this office and approved as their application. It was not completed --

or not decided, it was completed. The REMSCO office then established a TAG to review the application and our bylaws require and medical control plan require a TAG be established. That TAG consisted of Albee Bockman, Mobilemedic; Rich Muellerleile of Shandaken Ambulance; Michael Witkowski, who is the REMSCO President; Bob Cuomo of Putnam EMS; Rich Parrish from Ulster County EMS; REMSCO Director Bill; and REMSCO Medical Director, me.

Contemporaneously with the TAG's initial review a copy of their application and standards were sent to the State for the State's review. The response of the New York State Department of Health was that our procedure was somewhat flawed in that our requirement for a review of fitness and competency was not required as we thought. We thought that was a meaningful aspect of it just to be sure the individuals signing on as the primaries as the leading representatives of the new agency were appropriate for the role of the application and of having that

responsibility of running the organization. The State informed us it was not a permissible part of our application process as that had already occurred with the initial CON when they became BLS agency so it was not necessary for us to do that. And that there was no statute and no stature for a public hearing by -- New York State Department of Health decided we had no stature to require that there be a public hearing, that the only criteria for their application were A., that they were an agency in good standing, and did they meet our requirements for adequate coverage and sustainable plan for their performance as ALS agency.

So in the interim now TOW VAC has applied, we received it, we reviewed it as a TAG. And just last week the State told us that we had to revise our medical control plan to accommodate the changes that they made because our process for application of ALS upgrade was flawed.

So the first thing we did is ask TOW VAC to resend the initial application. They have

done that. They are very cooperative in that they pulled back on their application.

The TAG has decided that we are going to request members today to review and approve the change in our medical control plan that would just simply -- and it's not going to take a lot of review -- it is just simply removing the public hearing and fitness and competency aspects and that there is no reference at all to a public hearing. Assuming that we make those changes to the medical control plan today TOW VAC will promptly resubmit an ALS upgrade application consistent with our new standards, new standards being without fitness and competency and without public hearing. The TAG will meet again after TOW VAC submits their application. We will review the new application and if it meets our standards the TAG will bring it to this committee for the November 2014 meeting.

So it's a complex and difficult situation, but I think the office here has really done a good job of trying to remedy

it. The flaws were not generated by the office, they were generated by the protocol committee in good faith. It was our intention to make this as seamless a process and safe a process and as effective a process to approve a new agency, but we overstepped our boundaries.

So what I would like to do -- Bill, any comment?

MR. HUGHES: You have Mike on the phone if you want to ask him.

DR. STUTT: Mike Witkowski, the REMSCO President is here as well --

MR. HUGHES: Well, he's on the phone.

DR. STUTT: I to today the machine.

MR. HUGHES: Mike, is there anything you would like to add to that?

MR. WITKOWSKI: No. Dr. Stutt covered most of it. Again, unfortunately our best intentions and the State Health Department acknowledged our best intentions on this. Again, there is no statute that we could stand behind if the process was ever challenged. And after speaking with our own

attorney, as well as several other attorneys, the recommendation is the procedure that we are currently following. So it's kind of important that we go ahead and move forward with making the changes that are necessary in order to continue to move processes forward.

DR. WILSON: If I could recap so I'm clear on this? Dr. Stutt, you are saying that when the application was initially handed in the Department of Health stated that the fitness and competency portion of that is already met when they applied to the BLS level initially, therefore, it's not required at this time?

DR. STUTT: Right.

DR. WILSON: In addition there is no state statute or groundwork, framework, for us to have public hearing either, there is no law to base that. So those two things are going to be removed, but everything else stays in place, they are going to resubmit it after we clean that up and then we are going to move forward; is that correct?

DR. STUTT: Correct. So -- Dr. Shah?

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DR. SHAH: Was the review done by the TAG under the old way?

DR. STUTT: Yes.

DR. SHAH: And it was fine?

DR. STUTT: We were pleased and satisfied and would have recommended moving ahead. Is that the consensus of the group on that, that we would have moved ahead?

DR. SHAH: Our process was too cumbersome for the State, but they met those hurdles anyway --

MR. HUGHES: Everything, but the public hearing. We didn't have it the public hearing. And they did say that we have no -- if the public hearing was brought forward and there was any action taken against it we have no recourse to say why we have that and it was unnecessary. And the fitness and competency was just to make sure that you are -- that the State would tell us they were in good standing and that should be sufficient.

DR. STUHLMILLER: So I must ask since there is nothing additional required and only

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things are being removed, could we not --

DR. STUTT: They have to reapply --

MR. HUGHES: And you should actually review -- everybody should review the application. I do have copies for everybody here so that you can look at it and make sure everybody that is going to vote on it feels confident what the TAG is saying and information coming back from the TAG is good.

DR. STUTT: We have not been able to accept their application until we vote on changing our prior medical control plan.

DR. SHAH: Can someone apply straight for ALS? You can do that without the BLS, right? The reason --

MR. HUGHES: No. In the way New York State works you have to have a CON to operate as a BLS service. And then from BLS service it's a regional MAC decision to let them --

DR. SHAH: So anyone applying for ALS will have the CON and competency in place?

MR. HUGHES: Yes, they have to and then come to this body to become ALS service.

DR. STUTT: Any other comments or

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questions?

Let me just try to frame a motion.

So I would move that the REMAC eliminates the requirements for fitness and competency and eliminates the requirements for a public hearing from the application and requirements for ALS upgrade.

DR. WILSON: I second that motion.

DR. LARSEN: Whoa -- in relationship to this application alone.

DR. STUTT: Well, going forward.

DR. LARSEN: For any agency? Okay.

DR. STUTT: Any agency going forward. Add that please, if you would, going forward that the Hudson Valley REMAC eliminates the requirement for fitness and competency and public hearing in regard to applications for ALS upgrades.

Is that --

MR. HUGHES: Um, um.

DR. STUTT: Could I get a second?

DR. WILSON: Which I second that motion.

DR. STUTT: Dr. Wilson seconds it.

MR. HUGHES: I have copies of both

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Section five and six of the medical control plan of what the new plan does say. I also have copies if you want to see what the old plan says and see what is removed, but it was just the specific sections that referred to public hearing and fitness and competency, so if anybody wants to see that I have it.

DR. VAN ROEKENS: For discussion, this is pursuant to the recommendations by the New York State --

MR. HUGHES: It was New York State Department of Health, our legal advice -- Joe Owen, who is our legal advisor -- and both recommended that this was the best way to do this.

DR. STUTT: So we have a second.

All those in favor of the motion?

Any opposed? Unanimous. Thank you.

Under service upgrade Watchtower Bible and track CON, that remains incomplete. We are awaiting their application before we can move ahead.

DR. LARSEN: Sorry, what is the address on that?

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DR. STUTT: Watchtower.

MR. HUGHES: It's going to be in Tuxedo. I can't remember the exact address, Silver Mine Road, it's going to be there. They actually have two facilities, there is a 200 and -- I believe 250 acre world headquarters building built in Tuxedo. And then they have a secondary site that is about 40 acres that is going to be a training site that is within five miles of that. They also have two -- currently have two CONs within the Hudson Valley Region, one in Paterson, New York and one in Wallkill, New York.

We talked with the DOH on this one also and asked if it would be better to just extend the territory or put up a new CON and everybody felt it would be better to do a new CON for this area.

MR. PARRISH: The Wallkill is in Ulster County, nothing to do with the Town of Wallkill, which is in Orange County?

MR. HUGHES: Right, yes.

