TranExamic Atomized for Pediatric post-Operative Tonsillectomy hemorrhage - Pediatric Grand Rounds-1-17-25Meeting Recording

January 17, 2025, 1:29PM

59m 52s

Kamat, Deepak M started transcription

Meyer, Andrew D 0:13

OK.

Kamat, Deepak M 0:41

Good morning.
It's 730 on time to start over grand rounds.
The CME code is in the chat box.
We'll keep repeating it every 10-15 minutes.
It's my great pleasure to introduce this morning's grandmas, a good friend, Doctor Andrew Meyer, who is associate professor with tenure in Department of Pediatrics at UT Health.
He's a research physician at U.S. Army Institute of Surgical Research and Associate Faculty of joint.
Graduate programs in biomedical engineering at UT Health and UTSA. Doctor Mike is a physician scientist who integrates biomedical engineering and medical research to improve the lives of critically, I'll children.
Doctor Meyer received his Bachelor of Science degree in Nuclear Engineering and Material Science and Engineering, followed by Master of Science degree in Biomedical Engineering.
Doctor Maya received the Doctor of Medicine degree in 2004, completed internship and residency.
In internal medicine and Pediatrics in 2008 and finished his clinical fellowship in pediatric critical care medicine in 2011.
And then he joined ET Health.
In the critical Care Medicine division, Doctor Meyer received his certificate in Translational Science from Itasca in 2016.

Has an active research program committed to decrease coagulation complications associated.
With critical illnesses.
With funding from National Institutes of Health, American Heart Association, Children's Heart Foundation and U.S. Army Institute of Surgical Research.
Doctor Meyer has had an active research collaboration with U.S. Army Medical Research and Development Command since 2013. Specifically, his lab evalu anticoagulant therapies that reduce thromboembrile complications associated with life saving devices such as ECMO and cardio pulmonary bypass, in recognition of his excellence, Dr. Maya Rece.
A 2017 Junior Distinguished Research Scholar award.
And.
And became capability manager of organ support for Defense Health Agency in 2022.
The Society of Critical Care Medicine accepted Doctor Meyer as a Fellow of American College of Critical Medicine in 2024.
Doctor Maya, thank you very much for accepting our invitation.
We are all looking forward to your wonderful presentation.

Meyer, Andrew D 3:15
Thank you Doctor Kamat.
I appreciate it very much.
One of my colleagues is also on the call is Doctor Schwartz.
She's an assistant professor in emergency medicine and very big contributor to this talk.
We'll talk about her as we move along.
I hope doctor early can join, but she's quite busy.
Title of my talk is transmemic acid transexamic atomized for pediatric post operative tonsillectomy hemorrhage.
This is an ongoing project that's been for the last five years and that we will discuss.
Basically, the idea behind this trial and all the tribulations of how to launch your own randomized controlled clinical trial.
Let's get started.
First off, standard disclaimers. The army doesn't have anything on me, and neither does anybody else.

First off, I'm going to do a little bit of quotes throughout the slides just to sort of understand sort of the the relativeness and randomized controlled clinical trials. This is for Austin, Bradford Hill.
He's famous for the Bradford Hill criteria, which somebody remember from Med school.
And he was the one who did the randomized clinical Tri, attaching smoking to cancer anyway, he said no one who had been intimately concerned the inquiry could realize the multiplicity of problems involved in its organization.
This means trial planning implementation are properly conducted.
Comparison demand the cooperation clinician statistics administrator on a scale previously unseen and IA 100% agree with this.
It is a big undertaking and we will go through it.
And not to scare you all, but I want you to understand the complexities and difficulties.
Of what goes into developing a clinical trial.
I cannot do this.
Here's our agenda for the day. As always needed stated, we're going to talk about the clinical rationale.
We're going to talk about preliminary studies being done.
We're going to talk about that design, which could be the bulk of our study of a randomized control trial, how funding is obtained, the regulatory component, certain challenges we faced and of course I want to open it up to questions and answers at the end, of course these.
Are The Three Musketeers? Nothing can be done without colleagues and other component.
That's me on the left.
I am a pediatric intensive care physician.
I work on coagulation research.
Doctor early has been my colleague and friend throughout this entire process.
She is our division chief, Pediatric ENT and also the program director of the ENT Residency Program and Doctor Schwartz has come back to San Antonio.
We're so happy to have her as she is one of the emergency medicine physicians in the University Hospital emergency room and I'm so excited she's come back.
She was a resident here.
And went off for fellowship there.

Anyway, so let's go on.
So when did this all start?
So one night in the PICU so during the fall of 2016, a teenager been in University Hospital.
Pick you after a suicidal near hanging event.
Very sad. A component of it at that time during the hanging period she had developed what we call post obstructive pulmonary edema, when the pressure that builds up inside the trachea causes a little blood vessels and water and.
Alveoli to purse within the lungs and cause all kinds of pulmonary.
Edema within the required intubation and support two nights in a hospital stay got much worse and she had promised in blood coming up her endotracheal tube preventing oxygenation.
This is on the left is an example of post obstruction of pulmonary edema.
We see this sometimes.
The other one, we see it very commonly is in drowning.
Patients drowning patients can also have this component, and it can be very scary, especially when you have so much bleeding within the lungs.
To what? To do so you know at the time the fellow asked me. What do we do for significant bleeding in the lungs?
And there were some algorithms. This went from 20/20 was a little later, but it's pretty much the same thing.
You know, you follow the algorithm.
You know, it's a patient not stable, OK.
We'll intubate the patient once we did correct all the coexist we did.
You can get the bleeding side down, if that's possible.
Broncosby wasn't really a possibility because the patient was so sick.
So the patient hasn't stabilized.
We continue supportive care.
Or you can try to bronchoscopy.
You can also do angiography to try to embolize the bleeding source, but in none of this there was nothing really we could do in the middle of the night.
That was something that we could selective.
Yes, we could set up for bronchoscopy in the morning. So we tried to stabilize the patient.
Yes, we were intubated.

We increased the positive and expiratory pressure.
That's sort of pushed sort of like basically holding pressure on a bleeding site, then the lungs to corrected our bleeding abnormalities. We gave coagulation factors other things.
Middle of the night we do flexible bronchoscopy.
And by selecting imbalization.
No, sadly, it was like that CT scan before the bleeding was coming from everywhere.
And so, you know, what could we do?
So we were searching for what to do in the middle of night.
Classic ICU condition happens all the time.
What can we do for these very sick? Critically I'll patients.
Over a period of time. So at that time I had been publishing and working.
In U.S. Army Institute for Surgical Research and I had been hearing a lot about the crash. Two trial the crash 2 trial.
It's early administration. Transmic acid safely reduce the risk of death in bleeding trauma patients.
So this is a really fascinating study where they took several 100 patients have come into trauma.
The university United Kingdom into trauma hospitals for a period of time and given them transmemic acid upon arrival to see if that would decrease the bleeding component and what they showed was a significant reduction in bleeding.
And cause of death from bleeding cause of death. This is a big.
Big, big study.
And it really seems to have that 615 fifty patients went down significantly and that transamic acid was able to reduce the all 'cause mortality for these bleeding patients.
This is really important because bleeding is the number one cause of mortality after trauma and a significant part.
Of our research component.
So we're really looking to reduce bleeding.
This was an exciting Ave. to study.
And then since then, they've repeated the study multiple times, so they've even shown that reduces head injury deaths.
Treatment is cost effective for patients, for mild to moderate traumatic brain injury.
This was not done in kids, though. There have been studies in kids that show the same effect, and so it's almost become that routine care that we get transmic acid for