DR. STUTT: Evaluation subcommittee. Dr. Brooks?

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DR. BROOKS: Nothing to report.

DR. STUTT: Helicopter committee. Dr. Stuhlmiller?

DR. STUHLMILLER: The only order of business before the committee was a request from this body to revise the helicopter operations guidelines and the only response I received was a minor address change. So I would like to pass around the document specifically because there is an appendix with capabilities that the hospitals possess, including whether there is a helipad, whether there is hyperbarics, neonatal, obstetrical, pediatrics, intensive care, et cetera. So I would like to take advantage of the fact we have the directors in the room so they can update this appendix. And my plan will be to revise minorly this document and present it back to this body at the meeting in November. I can submit it prior to the November meeting if there is a required time period for review that everyone would appreciate, I can certainly get it done by that deadline.

DR. BENNEK: Will the appendix or

hospital capabilities be on-line that we can access --

DR. STUHLMILLER: It's currently a pdf and I have it into a word file and I can modify it, but I don't have it posted anywhere on-line.

DR. BENNEK: Okay, will you do that in the future?

DR. STUHLMILLER: Does the region have the ability to have on-line posting of that? It may already be on-line.

MR. HUGHES: I don't think it is, I don't remember seeing anything.

DR. STUTT: So, Dave, you submit it to Bill and Jeff.

DR. STUHLMILLER: I'll pass -- certainly I'll pass this around and ask everybody to put a check mark and please fill in the appendix to the tables, otherwise I have nothing else to report.

DR. STUTT: Thank you. Quality improvement report. Jeff Crutcher?

MR. CRUTCHER: Agency audits are ongoing, so far 11 agencies have been

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completed. Basically comparing the information we have on each provider of ALS agencies in comparison to their home agencies and secondary agencies, making sure we have copies of all the cards, credentials up-to-date. It's progressing fairly well.

Provider Portal, the new data base, we are about two weeks from the first look at it. The project seems to be moving along in a good pace.

Provider photo IDs, this past summer we purchased a printer and software necessary for making actual laminated photo IDs for all MAC providers. So we are in the process of finalizing a couple of design options and we will go forth from there.

MR. LAMARCA: Just a question, how are we going to get each MAC certified person's photo.

MR. CRUTCHER: The theory being that some will have to come in for photo IDs taken, but if the agency already has photo IDs we can import the photos right from there so it's not too cumbersome a process.

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MR. LAMARCA: It is a badge that has to be displayed I guess?

MR. CRUTCHER: Yes.

MR. LAMARCA: That is a cumbersome process, they are already wearing IDs.

MR. CRUTCHER: Alternatives, they could carry --

MR. LAMARCA: It's fine to carry, but not necessarily to wear.

MR. CRUTCHER: Yeah, either/or.

DR. LARSEN: Will that be provided to members of this committee?

MR. CRUTCHER: Absolutely.

DR. STUTT: Any other comment on that, the provider photo IDs?

Under new business Bill Hughes is going to tell us about the office move.

MR. HUGHES: Well, December 31st, our lease is up on this office. We have about been here three years. We didn't think it would go that quickly, but it did. The landlord here is not very conducive to us staying. He's doubled our rent and it's not something we can afford. So we were looking

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at multiple places. We do have one that we think is fairly close to here. It's in the airport area, it's 33 Airport Center Drive. It's an office space with an -- in the building it has a common conference room that is a little larger than this and will seat everybody that would normally come to the meetings. So we can get more office space for less rent and still get the conference room associated with it. So that's really the one that's on our list right now. We will let you know. But the November meeting, we are looking to get out of the lease a little early so we might have the November meeting here or there, so we are not sure at this point in time. We will let you know. But it would be the same transportation in the area, it's only maybe a mile, two miles down the road.

DR. STUTT: Next item are the medical control contact hour lectures provided by medical control hospitals.

Section 9 of our medical control plan it's delineated that a medical control

hospital must provide one medical control contact hour per course -- per quarter -- one course per quarter. The medics must get 24 hours every three years of medical control contact hours, in addition to other CME they require -- other documentation of CME. With few exceptions most of the hospitals in the Hudson Valley Region have not been providing medical control contact hours to the rate of one per quarter or a course per quarter. And the issues with this are multiple. One is that our medics are not able to get adequate medical control contact hours if it's not offered in the areas where they work. Secondly, they are not establishing the relationships with the medical control physicians that this would allow if there were courses once every quarter.

And at issue here is this is a standard we all established, all of us established it. And everyone in the room is responsible for providing CME as part of their agreement to participate in the REMAC. How can we make those two areas meet so that we are providing

those needed contact hours that we all agreed to do? How can we improve this for the county and how can this office help you with that requirement?

DR. BENNEK: Can I ask you to define that a little bit? For example, if we do monthly case reviews and a lecture does that qualify as medical control contact hours? Is that what we're supposed to be doing because that's what we do. I don't know if --

DR. STUTT: I'll ask Jeff to clarify that.

DR. BENNEK: I want to be sure, is it -- for example, if I'm there answering questions is that adequate or do I have to actually give the lecture?

MR. CRUTCHER: You should have maybe 50 percent participation within that presentation lecture or question/answer period for that to be considered medical control.

DR. STUTT: Mr. LaMarca?

MR. LAMARCA: We did put together for the last review of policies and procedures a

companion document to help distinguish between CME and medical control contact hours and also some suggestions for the facilities. And certainly what you are talking about certainly does meet the requirements and as Jeff pointed out you are supposed to have 50 percent of medical control physician, medical control nurse practitioner, or PA to conduct it so it counts. The only other thing we did put in there was a lot of what they are getting probably if you look at it closely is not usable because in many cases it's beyond their level. I mean, we had a lot of presentations that are done because somebody had it -- I guess I would say -- and it's above the level of the paramedic sometimes too. So that document also talks about trying to give you perspective on where their level of training is so that it could be appropriate to them. And the difference between CME -- because the region only controls medical control contact hours or physician contact hours. When you use the word CME, since so many of our providers are

refreshing their state credentials or state EMT or paramedic card through the CME program, that's very specific, so if you are engaged in that you have to take a look at the State criteria. But there is a document I think everybody has access to, it's on-line and hopefully can help you.

DR. SHAH: Are we strict about the quarter or four in a year?

DR. STUTT: I think four in a year.

DR. SHAH: But could it be four hours one day?

DR. STUTT: It could be medical hours offered as medical control contact.

DR. BROOKS: Yeah, I kind of feel strongly about this. You know way way back when LAFA (phonetic) started part of the joy in being medical control is working with the prehospital providers to establish the relationship with the providers that come to your hospital. And, therefore, they are kind of understanding what we need from them and they understand they need from us, you know, vice versa. And what happens when you don't

do these audits -- I call mine CMEs, but they are basically case reviews in getting the CME content out. And you become much closer to these people who are working under your license and it makes it easier for them to come with questions, problems, any kind of issues out there to remediate them even on a personal level and not just educational and actual medical level. And they are the providers that sometimes determine who may live and who may die by doing it right out in the field. And when we are not adequately educating the prehospital providers we are not doing our job. And they are going by what is written in black and white, but not getting a feel for what we need.

So for me and I know a lot of us at this table have spent years doing a lot of teaching and it's been very fulfilling and as a result I think the care improves out in the community. And problems arise when there is not that kind of relationship between a hospital and the prehospital providers in that area. And even giving it four hours one

time a year, nobody is establishing a relationship. Unless the prehospital providers come in and we feel comfortable and have time and the physician or nurse practitioner or PA has time -- which we don't -- to go over cases right then and there. It's not like years ago when we used to do that, it's very difficult. It's a revolving door, it's very very difficult. So even though four per year is fun and satisfying the requirement, it's to me not fulfilling what our responsibility is as a 9-1-1 receiving hospital.