patients with significant bleeding and.
So transmemic acid was on my mind.
I'll tell you a little bit more about why it was on my mind for this patient and that is because.
Tran Examic acid sorry is an antipyroidlytic.
An antibiotlanic is basically a competitive analogue that blocks the effects of fibrin breaking down.
So, generally, fibrin is the last step of the coagulation.
Cascade is a fibrin clot, but you know when you're building a brick wall, you have your platelets, you have your cement. You're building the brick walls.
It's moving up and up and up.
Right. And then you have this extra stuff that's kind of like stuff and you need to scrape it off and that's what fibroidlysis does. Fibroid and lysis scrapes off that extra stuff.
So you don't cause clots and that's what's designed. But also there's clots there that don't need to be there.
It breaks them down and So what happens is tissue plasminogen activator and plasminogen come along.
They link together and they break up the clot and we see things called fibroid and degradation products.
What txa does it says?
Nope, it gets onto that clot and says do not come by and break it up.
We're still bleeding.
We're still having troubles.
Another alternative is carpoolic acid.
That's another consistent anti fibroidic that does it and basically blocks in there to block the natural process.
So I knew at the time that trauma patients were getting txa and I knew that some people were doing topical txa and they're having a lot of success and decreasing blood loss, orthopedic, plastic surgery. And I found this one paper from 2009, a pulmonary hemorrhage, a.
Nominal motive therapy and me and the fell at the knight were like.
They mean this will work as we read this paper and in this paper they were doing parthos copies.
To an added txa to bleeding sites in the bronchoscopy.

So we're like, that's really interesting.
And then we found one other paper of a novel, two step therapy, where they gave nebulized transmemic acid and were common factor 7A in children intractable diffuse hemorrhage.
And we're like two papers.
This was cool.
And so we were like, what if we tried transmemic acid?
You know, this patient wasn't doing very well.
All night we're trying everything else.
So we ministered it nebulizer and we also just reported down the ET 2.
And miraculously, I mean this was like one of those amazing things. We're having tons of blood just pouring out of this ET tube, just significantly having issues and then suddenly just stopped all of a sudden.
And it was just so Frank and so amazing that we were all kind of like stunned.
Unfortunately, this patient did not do well overall.
It was a horrible case for us to brain death and didn't do well, but I mean, this was an important point.
And Doctor Schwartz, I believe her timing is this time she kind of heard about this and she's like, that was cool.
I need to remember this and we'll get back to why she remembers as we moved on.
So anyway, I left at this thing thinking oh, txa may be helpful for our bleeding.
I told a couple of my colleagues, of course, some of them just jumped on.
It started.
Giving to everybody started bleeding out the ET tube.
That's frustrating, but that's how life is.
But I was starting this really interesting process.
Not much is published about it.
There are only these two papers that we had found.
There wasn't really anything going on.
So doctor, early at that time was a new faculty member, and she was, you know, interested in aggressive and really want to get involved in in different care. And she came by and we were talking about doing different research projects. And she said, hey, did you know that?
One out of twenty of our tonsillectomy patients come to the Ed with bleeding, and I had a clue about this, but I didn't really know.

And I'm like no.
And I know that. I just knew I remembered my last patient.
That was, you know, was this bleeding coming out of the E?
And I thought about my other previous patients.
I'm like, boy, that must be really hard to secure their way.
And she goes, that's correct.
I wish there was a way to stop bleeding without having to perform surgery, and I said, what about transmic acid? And she said I haven't heard about that. Let's talk more.
So this is sort of one of the things that happens in the beginning parts of a study where you have a solution for one scenario and then someone brings a different problem that might even be better for the solution that you're going to do. And these two come.
Together.
And So what I want to say to all the junior people on the call, you know, this happens and at this time write this down and think about it because it can build into something big, like we're going to talk about, OK.
So first of all, let's go back to what doctor early was saying.
Tonsillectomy is a very common over half a million, I think it's up to 600,000 now per year are performed in the US. That is a large surgical operation.
I think it's #2 in terms of pediatric surgical operations.
I don't remember what number one is.
What has happened?
Well, we're not having more tonsillitis.
That was the common reason with tonsillitis in the past. What we have found and consistently found is tonsillectomy is the number one way to treat pediatric obstructive sleep apnea, and you can see from this very exciting study in 2013 New England Journal of Medicine significant reductions in.
Sleep apnea and sleep components. When you have a tonsillectomy, an early tonsillectomy seem to improve overall everything component, and now it's becoming almost a standardized practice.
Known for patients who are younger.
To get tonsillectomy to help their sleep breathing as they get older.
However tonsillectomy they were, very common procedure has a significant complication of that one out of 20, about 5% will bleed on day five to seven, which