Why it's not done, I'm not sure. I know in Dutchess County we give so many CMEs -- audit, CMEs, whatever -- and we have basically a good rapport with our prehospital providers. So I think you should question why you are not doing it and then how we can help you do it. Even if you need to borrow somebody that does it all the time to go there, that was an option we talked about before the meeting. Though, again, one of us doesn't have the same relationship with the

prehospital providers. But I would look at it and if you guys can't do it as directors have a designee who likes to teach. We all as physicians like to teach, we have grown-up in a teaching environment. So if you can't do it -- directors have a lot of responsibility and very little time, but there maybe somebody in your group that really likes to do it. And you can ask them to be in charge and produce one every quarter, you know, a two-hour session every quarter. It would be much appreciated on both ends. But that's mandated by what we need to do as 9-1-1 receiving hospital is to maintain that credential.

MR. LAMARCA: Just for a point of information, some regions throughout the State and some other states have kind of started like a library of presentations that sometimes can be used in these programs. And so if anybody from the region wanted to share for the common good, I'm sure we can library them here. So, you know, if you want a little variation you can do -- really right

now one of the biggest things if you take a look at the total amount of educational opportunities, count how many stoke centers we have and know they have to do two stroke preparations a year, we will probably have like 30 stroke presentations. It's so disproportionate to everything else we do. So if you wanted to open up and share your Power Point program, something like that so others could use it that might help make it easier.

DR. BROOKS: But you want to use cases that come to your hospital or area, that's part of the point and use the protocols, it's protocol driven. So it would be nice to use the cases that come in and people have heard about it or are aware or as teaching points of what really happened.

DR. STUTT: Maybe those two concepts could be combined. You could have case reports pertinent to the CME part of the discussion that is going on, but tie the two together and make it real life. And like you said, having that contact between the

physicians and paramedics is invaluable.

DR. BERKOWITZ: The way I've done it -- I do a fair amount of -- I have a pretty large library of talks either I put on or people have given me, I'll go through a bunch of cases and find and say this relates to this talk, then say now I have this case and this existing talk I have given maybe two or three years ago that my friend sent me, or whatever. And I can say I can do a talk and talk about the medical content using the lecture I have, talk about the case and then what the protocol we have is and it makes an easier way of doing it rather than having to kind of invent all of it at once. It's hard enough to find the cases, you know. It's hard enough to find cases that are worthy of talking about that are interesting. So at least if I can focus most of my time on finding the right cases. I have a lot of talks I can adapt or work with, it makes an easier. So I think the idea of a library might help people -- obviously we need a librarian.

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MR. VIOLANTE: How much will that pay?

DR. STUTT: You weren't volunteering?

DR. BERKOWITZ: I was absolutely not volunteering. I have lectures I'm happy to share. I'm happy to share on stuff that is -- to Andy's point I have tons of stroke lectures.

MR. LAMARCA: Don't feel free to send them.

(Everyone is speaking at once.)

DR. BERKOWITZ: No, but I have -- I think there is lot of other stuff out there too.

MR. LAMARCA: One point to emphasis Dr. Berkowitz's point, the protocol driven is a key thing. A lot of times presentations never reference either the current BLS or ALS protocols, but that is kind of a nucleus --

DR. STUTT: Wasn't that part of the design to CME? It had to be related to the protocols and had to be approved by the region.

MR. LAMARCA: You would be surprised how many presentations never reference a

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protocol.

DR. STUTT: Anything further about CME and medical contact hours?

DR. LARSEN: I just have one note back on this document that was circulated, the Regional Air Medical Services Utilization Guide. People are supposed to check and update as Dr. Stuhlmiller had suggested. One thing I noticed is that there is not a column -- and maybe we should add a column for cardiac intervention? No? Yes?

DR. STUHLMILLER: There used to be a column for cardiac intervention.

DR. LARSEN: I don't see it. Am I missing it? I don't know.

DR. VAN ROEKENS: PCI cardiac surgery.

DR. STUHLMILLER: Please add a column. Thank you, Dr. Larsen.

DR. LARSEN: Okay, we will put that in. And I mean there is a lot of names for it so we are using PCI, is that --

DR. STUTT: PCI, PCI capable.

DR. LARSEN: Okay. That's all. I'll pass that around. I'm just adding that

column.

DR. STUTT: Item nine is the SEMAC report, that's going to be deferred until November -- the November meeting.

Number 10, there are no PAD proposals, Epi-pens, Albuterols, glucometer, or Narcan updates.

But I want to revert back to new business, we jumped out of that it -- was my mistake.

Two other items for new business are that the regional office has undertaken to become an opioid overdose prevention program community based organization. And there are two aspects of that. One is that the region will now be able to offer courses to the community on opioid overdose prevention and be able to distribute nasal naloxone ampules to those trained for their own personal use, family use, friend use, contact use.

The other aspect is because we are now a community based organization any of us here can sign up as affiliated prescribers to the community based organization. Meaning that

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you can sign prescriptions if you are a member -- if you are affiliated prescriber you can sign prescriptions for other agencies that have the right to deliver Narcan. BLS and ALS personnel don't need you for that, they have medical directors for that. But it does allows for police and other community organizations that want to have a program to deliver nasal naloxone, they need prescriptions for that.

Police particularly are becoming very involved in getting their staff to all be able to carry nasal naloxone. The Department of Criminal Justice Services has been offering courses throughout the State, but they are individualized courses and not geared necessarily to the time schedules that police departments have. Many police departments are looking for medical providers to be a medical director. If you sign on with our community based organization you can then write prescriptions for the programs, they can be approved by DCJS, operate under your approval and will require your oversight

for reviewing cases as they occur. It's their agencies' responsibility to send it to the State on a yearly basis.

And there have been a remarkable number of saves already -- is Mike Murphy here still in the back?

Mike has been instrumental down in Rockland County getting many of the agencies involved down there and they had a surprising large number of safes in the last few months. So if anybody is interested in becoming an affiliated provider let Bill know --

DR. NEIFELD: What is the process?

DR. STUTT: You just have to sign on as an affiliated prescriber for the community based organization and you can be a prescriber.

The way the police agencies work is different than EMS agencies. In EMS they have the right to provide medications to each ambulance unit or each ALS bag, police each get an individual prescription. The way it's been working is you write a prescription for each police officer. It doesn't necessarily

mean that every police officer get their own prescription, but each of them have the right to be using nasal naloxone. The agency itself, the police department, can buy X number of units to distribute to each car that they drive, but it's under the prescriber's name. So each police officer will have a prescription for that.

DR. VAN ROEKENS: Just for the record, I'm going to say this state has really not done this right again. And the costs are kind of ridiculous for the police agencies. And it's unfortunate that we have to kind of help step in -- I think it's good, we should be doing it. There is no task force for Orange County, last night we had another death of a young individual, it's really a problem.

DR. STUTT: For those of you connected to different police departments you might encourage them if they want to do to it, to do promptly because the DCJS is providing premedications through December for all prescribers, after December nobody knows

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where the program is going to go.

DR. NEIFELD: Is there any downside for us all not signing on? What is the oversight involved?

DR. STUTT: It's reviewing cases -- make sure their educational program is consistent with the DCJS, which is in a printable format that I can send to anybody that is interested. Every police officer that gets trained has to be trained by a DCJS trained officer, not necessarily trained in narcotics, but hs to know how to provide education to police officers. You don't have to be the medical director, you don't have to be do the presentation, you just have to the do course, which DCJS has canned already. You have to be taught by an instructor that provides a list of names, you write the prescriptions for those officers and do the oversight every time they use it and they report to the State.

The prescriptions don't come to you, they go to the agency. You can sign up with a multitude of drug distribution houses

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Moorehead or Bound Tree -- David?

MR. VIOLANTE: -- the cost of these things as an aside, it maybe beneficial for you guys that have BLS squads to try and make inroads perhaps with your hospital pharmacies as potential sources for providing these medications.

Just to give you guys an idea, the Epi-pens that ALS providers are supposed to carry, the double pack is about $500.00 and they expire every 15 months. So it's becoming a little onerous for the squad so having a common place where they can have a higher volume replacement --

(The speaker cannot be heard.)

DR. STUTT: The nasal naloxone is 25 to $35.00 per two milligram ampule and the atomizer is 6 to $8.00, so it's $35.00 per prescription and everybody is supposed to carry two. As you can see -- as Dr. VanRoekens was saying, they expired in a year for police departments that have 60 officers it is not cost effective to replace them, it's much more cost effective to have four

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five six to go on each rig and replace those as necessary under anybody's name.

Any comments on that the opioid overdose?

We have come to that point in time where we read the Department of Health enforcement issues.

First is Coling Medical Transport from Brooklyn, New York. For violation of Public Health Law 3010 subste 1. Suspended for three years effective September 2, 2014. Suspension is stayed. They were assessed a civil penalty of $8,000.00.

Patrick Manning of Grand Island, New York for violation of Part 800, suspended for one year, effective August 20th. Suspension is stayed. Placed on probation for three years, effective August 20, 2014. Not allowed to apply or recertify for instructor status for one year effective August 20, 2014.

Edward Kasperek, Fulton, New York. Violation of Part 800 suspended for six months, effective 8/15, placed on three years

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probation, civil penalty of $2,000.00.

Joseph Baldwin of North Babylon, New York. Violation Part 800 suspended and deemed to have served concurrently with the Respondent's actual suspension by the Suffolk County REMAC. Placed on probation for three years effective April 30th. Assessed a civil penalty of $2,000.00.

Gaby Day, Brooklyn, New York. Violation of Part 800. Suspended for one year effective May 19th, 30 days actual suspension effective May 19th to June 18th. The remaining 365 days are stayed.

Open forum? Jeff -- sorry -- Mr. Murphy?

MR. MURPHY: Good morning. I just wanted to comment briefly on the idea that the -- to the TAG's idea of inserting fitness and competency in the ALS upgrade and what our mentality was at the time, even though of obviously perhaps we used the wrong terminology. Service upgrade, often times the folks coming in to do the upgrade and are running the upgrade proposals are not

necessarily the BLS principals or the principals of the ambulance corps. so we wanted to make slur that the REMAC looked at the folks doing the upgrade and not only looked at the business plan.

Speaking now as a resident of the Town of Deerpark, we have our own ambulance corps. Port Jervis Ambulance Corps. in the newspaper recently is suffering significant financial hardship, which they have had for the past couple of years. They have gone back to the two municipalities to ask for funding -- which they are not going to receive -- so now they are in this dilemma and they are going to put the citizens in the Town of Deerpark and City of Port Jervis in dilemma because in they may not have had a proper business plan.

We have not seen those municipalities since they got their upgrade, nobody from operations ever come to REMAC meetings, we have never seen the medical director. Now we have a city and town in Orange County which may have -- maybe severely impacted in the loss of ALS and the subsequent void that is

being created because one may have not had an adequate business plan in promoting their ALS upgrade.

So it was our intention even before the news about Port Jervis had been released that when ALS upgrade is done that the organization provides an adequate business plan as to how they are going to be able to service their communities for the long-term. And that was our intent with the fitness and competency is that we not only examined the black and white of the application, but you also looked at the impact upon the community, the surrounding services and whether there was adequate business plan for long-term survivability.

MR. HUGHES: One of the things that New York State Department of Health did do is compliment us on our effort to do that. And I think what they basically said is the way we went about it is not correct and that would we have to a set the criteria and the expectations in the body of the upgrade documents.

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Now, we have done that. I think we have, in what we have reviewed and what we have asked the TAG to look at. So I'm not sure as how deep we can go into the financial aspect of that. But I know that we can make sure that there is criteria there for at least a length of time. And the second thing that they suggested was that maybe we expand some of the probationary periods. Right now any agency that moves to ALS status is on probation for a year with a six month review by -- they are supposed to come here and give us a six month review and then another annual review before they become a permanent ALS service. It was suggested that we look at a longer length of time, could be 24 months, with 6, 12, and 18 month review, something of that nature that would allow us to at least see how they are progressing with that business plan. Those are things I think we have to look at and I think what we should do -- you know, we need to get through this process because Wallkill was in process already -- would be to take another harder

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look at that and make sure we have that criteria listed in the actual update plan and make sure what we can do to make that criteria of a business plan be much stronger.

MR. WITKOWSKI: Dr. Stutt?

DR. STUTT: Yes, Mike?

MR. WITKOWSKI: If you wouldn't mind I would request the MAC to create a TAG specifically to address the medical control plan. That TAG will probably meet simultaneously with the current -- or the one that will be currently in progress. What I would like to do is get that setup so we can start looking at the changes that need to be made to tighten up the processes as well as the back-in process of the ALS upgrade.

As all the MAC members are aware the action we have just taken is steps with the current -- what would be with Town of Wallkill will be going, any changes that are made to the medical control plan at this point we will not be able to consider -- actually, we could consider them, but we would like to get a TAG started so if we

could get a group together, or get a TAG setup for the medical control plan review that would be beneficial so we can get that started as well.

DR. STUTT: Well, Mike, let me point out that seated at our table now are several principal members of the protocol committee that worked from 2012 to early 2014 revising the medical control plan. And it might be worthwhile to utilize those personnel as well, or specifically utilize those personnel because many of the suggestions from the revision of the medical control plan originated with that protocol TAG.

MR. WITKOWSKI: That would be fine. We can use the same thing, we just need to make sure have we have an identification of who the people are and that everybody is aware that they are going to go ahead and start so anybody from the agencies wants to have additional input we can make them aware when the meetings will be and whatnot and anybody can -- just make them aware anybody can have input into the process at this

point.

DR. STUTT: So would you see that specifically delegating that subcommittee or sub TAG to look at the ALS process --

MR. WITKOWSKI: Correct.

DR. STUTT: Okay. I think that could be done. We could probably institute that, get the protocol committee members back together prior to the next TAG meeting after today's vote -- which we already completed.

MR. WITKOWSKI: Perfect.

DR. STUTT: What we are saying is we are going to get the protocol committee back together, the people who were instrumental in revising the medical control plan, look at those areas that are pertinent to the ALS upgrade, see if any further changes need to be made before we go ahead and submit TOW VAC's application to those standards.

Members of the protocol committee that are here feel okay about that? Good. Thank you.

Okay, so noted. Thank you, Mike.

Okay, Mr. Parrish?

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MR. PARRISH: Under open forum. Health Alliance of the Hudson Valley Broadway campus we are having big issues with getting PCRs both paper and electronic and checking with other hospitals, it's a problem across the system. One agency adamantly refuses to do PCRs or even send them to us electronically. They want us to install a desk top on our charge nurse's platform and have her sign on and then download the PCR. No other agency requires that. I know only one hospital, Bon Secours, has done it, but all the other hospitals have not and they have elected not to go that route. Checking with other hospitals, they all have the same problem, they are not getting a copy of the PCR, either paper or electronic.