we call secondary post tonsillectomy, hemorrhage, or PTH.
So if I say PTH for the rest of the talk, that's what I'm discussing.
Primary PTH occurs in the 1st 24 hours and that's usually governed by, you know, they didn't really seal the clot as well.
Burn it down a component aspect.
But secondary PTH is what we worry about because they go home and about five to seven days later, that area that they've burned off and they've taken all from the tonsillectomy falls off and you get hemorrhage.
Not every patient, but it can be and. And the reason why you get hemorrhage is because this is an area that's very difficult to form a permanent clot.
It's wet, it's component and the other part is that there's very little area. There's nowhere to apply direct pressure.
So current standard of care is it comes off, they come to the emergency room, usually late at night.
Talk about and. There's not much to do except to take him back to the operating room re and debate them and apply more cauterization. And we basically start the whole process over again.
So really we need a way for the emergency room physicians and the ENT docs to do something that might decrease the overall times of going back to the operating room because it's really not the most successful process.
So at that time we're growing and growing more and more studies that transamic acid works for hemoptysis hemoptysis of course being blood.
Coming out from the lung and in 2018, Juan published the first randomized control trial, a transmemic acid nebulized, to placebo for hemoptysis bleeding, and he published this in he's from Israel.
It was a large study, but showed significant reduction in the patients that bleeding several years later.
Erika O'Neal, who is actually one of our wonderful faculty from Bamsey.
She's a pediatric ICU director.
She's currently deployed right now.
Published another study.
So the transmic decrease from Optus is.
And critically, in children at Texas Children's, and of course, that other study in 2015 that we talked about that was done by. So there was growing growing studies for transamic acids working for this internal bleeding within the lungs. But you know,

would it work for ton?
Well, at the time the current management was, as I said before, 3 to 5% of tonsillectomies present in the emergency department with post.
On the contrary, of course, they always come at night, 17 to three eight because you know they're having trouble all through the day. And then parents get home, finally taking emergency room.
Non operative measures like gargles, silver nitrate, topical Benz, they didn't seem to work.
You can see someone trying to put silver nitrate on the tonsils there.
I don't know how they got that person to stay still and the majority of 20, Andres went to the emergency room, went to surgery and Doctor Schwartz, she was like at Dell Children's getting her fellowship in Pediatr may be remembered. Our previous use of transaminic maybe not.
And she said, what if I give it to this little 3 year old that had come in?
With significant PTH.
And so she did in the emergency room.
Now the child still went back to the operating room. However, when they got back to the operating room, the bleeding had stopped and she published this wonderful case report in 2018, which really cemented the idea that this is something that we could do. So doctor early and.
I saw this and we'd already started thinking about how we do studies and we started to work harder to develop.
This is a therapy that's worth pursuing, OK.
And so we did a study at University Hospital, which a retrospective study.
So we looked at the last 58 patients.
From 2016 to 2019, and 14 of them, we treated with nebulized txa and we noticed our pediatric posterity about 5.8% and after nebulized txa, we decreased as you can see from the left, how many patients went back to the operating room by 40.
4%, which is huge, huge reduction in patients going back that early went from a skeptic to a believer that this is a miracle drug that you can give the patients.
And I'm going to say one of the things was most exciting about this study.
Is that we got to work with Dylan Irwin. Who now I think is AP GY5I might be.
I don't know if he's. Yeah, he's almost finishing his ENT residency, but at this time he was a Med student, very excited about getting into ENT.
And he actually drove to write the study for US control Nebula Transmic

retrospective coord. Sorry. And he was first author and he actually got an MD with distinction and research, which was a really exciting process to work with a student that closely.
Anyway, this was real exciting.
He published a study.
And actually, people done journal clubs after the study.
Which was the most exciting complement I've ever had of a study that I published and very exciting.
So we at the end of this were like trans amic really works, but what are we going to do with it next? This is like basically end of 2018, early 2019 took a while for us to publish the study, but that's what we were looking at.
Of course, you know pandemic happened, but this was early 2019.
Floodgates sort of opened up, though later in the years just for excitement, confirming our theory.
A large paper in 2022 came out from Shin, looked at over 1000.
In case of a PTH, an 83 txa and they showed almost a 30% reduction in the retirement to the operating room, which is very exciting and I repeated bleeding went way down consistently.
The next thing was Spencer American Journal.
Auto Errandology also showed in a small study that they could decrease the txa.
Another study came 21 patients for visit control hemorrhage need operating intervention decrease very much significantly and even a systemic review.
That's where you know you're getting up. There was done in 2024, looking at the basically topical txa or nebulized TXA was the best way to decrease post doctor operative blood loss for time selective hemorrhage so.
Now we're moving on, so we're going to talk about another quote.
This is doctor Archie Cochrane.
A lot of people know this from the Cochrane studies. It's a very important trial.
We all go to this for randomized controlled trials.
He was kind of the father of evidence based medicine and advocate for high quality research, primarily from randomized control trials, and he said randomized control trials seem the obvious way to test the treatment's effectiveness.
But when I proposed them in my early career, I found myself under the complicated logic patient recruitment data collection.
Entrenched BI doctors already knew what treatment work best, and this is a big issue.