What we are looking at doing at our facility is coming up with a small three by five cheat card, like the EMS, so before they leave they at least give us that pertinent information. It appears to be not just a problem at our facility, but all facilities.

DR. STUTT: Have you initiated that

small card?

MR. PARRISH: Right now it's draft form.

DR. STUTT: Any input from the agencies --

MR. PARRISH: Right now the physicians have looked at it. I'll pass it out to the other agencies. I know one hospital down in Putnam that if you don't turn in some type of paperwork they will not sign a PCR and they will not replace supplies until they get a document.

DR. STUTT: Sounds like a --

DR. LARSEN: I strongly second that, it's a huge problem at our hospital. I look over records and look on there how did the patient get here, EMS, ALS, BLS, never see an ambulance report, or -- you know a PCR.

MR. PARRISH: And it's putting the hospitals in violation of the Hospital Code 405. And when I addressed this with Mike Taylor, oh, that's a hospital problem. No. It's a system problem. All right? We are required to have in our medical records a copy of the PCR and it's not there so when we

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get audited, that's an issue.

What really brought it to light is we got a subpoena and we did not have the PCR to backup what the EMS agencies did.

MR. VIOLANTE: I don't disagree with anything that has been said here and we find it an issue with agencies as well that don't have the ability to print a PCR because they don't carry a machine printer in the vehicle, or there is not a printer at the hospital, or whatever.

I think a good way forward is to be able to integrate electronic PCR with the electronic hospital systems so the PCR is there electronically and all the data is moved over into the appropriate detail seven code and that kind of stuff and then it's available otherwise throughout the entire hospital. Some other issues is dropping off a PCR and it not getting to the patient folder, or being missed here and there.

So perhaps the region can help to facilitate even with the local REO (phonetic) a way of getting electronic data from the

hospital environment to electronic data to the --

MR. PARRISH: Again, I talked with Mike Taylor and that is his long-term plan. But we need something now at my facility. We give them two fax machines, Mobile Life has a dedicated fax machine. We give them a printer. It's there and we don't get it.

DR. STUTT: So, Mr. Parrish, I can understand they may not be able to integrate from their ambulance or an arrival PCR, could they not when they go back to their base could they not print it out there on their platform and then fax it to you?

MR. PARRISH: Another agency -- another larger agency in Ulster County does that, within an hour we have a copy of the PCR. They go back to their base complete it and fax it in.

DR. STUTT: So why don't the smaller agencies do the same? They have to be able to download it for themselves, their own records, and they certainly have fax capacity or scanning -- I imagine they do. I'm not

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certain --

MR. PARRISH: Again, we make faxes available to them, we do have a printer available. This one particular agency adamantly refuses. We have given them the fax numbers and all -- nope, you have to go on-line and download.

DR. STUTT: Was there any other comment?

DR. WILSON: You know I want to say the logistics of actually integrating electronic medical record with numerous EMRs is much more difficult than people understand. And it's -- I know we just even did a new EMR for our hospital system and it's very difficult. The registration in our hospital can't even talk to our electronic medical records. I think records like this are scanned. The easiest remedy is to either have fax or paper copy printed out and then it's scanned in for anybody in the hospital, then it's incorporated as a scanned document.

But I question -- I'm just wondering are you looking for the committee to somehow enforce or mandate a rule --

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MR. PARRISH: I need direction when --

(Everyone is speaking at once.)

DR. STUTT: I believe that exists in our medical control plan, that a copy of the PCR must be left at the receiving facility. And that's been there for 20 years. Enforcement is another issue, but the policy exists there. Good common sense dictates it should happen. You can't -- you can, but you are compromised trying to manage a patient not knowing what was done before you put hands on them.

The State had comment on that also about what is acceptable for electronic PCRs and whose responsibility it is. When the State says whose responsibility it is, it doesn't really matter. It's really an issue of cooperation. I mean, we should be one seamless system, even if our electronics are not, there are ways and as you suggested they can fax it, they can scan it, e-mail once they are back at their facility, it maybe 20 minutes later, but it's better than not having it at all. Ideally, the hard card

idea is good because it gives the provider a real time handle on what is happening. Whatever you might have on your card it might be great at another time to just say, yeah, these are things we all need when we receive a patient to be able to manage them so we don't duplicate medications. And I see what pathway you are going with that, maybe it should be the medical directors of each agency to address that directly with their agencies and say you have to find some way to cooperate, be it fill out the cards at Kingston Hospital, fax it, scan it, e-mail it. They have to have something.

Mr. LaMarca?

MR. LAMARCA: I would just urge everyone back and check what the status is at their facility. I got to tell you we bought more fax machines than Best Buy to put in the hospital and half the time that number is given away to the pizzeria and the lab and half the time we are trying to fax in the report and you know can't. So look at their own system, but when we butt up against IT in

the hospitals, they have no humor. They are protecting the castle for the most part and it's ridiculous. We have had cases where we are inside trying to wirelessly transmit the electronic record, we are blocked. We have to run back outside to pickup a signal in the trucks because inside it's protected. And so somehow if you could take a look and see if you need to maybe facilitate something between the IT and the field units -- and that doesn't cover guys doing it hard copy, but the electronics sometimes has been stymied by not being able to get a meeting with somebody.

DR. STUTT: I bet Mr. Parrish has tried that.

MR. PARRISH: We have talked to them.

DR. SHAH: Which hospital has a pizzeria?

MR. LAMARCA: Orange Regional, you have pizzeria, right?

DR. VORHA: We might, yeah.

DR. STUTT: The next item is a new product that has been introduced to BLS. And

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I'm going to ask Jeff Crutcher to provide the introductions.

MR. CRUTCHER: Carol Ackerman, come up and take-over.

(Discussion held off the record.)

MS. ACKERMAN: Hi everyone, I'm Carol Ackerman. I'm clinical educator with Innovative Trauma Care, we make the IT clamp and I'm also a paramedic up in Rockland.

So Jeff asked me and Dr. Stutt asked me to talk about the IT clamp. It's another tool in our EMS toolbox -- it's another tool in our EMS toolbox for hemorrhage control. It's relatively new, it's FDA approved for the last year or so and just starting to be used on ambulances in New York. It's being used in Chicago, Atlanta Fire Department, training Kentucky next week. So it's definitely picking up, the military has been using it for a couple years now and internationally it's been used for the last two years. So I just wanted to give you a little bit of overview.

This slide, this is sort of mid

training. I go through a pretty detailed training program with EMS providers and ER staff that are going to use this. It's very important to go over when it's appropriate and also how to take it off. So -- and safety -- so as you'll see it's a little bit sharp on the bottom.

So basically this is our spectrum of bleeding wounds. So on the left side we've got our minor bleeding, which can be easily controlled with direct pressure and wrapping it up. On the right side we've got our traumatic amputation, which you would need a tourniquet for. Anywhere you can't approximate the edges of the skin would not be appropriate for the IT clamp.

So difficult to control bleeding is really what we talked about when we were considering what to use. And my difficult to control maybe different than yours based on my experience, how long I have been in this field, how -- you know -- detailed my education has been. So we talked about what difficult to control bleeding might be for an

EMT, might be for a medic, or further as an ER physician, or one of the nurses, or PA's.

So minor bleeding that we talked about is very easy to control. And then our traumatic this would not be appropriate for, it would be definitely a tourniquet, stopping the bleeding and addressing any other injuries.

So in the middle we have difficult to control bleeding are scalp injuries and this is definitely something as EMS providers we don't really have anything good for right now. What the IT clamp does is can address the bleeding wounds where right now we'll put direct pressure and wrap it up like a turban and usually we get to the ER, they pull it right off, which undoes everything that we have done and reopens the wound. So the scalp injuries -- and I did bring a scalp so I can show you.

As far as other open wounds, basically anything, deep wounds, anything you can approximate the edges of the skin, muscle bleeding, junctional, arterial bleeds, our

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priorities are stopping the bleeding and addressing everything else.

One of the concerns that we have -- this is our scalp wound. This is a sample of a scalp wound that was a car accident, one of the nice things about this is you can put it on in less than 15 seconds and you are done. And you can keep visualizing it through transport and to the ER. Also, the patient can go into CAT scan and x-ray with it on, just not MRI because it has metal. So you are not putting your patient at risk by sending them off to radiology, which I know happens in the ER. So even our little trivial wounds that happen on the scalp can bleed out and it's something that EMS providers are no focused on. We are more concerned, you know, with ABC's and getting the patient to the hospital, those little wounds in the scalp that can be easily addressed are not until we are in the ambulance and on our way. So it's usually a 10, 15 minute extraction time and then we are addressing those.

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So this is what the IT clamp looks like. I think Dr. Berkowitz referred to it as the hair clip from hell -- thank you for that. It's got eight suture needles, twenty-one gauge. It basically is -- this is what it looks like and I'll show it to you so you can play with it afterwards. So what we have now is direct pressure, gauze, we've got the IT clamp, hemastatic agents, tourniquets, and TXA, which we don't have in our region. So standard guaze, direct pressure, one of the, we looked at when we were doing this training and putting this together is that there was a Littlejohn study -- if you don't have it we can send it to you if you want -- it compared standard guaze versus hemastatic and it was found -- the outcome was it's just about the same as far as patient outcome. So just an interesting study if you are interested in reading it.

But direct pressure is perfect. But the question is how long can you hold direct pressure? We have provider fatigue, long transport times, and are they doing it right?

Another study I read showed direct pressure wasn't being done properly, wasn't being held properly, especially after a few minutes.

So this is what the IT clamp looks like on the bottom, there is eight needles as I said. You can put it on very quickly, it stops the blood flow at the point of injury in literally second and it maintains the distal flow. One of the nice things when I talked to police officers about this and lot of them are bringing it on in their units, is they can put it on themselves or each other and continue shooting. You know, running the other way, but they like it because they are not losing function like they would with a tourniquet. And there is minimal pain, the average is one to three on the pain scale and application.

So this video you are going to see -- and I hope nobody is opposed to seeing animal testing -- this an anesthetized pig, I got to see this live. They made a femoral laceration and they just popped the femoral artery item and let it bleed out, in five to

nine minutes this patient would bleed out. So they took the IT clamp out of the box, they put it on and what you saw there was a safety sticker that just popped and that was the blood that popped up. So they are cleaning it up and making sure it's stopped bleeding from the outside. So basically the blood is continuing to flow inside and then it runs out of room, it forms a clot and puts pressure on the open vessel from the inside. Upon arrival to the hospital -- this is what we teach to the ER -- they are going to remove the clot that was holding that pressure and between this blood -- the clot there and the initial blood you saw, that was the total amount of blood loss for an arterial bleed. Now they are poking around to see if they can make it bleed and they can't.

What you see on the right here, this is a cadaver. And you see on the right is the IT clamp in place on the x-ray and the flow continues. So you can see the clot holding pressure on the vessel there and the flow is

continuous.

Some of the history and the evidence behind it, there was a swine study that was done on the right. You can see that they made that same incision that you saw before, laceration, and they let the pig bleed out and 100 percent of them didn't survive. The next one over, they did direct pressure and standard guaze packing three minutes post injuries and 60 percent of pigs survived, which translates to 40 percent of them did not. Then they use the IT clamp during the injury, 100 percent of them survive with just under 500 milliliters of blood loss. And then put on 10 seconds post injury, just what you saw in the video, 100 percent survived and only 120 milliliters of blood loss.

As a medic sitting in an ALS in-service and looking at this I said 100 percent like it just sounds a little too good to be true, but to this point we have not seen any adverse outcomes. I've only heard one anecdote of a story that when the crew moved the patient from the stretcher onto the ER

stretcher it popped off, but at that point it had stopped bleeding anyway so they didn't need to reapply it. It's 100 percent effective at controlling fluid loss in all compressible zones.

So FDA approved right now is for scalp and face, not around the eyes. I heard recently of a dog bite on a child that they used the IT clamp to close on the face and they were able to wait several hours for the plastic surgeon to come and repair it and they didn't have to do something quick in the ER. So it's approved for the face and head.

We are waiting on FDA approval for the neck. My understanding is that in another country there was a gang fight and a guy got slashed across here, they put two clamps on, by the time they got to the hospital he was on the phone ordering a retaliation hit. So, yeah, this is what we want to encourage.

So any compressible zones and especially where we don't have tourniquets that go on the axial and inguinal spaces, it's great for extremity use, upper chest, and the entire

back.

So this is -- we go through what we have. This is part of our training. So agency that signs up to get it they get a full discussion of what is available, what is in your EMS toolbox and then what options are out there. So we talk about all of it.

Another thing that we don't like to talk about, but has to be part of our training, is mass casualties. This is a very quick and easy thing, we get multiple school shooting god forbid, or stabbing that was recently in Pennsylvania where you can just clamp them off really quickly and get out quickly. One of the benefits of this over a tourniquet is it takes a lot less time to put on and you can transport.

A couple of case studies. This was a 36 year old male, who got drunk and in a bar fight hit, was hit by a baseball bat. He had a couple of bleeders that stopped on their own, but that one wouldn't stop, bled all over the bar, the floor and the ambulance stretcher.

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One of the nice things, especially EMS crews, the feedback we've gotten from the agencies that have used it, is that the turnaround time is quicker. They don't have to decon the ambulance as much. It goes on quickly, the blood is not everywhere, on the stretcher, on the floor and the crews can get back in service. You also don't need two -- what's it called -- ambulances out of service where you need multiple people to hold pressure. The ER doctor liked it because it allowed continuous visualization of the head and swelling of the skull. Next to the IT clamp base you can see the swelling, that's the hematoma under the skin. Bulky dressing wouldn't have allowed them to see it. Bleeding stopped in less than ten seconds, the IT clamp was placed on in less than five.

This was a gentleman walking to his car, tripped and fell, cut his hand. He held pressure with napkins from his car on the way, but drove himself to the hospital. Got to the ER, what is the first thing you guys always say? Let's take a look. Opens it up

and the blood spurted across the room and the patient had a -- the palmer artery was lacerated. So the staff -- this is what I just told you. So the clamp was placed, there was still some bleeding because of the shape of the hand so they put some adrenalin soaked gauze and were able to stop the bleeding. Without the clamp the patient would have probably needed temporary closure and would not have been able to wait for the hand surgeon.