Two that we're going to talk about is even though you have a study that shows this improves, you have to convince physicians this is the study they need to do.
Either you have to convince physicians who are already doing it.
It needs to be studied or you have to convincephish physicians who don't want to do it, that it requires study and that is a a complicated thing. And the best thing that we all accept is how do is to blind the participants and randomize them to two arms.
And really, to see what the actual true efficacy is.
So back in 2019 I getting all this research I read Doctor Schwartz's paper. I was getting really excited about doing a randomized control, figuring about maybe I need to do a randomized control trial.
And so I called up one of our compliance officers here at UT.
There's a great group of people that work within the Research Office and this is Miss Nyland. She's a previous pharmacist.
And then she works in the Office of Compliance. And I just said this said to her, hey, doctor, Elaine and I are about to publish.
But as txa decreases, potentially, she's like, that's great.
What's the next step?
And I said, I think we need double-blind randomized controlled kundal try.
She's like, well, first thing you need to do is you need to get Ind approval from the FDA. And I said I and D what's that she's like, let's tell you more.
So what is an Ind?
An Ind is an investigational new drug request. Authorizes the Food and Drug Administration. OK.
It's a basically if you even have a drug, we can go through the steps. This is a drug, biologic product.
For us, it's yes.
Is drug product using in clinical research? Yes.
Does your collaboration, non industry designed to sell? Yes.
Is it exempt?
No. And so an Ind is required.
So even drugs that are approved, like transmemic acid, if it's a new indication, a new process, a new method that you're going to be doing the study with, if you want to do a study in human subjects, you need to have approval from the FDA that this is.
Something that they can go through, and it's mostly for them to traffic, I mean.
Not traffic track.

That you're doing the study.
And so they're able to get it ready for a possible new indication as the study goes on.
And so you present information on the product, the drug or the biologic, right?
And it goes to the Center for Drug Evaluation and Research.
They look at the regulatory pathway and then the ways that they get to proceed.
So this is what an Ind is.
It's basically submission of a protocol to the FDA says.
I want to prepare this study.
This is how I'm going to do the study.
This is what's going on.
They look at the evaluation of safety and the effects and then they give you approval.
And so you can't do a study unless you have an Ind.
The Ind application is it's not as extensive as people think it is.
I did this sort of in the beginning of the in the late 2019. I kind of did it because I wanted to see how it would go.
It's mostly writing a clinical trial protocol, which we will go through the steps.
The FDA is actually very responsive and very good about communicating.
And don't be scared of the FDA. There is a little bit of a, a, a little kind of A twist on this one.
Most of the time, companies who develop drugs find physicians.
They're the investigator and then they are the sponsor to study in this particular scenario, I was both.
I was both the investigator and the sponsor, which makes things a little more complicated as we will discuss as we move along, but is also a common, but it's just uncommon grand things most times it's company sponsoring the the drug trial and the investigator doing them. So I.
Just proposed a simple clinical protocol that's gonna randomize.
Hide what kind of drug we're gonna give.
Transcending versus sailing to see if a decrease postontelectomy hemorrhage at the time of this supposed to say dose I tried to see what dose escalation would make a difference.
I submitted this and well and behold, by early 2019, thinking about this all for 2018, I was able to get approval.
As you can see down here in the end of 20 sevent and 2019. So one of the things when I was doing the study, the FDA asked me about is something called