This is 36 year old male who was actually stuck in some sort of machinery, industrial accident. There was extended extraction time so while they waited for the helicopter two tourniquets were placed on because the bleeding didn't stop after just one. These are the vitals upon arrival to the ER. As you know, get to the ER, they loosen the tourniquets, so the bleeding continued, but not from where they thought it was. It wasn't so much from the open fracture, but from a little -- I think it was a three centimeter wound lateral to the knee

joint. The tourniquet was taken down, they put the IT clamp on with some packing inside, which studies have shown -- from our studies anyway -- it's not necessary to put the packing in, but either way as long as you are approximating the edges, that's fine. So because of the IT clamp put in place -- which you can see there -- the patient was able to get a full ED assessment. The arterial hemorrhage was controlled. Patient went to x-ray. This is what they saw. You can see the IT clamp up on the left side in place and there is the CAT scan. The nice thing about the CAT scan, the radiologists that have seen it and ER doctors that have seen it, it really doesn't cause a whole lot of artifact, so they are fine with it being in place. The patient had one surgery and actually the first surgery was orthopedics, not vascular, vascular wasn't done until nine hours later, FDA approval for the device is up to twenty-four hours. So the bleeding was found to be a torn popliteal artery.

So it can be used in any types of

wounds, high velocity gunshot wounds, knife wounds, entrance, exit. Pediatrics -- approved for pediatrics, geriatrics and anybody anticoagulated. No MRI, we said that before. Mass casualties, it is great for care under fire, natural disasters, very easy and quick to put on.

So our rule of thumb is if you have longer than a thumb, you need more than one. The reason we don't have it bigger is because it's really hard to get around those rounded extremities or areas. You will know if it's not placed properly because it will still ooze or bleed. You can easily take it off and put it back on. It can be used with anything else, you can poke a lot, you can put your -- the tourniquet on if need be if it's still not stopping.

So basically that's our presentation. I go into a lot more detail when I'm teaching as far as how to use it. But just for some other case studies. This was -- I was teaching in Chicago and this came in while we were teaching. I went with them, Chicago

Fire Department. This was a pretty decent knife wound and they actually were able to put on two clamps. They were done in about 30 seconds. Not that it was bleeding a whole lot, but of course you want to cover and close it for infection purposes.

This was a young man who decided to get drunk and play with his chain saw, so he had a pretty decent injury on his left arm. They put on two clamps, this is what it looked like when they arrived at the ER. This is him six hours later and if you look closely -- I don't know if you can on here -- but he had some stitches over here, but the rest of this was closed with the IT clamp. That's what it looked like. You can see a couple holes from where the IT clamp was in place.

I don't know if there is anything else I can show you. It's really great for scalp lacerations -- I don't think I have the other one.

This one is a 92 year old woman who tripped and fell in the nursing home.

Apparently EMS reported that there was blood everywhere. They came in and put on the clamp and it stopped bleeding immediately. She was on Plavix. I'm hearing a lot of these, especially scalp uses across the country that we have been training.

One other note is for car accidents. As they are holding stabilization they notice a bleed, the IT clamp goes through two layers of denim. So it's a nice way to temporarily stop the bleeding in that kind of situation and then when they get the patient into the ambulance they can reposition as needed.

DR. BENNEK: What is the cost of these?

MS. ACKERMAN: Chuck Margarites is with Health Care Technologies, he is the distributor. I'm the educator. So you want to --

MR. MARGARITES: Chuck Margarites. So I'm the distributor for the product. I'm also 25 years in prehospital EMS flight nursing.

What you've got is a mechanical pressure dressing so all you need to do is bring the

edges of the wound together and this proves to be a safer, faster -- it's actually cheaper -- validated product. So what you are looking is that the flow is going to be maintained, unlike with the tourniquet, that's one of the benefits of using this. So I see that as being the primary reason to use this.

The other is that I want to share one quick case study with you. In Upstate New York REMO region we just had a deployment the other night where we had a patient who had an INR of seven and had a scalp wound where they couldn't stop the bleeding. So they applied one of the clamps, the bleeding was stopped in matter of 10 or 15 seconds. So basically what happens is you bleed into the wound pocket, the edges of the wound are closed, as soon as you build up enough pressure above the systolic pressure you establish stasis. Stasis will be --

MS. ACKERMAN: Just to do a quick demo since you are playing with it --

DR. WILSON: The question was the cost.

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MR. MARGARITES: I'll answer that.

(Everyone is speaking at once.)

MR. MARGARITES: -- we are cheaper than tourniquets. So 39.50 per unit is what we are doing right now, 39.50 per clamp. So if you are buying the Cat or any other tourniquets --

MS. ACKERMAN: All right, you guys are like children, you already took them out of the box.

So the way I teach is you have your gloved hand, you are doing direct pressure. I teach as if I'm alone because typically you are. So you pop it open with the other hand, you take it out by the metal bar, you put it onto the wound and squeeze it closed and you are done. And this is your airtight, fluid tight seal. If you wanted to remove it you do two Cs, squeeze the wings, which takes pressure off the pressure bar, and that opens up the wings. So one side moves, the other side doesn't.

So if you want to try and get it open since you closed it over there, squeeze the

tension bar and then one wing moves. I also have a scalp so you can see.

One of the nice things about the scalp is that it's very easy to close. But we do have less skin on our scalp so you can adjust the opening of the IT clamp so you can only grab a little bit of skin.

DR. STUTT: Carol, suppose you want to just grab a small -- when doing it over the radial artery as well.

MS. ACKERMAN: Basically you are just closing the skin, you don't need to grab a lot of skin.

(Discussion held off the record.)

DR. STUTT: Ms. Ackerman and Mr. Margarites, thank you for your presentation. Very interesting, you know, I can see the level of interest here, everyone playing with the new toys.

And I think what we need to decide is if this is something that would be considered -- there is no foundation here for us to have anything else to rely on other than what we discuss right now. If this would be

considered a direct pressure device BLS now allows direct pressure devices for direct pressure as well as tourniquets to control uncontrolled bleeding. And I'm not sure what precedents there are for us to just adopt it as a direct pressure device. I'm not sure if the representatives -- Craig?

DR. VAN ROEKENS: Just one comment, again, we talked a little about it. The issue is where is this applied? If it's vascular structure such as fistula -- and I can see less informed person potentially doing that -- and attempts to stop bleeding that could cause significant vascular damage so we want to think about that. It's not a typical vascular direct pressure device, this has teeth that could damage and harm the skin so if it's not used properly.

MR. MARGARITES: As the distributor, the teeth on the device when closed completely are four millimeters into the skin. So it's the way it closes. I know that addresses some of the concern, but not all of it --

DR. VAN ROEKENS: -- but fistula --

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DR. BENNEK: It seems to me that it wouldn't be a simple pressure device, you would have to some training beyond the tourniquet and the common things that are used for bleeding control. So I don't know if it's as straightforward as a pressure device and to approve it I don't know what the process would be, but I think that training just to avoid a complication would probably be appropriate.

DR. STUTT: We had a discussion down here whether we needed to pursue this further with perhaps State BLS folks to find out where we would stand if we did introduce it. And perhaps we ought to hold off on that, the consensus seems to be in the discussions. It looks like a useful device when properly applied, but where is the approval? Unless you can tell us about approval from New York State Department of Health?

MS. ACKERMAN: What we understood and gathered is New York State doesn't approve or disapprove any medical device. It is actually being used now for the last four

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months up in Saratoga with Mike McAvoy and --

(The speaker cannot be heard.)

MS. ACKERMAN: -- it's a training, you know, and that's my job, to go and make sure everybody is properly trained on how to use it and when to use this. So you know the FDA approval is there for all levels so it's really -- will set the protocols in place and make sure they have proper understanding and education before we deploy it.