aerodynamic size particle distribution.
I had no idea what this was.
So when you nebulize a drug, it turns into tiny small little particles that move throughout the Airways.
And what's interesting is the size of the particle depicts on where it's going to land within the respiratory tree.
So largest particles will only stay in the nasal cavity.
Slightly smaller ones will go to the trachea.
The bronchus would be the even smaller ones.
The bronchial's even smaller and alveoli even smaller.
O deending on where you want to treat that the FDA was trying to ask me is when you nebulize this drug, where do you think most of it's going to land?
Because that tells them sort of the severity of it, so.
First off that I was able to get a collaborator in Australia actually had been doing this to actually get a study looking at transamic nebulize through one of our common she had done it from previous things and she found the average particle size was around six microns.
So that pretty big should hit the trachea.
This was very exciting data.
We did not need this data to get our Ind approval, but it was an important piece as we moved on. The other thing is how do we choose a dose?
Well, First off, we knew that four dose would be much more potent than a than a nebulized transmemic dose.
And so we worked hard to that. We could take almost the same dose as the IV dose and probably less thing. Next thing was how we choose nebulizer.
Well, a lot of RTS have been trying this on different patients. When we've done the 14.
And they found the jet nebulizer clog the least.
And then that's how we did the six aerodynamic particle size microns, and also just for particular. This is a very large compound that does break up easier, but this gives me ideas that we do need to maybe reformulate it to go to different areas to treat things better.
A period of time, including nose bleeds, which ENT uses consistently.
Transmemic acid, where they can apply them pledges.
But what about hemoptysis and our other patients like cystic fibrosis?

And congenital cardiac disease.
So the other question you have to ask yourself when you design your trial and this was all went to the FDA is what is the outcome of the trial. This is a common common question. I ask all fellow residents when they come to talk to me, what are? You trying to measure and for us it was not returning the operating room.
How can we make a decision that the oblivion stopped and the surgeon felt comfortable not returning the operating room to other discussion at the surgeon's saying that and when you do that, you need to figure out your power because you want to prove this is an effect.
Outcome.
And I just put up this my little graphic of showing that you're really looking at the differences in means, OK.
This is how you figure out an effect.
Size. Everything in research is powered a little bit by a power study interesting by this change in effect size, the larger effect that you want to measure the smaller number of patients that you actually have to enroll and recruit.
So what was our difference?
We found 72% without Txa, 72% went to the operating without txa 20%.
Tfid that gave us a risk difference of 40.
34 That's pretty high and a lot of people would be like, oh, I don't know if that's too big S more conservative, around 20% when we plug into our power calculation, we figure that does transmit reduce the surgery you want to pick a alpha, which is.
Your Type 1 error component to reduce your false positives so you can pick between .025 and .05. We picked up conservative difference of .2.
That's our effect size.
This is your beta.
This is your type twos reducing false negatives.
You see, when I pick .8 and we found that total sample size split equally would be up in the two hundreds to three hundreds for us to actually power the study thing. And I said, whoa, I think I've over thought this.
I don't think I can do this as a single site study. I'm going to need help and that's where I turn to wonderful group of people who do emergency room studies across the country.
And that's pecar.
Pekarn is the pediatric emergency care applied research network.

This is a federally funded.
Multi Institutional Ed network.
Has over, I think, 30 eds across the country in 10 different nodes. You can see all the little dots across the country at different centres. These people have brought us multiple multiple studies, including seizure management in CT management of head trauma, terrific group of people. They're very active.
And one of the interesting things is that when I was looking at is where do most children post to me hemorrhage approach?
They don't come to clinic, they come to the emergency room.
So this is a great group of people to help me design A multicentre trial.
And I was really excited to work with them. And here are the two people I got to hook up with.
I I kind of cold emailed them and they said, oh, we're very excited and started talking and that's Thomas Chun, who is the lead principal investigator in Providence, RI, and Daniel Shima, who is actually doing his own studies in Davis, CA, looking at transmemic acid in Pat.
With brain injury, they called the TikTok study.
So first I chatted with them and said, hey, I've got this idea.
They said it's a really great idea why you put a presentation together.
Just brief, just to talk to our different nodes and our investigators.
I know, so I did that and the note said, hey, I think this is a good idea. You need to go on to the the larger group.
So I put a concept presentation together a little longer, about 20 minutes and a two page summary saying to the mainstream committee and mosaic are over 120 investigators on the call.
Is this something that we want to work forward towards? And they said, Yep, this is a great idea.
We like the idea.
We want to do something urinary department so went on to writing a protocols and then I wrote a protocol. Now a protocol in in terms of the FDA in this process is a very lengthy document.
There's a large amount of processes.
Basically, it's designed and description of the clinical trial in a very standardized way.
The nice thing about pecarn or bad thing depending if you want to move fast, but if you want to slow, is it really helpful in developing the protocol?

So once I made initial protocol presentation, this is how we're gonna do the trial. And I talked about the next. We went through six subcommittees that would review the trial and actually give me comments and put them back.
And that's a protocol review grant writing.
They looked at my budget, looked at the quality and the safeties for affairs.
The coordinators weighed in.
And how we're going to disseminate the study to the greater public if we got to publish so then I revised the protocol, went back with all the different comments of the study. This took about a year, year and a year and a half.
To this whole process and then the executive committee voted and provided a letter of support, and I I have to tell you, I am very grateful, even though it's a long process that I learned so much about how to design and write a strong clinical trial and is.
Really proposed us forward as we move so as we did this now we're going to talk about what, what do we come up with when we started talking to pecan about doing like for first thing you need to do is a pilot. They said you could jump into.
A large trial.
This is an FDA approved drug.
However, funders are very weary about you doing an FDA like randomized control trial without proving that it works.
So do a pilot.
And so we said, OK.
Well, what do we need to ask the pilot? And the thing first, we need to ask is can we enrolled kids in the EV?
And I'll talk about that. Why?
And then what is the actual concentration?
Nebulized txa that gets into the blood. And what are we going to look at?
We're going to look at how well we can enroll people and how much the consent process, how manipulations we can deliver before they get whisked off to the OR or not.
And then what is the local deposition and all this information will help us design and improve our phase three trial.
So this is the aims that we came up with the phase three trial. Then we can love this little picture of a child who's had a concealed commandment getting txa.
This is the mechanism and we are looking at.
There's always try to get the fellows first.

Take your problem and your hypothesis post operatively.
Finalize can be excessive. Breaking down clothing, hemorrhage.
We believe that nebulized txa non invasive treatment.
Can block that fibroidisis and decrease BTH severity.
And so we worked on developing that trial and we moved forward.
Why? Performance consent? Needy?
This is a great question.
Well, most of the reason why is for 5% of tonsillectomies have PTH.
So if I want to recruit 10 patients, that means over 200 of them.
Were were previously having tonsillectomies prior, so a lot of people ask well, why don't consent them in clinic before they get surgery?
We'll have to consent 200 patients to only get possibly 10.
That's a lot of work for patients that aren't actually going to maybe get a Poston to lactive hemorrhage, right?
And also we notice that post doctorate haemorrhage patients don't all usually come from one ENT group.
There are three.
There are two to three ENT groups in the in the city.
I think it's just two now and some patients come to our emergency room from one doctor and some come to the other.
The other thing is that P carne insured me and one of the things that we wanted to show.
Is that that they could really recruit and enroll patients even in in traumatic situations in the emergency department. And so we thought this is something we need to go.
Then we looked at our rates and we noticed a different rate to post something hemorrhage. This is actually down.
Here at San Antonio, how often they went to the operating room at the time and how often they come to visit.
So we're like, oh, we could probably get at least two to three patients per month or at least approach two to three patients per month. So that gave us a big question that we could do the feasibility.
Can they get consented? We're going to see.
So we had some pilot objectives we wanted to make sure that we got greater than .6 patients per site per month that elites achieved their enrollment. If we could do that in the pilot, we know that we can do that in the larger trial and we want.