DR. LARSEN: Look, when we started seeing these hemastatic devices come out, you know, they have -- I mean, even the first once when the granules came out, okay, so the granules had some downside too because they generated a lot of heat and those kinds of things and they could be left in the wound, people came in to hospitals and didn't know what they wore and a variety of different things. So, I mean, you have the same sort of thing here and, you know, in terms of just a simple bandage you're training medics and EMTs to use bandages in a certain way and there is all different kinds of brands and

stuff like that, some maybe better, some maybe, worse but we don't approve or disapprove one of those brands.

So I think it falls under, you know -- I don't think we should make an exception for this. We haven't made exception for other devices. I think it's the responsibility of the company, they are going to train folks and also -- look, there will be some liability on us, but there is also going to be liability on them just as with all these devices if some enterprising person decides that this device caused a major problem. So I think that we can't make a special exception for this and it should basically fall under a pressure device.

MR. HUGHES: Within the office and within the region there has been a lot of agencies that called us and asked us about it and we weren't sure how to answer the questions. Is it just a direct pressure device that would be used by anyone, or is it something that has to be MAC approved? And that's why we asked them to come today and

show it to you and see what you think and see what we need to do with it.

The other reason we asked them to come is so if you did see it come into your facility at least you know what it was. As far as the region we don't know if it's good, bad, indifferent or supporting anything on it, we wanted to make everybody aware it's out there. And we don't know if agencies are using it, I was talking to an agency yesterday said they would put it on their trucks tomorrow. Oh, I don't know if that's good or bad. I don't know if they can. That's why I wanted to have it here to decide what we should do with it, is it a direct pressure device, and BLS can use it, or is it something that has to be approved?

DR. STUTT: How can we get that documentation whether it's simply a direct pressure device? Is anybody in the State going to give us that answer?

(The speaker cannot be heard.)

MS. ACKERMAN: -- as mechanical direct pressure -- so you know that's what the other

agencies in Westchester that have started using it are using as their protocol.

DR. LARSEN: I mean airway devices fall under the same sort of thing and we have all kinds of airway devices out there. We are not approving each airway device, some have been good, some are bad. And so I don't know, I just think we have to do it in comparison to some of the other things.

DR. STUTT: Do our state representatives have any insight to where use of these devices would be.

MR. ROBINSON: Richard Robinson, State Health Department can't --

(The speaker cannot be heard.)

MS. ACKERMAN: Again, my understanding is that it had to be regionally, the State would not approve or disapprove any particular medical device, that's been my answer.

MR. ROBINSON: I have to check with Mr. Johnson up at State Health and ask.

DR. STUTT: Mr. LaMarca?

MR. LAMARCA: The only thing I can think

you can ask the State is how would they classify the device? Not any endorsement because the State won't endorse -- nor will we. I think the only thing you will get from the State is is it a pressure device or hemorrhage control device. I think the only thing is what is it approved for by the FDA? If I heard correctly it's only for the scalp and face and not many of the things we saw in the demo.

MS. ACKERMAN: Any compressible area, extremities, inguinal --

(The speaker can't be heard.)

DR. STUTT: Mr. Robinson, with your access to Mr. Johnson could you get us an answer whether this is considered a wound compression device.

MR. ROBINSON: I'm e-mailing him right now.

MR. VIOLANTE: So the November meeting?

DR. STUTT: So I'm going to suggest we put this on the agenda. It was a good presentation. We were interested in the product, it looks like it has great

potential, but to make sure we are doing it the right way we will wait and see if the State considers this a direct compression device in case we can turn it loose with proper training, of course. It would behoove each agency to have proper training for it, but would not require our specific approval.

MR. LAMARCA: Unless I'm wrong, I don't think the region has any status. I don't think you can approve or not, the agency can make a decision --

DR. STUTT: If it's considered a wound compression device. Right now we don't --

MR. LAMARCA: Even if it's not it might not fall underneath the parameters of anybody having any say in it.

MS. ACKERMAN: We do have literature that it's a compression device.

DR. STUTT: Well, it maybe the region doesn't have to make a decision about it, you maybe right we don't have to approve it, but no agency can use it unless the State says --

MR. CRUTCHER: It's been deployed in the REMO region.

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DR. STUTT: It has?

MR. CRUTCHER: Yes. Under the auspice that it's a device, not a drug, didn't need REMAC approval. They saw the device and started using it.

MR. VIOLANTE: I think as long as the FDA approves it you are good and it's unto the agency to decide if they want to use it and the medical director wants to get involved.

DR. STUTT: Given it doesn't require our vote perhaps the minutes should just reflect that we received an educational session on the IT clamp by representatives of --

(Discussion held off the record.)

DR. BERKOWITZ: It sounds like we are not in a position to approve or disapprove, but is there anything we can do as this body to improve the safety of the device -- is there anything we do have the power to do, either to make recommendations on what we should include in education -- or is there anything we can do to improve it? Because we are not going to be the ones to say thumbs up

or down. All we can do is make some recommendations. So my suggestion would be in November if you want to think of any recommendations we can make to improve the safety, I think that's something we can do.

Is that something that is within the power of this body?

MR. LAMARCA: I think you can share it --

DR. STUTT: It would certainly seem that some basic education would be necessary for the personal safety of the medics applying it.

Ms. Ackerman is not going to be able to go to every agency --

MR. HUGHES: She is.

MS. ACKERMAN: I am --

DR. STUTT: You are going to every agency to wants to use it, correct?

MS. ACKERMAN: Yes.

MR. MARGARITES: We have a team of field educators that will do the training, so the agencies -- each one of the agencies will be trained and signed off before they deploy.

That's the strategy, it's the same exact system that we used initially by the care product EZIO. We did the same training. We sent educators, made sure people were signed off, validated and comfortable, gave them a one hour to two hour block before it was turned loose. I know later on down the line that changed when we initially rolled it out, but that was the way we handled all new agencies coming on board.

MR. HUGHES: If you train an agency in a particular area and they are going to a hospital facility --

MR. MARGARITES: We train the receiving facility as well on how the device works, on how to remove it. In addition to that we have cards that come in with the condition that -- it's similar to the other manufacturer that I represented in the past -- they go in with the card, it has a telephone number that has customer support available to them right away and they will have access to clinical specialists and people like myself as well.

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DR. SHAH: There is a GPS unlock --

MS. ACKERMAN: So, you know, it's -- the people that started this company, they are the same ones that started EZIO company, so they are rolling it out similar to EZIO. We trained people -- I have field educators that come in my absence if I can't be there just to cover more territory and more shifts and make sure before it's deployed and everyone is comfortable with it.

DR. BENNEK: A lot of devices are -- you have to get a carton of 25 or 50 of these devices. How do they come.

MR. MARGARITES: We can sell them individually or in packages of 10.

DR. STUTT: Any other comment on the IT device?

MS. ACKERMAN: I have a question, just getting information properly -- I have a couple of agencies, BLS agencies in Rockland who are interested in moving forward in the next two weeks. So it's based on their medical director approval, if their agency approves it? Is that where we are leaving

it?

DR. STUTT: It's our sense we don't have any comment to support -- to approve or disapprove it so.

MS. ACKERMAN: Okay, thank you. Thank you for your time.

DR. STUTT: That concludes our agenda unless there are any other issues that anybody wanted to bring up?

Can I get a motion for adjournment?

DR. BENNEK: Motion.

DR. STUTT: Second?

DR. BERKOWITZ: Second?

DR. STUTT: All in favor? Closed. Unanimous.

THE FOREGOING IS CERTIFIED to be a true and correct transcription of the original Stenographic minutes to the best of my ability.

Yvette Arnold