To make sure at least 90% of them receive 2X TTX name nibs and then we get some samples to figure out what the absorption in txa in the blood.
Secondary objectives we also want to look at several other things.
How many go back to the OR?
Does anybody get a blood loss or or transfusions? And what in the week following, do they actually maybe have another bleed again?
And then the last was is we really wanted some patient centered outcomes.
What kind of pain occurs?
What was the parent's anxiety and say all these things are leading to us divine better and more improved trials?
So our first aim was feasibility on multi and this is how you need to write it. A multi center randomized control trial patients with post traumatic treated nebulized txa compared to placebo. As I said before, our goals were enrollment not goal of efficacy but enrollment. How many pat?
Can we enroll per site per month if patients turn us down?
Well, that's one group versus patients that agreed.
Well, that's a positive group and that's what we're trying to look for. The things we don't need a lot of patients because we're really just trying to figure out.
Over one year, if 22 patients.
Can be enrolled OK and if they can receive at least nebulize 2 doses of txa, we may have another group over here where we approached 50 patients, but only 22 agreed.
And then when our endpoints are one months after a year and a percent administration to be.
Enrolled. So that's how we've powered our study.
Inclusion criteria discussed very significantly.
They had to have had a tonsillectomy, and then I think about tonsillectos. Most people are healthy before they get a tonsillectomy.
So other cofactors were decreased.
They had to come in with secondary post signs. MD.
We didn't want people to bled right after the OR.
We want people to come back with that fiber and license process.
We decided a large group of age and then other exclusion criteria, bleeding clinic disorder, and we didn't want anybody who was so sick there to get intubated. That would prevent our our study from real efficacy, pregnancy, hyper sensitivity, allergic.
If we enroll the patient for the award of.

The state, or if they can communicate in English or Spanish, all this has to be worked out.
Study steps so one of the things we tried to do is we want to warn the parents that we're doing the study.
They're not totally scared when they come in emergency room, and so we're going to give them an information sheet in the NT clinic that talks about the study.
Then they'll get their tonsillectomy.
Everything goes well and they come back to emergency department with post on site hemorrhage when they show post hemorrhage. Hopefully they've understood the studies going on and so when we screen and discuss it with them, they're not completely surprised, but I'm sure some we reach out to them.
As soon as they get admitted, this is something that we're working on and the research staff will discuss for consent.
If consent is approved, the nice thing is we come with this process instead of having to randomize right there, we randomize the boxes of supplies.
So somehow sailing somehow not they just grab the next box and the next box tells it which point we give them three doses as much as we can, and we'll collect two blood samples over a period of time.
And then just evaluate their objectives. If they go to emergency room, if they go to the operating room, they go to the operating room.
Either way, that's how they.

Nicholas 36:50
Video turn the video.
Good morning.

Meyer, Andrew D 36:54
Someone please mute.

Nicholas 36:57
So are you my people?
We are.

Meyer, Andrew D 37:01
Hello.

OK.
All right, so 3 nebulizations of txa or saline that we wanted to give them over a period of time. So you can see one of the first things we had to do is actually get saline and txa to look in the same vials and then we'll give it.
Over pairing mask and then we'll use the next box process that we do.
So all the nice thing about all this is very cheap and very easy to obtain.
Next question we had to ask for the FDA and for everyone else is what's the dose well in cardiac surgery for our little neonates, we give a large amount of takes A to decrease bleeding over 100 milligrams per kilogram and we give A10 millig the cake per.
Hour drip.
So that's a huge dose, an average 4 year old gets about 1500 milligrams a period of time now.
Nice thing nebulized txa.
We're not going to have that much, so we can shoot for this high dose 'cause. We know we're not going to actually appreciate.
We also want to get fixed dose because weight based dosing will make more complication calculate each weight.
Comes in the patients. We find a safe dose that we can give that when things can justify this and it's broken up into three nebulizations of 500 milligrams each and then very surgical studies in the past. It showed no adverse events.
There is adverse events at Txa very high doses over a long period of time.
They can get seizures, but they are rare.
But that was something that the FDA wanted to do.
But because incense was so low, they didn't really think we need to exclude those patients.
Then we want to determine the second aim was what was the local deposition systemic absorption?
And I'm going to discuss a really interesting process of how we figure this out.
We're going to verify this with a pulmonite physiologically based pharmacinic model, and I'll explain why we need to do that all. But instead of a regular Pharmac model, you have to collect samples multiple times throughout the day at 5 minutes, 10 minutes, 15 minutes, thirty minutes after you.
Get the drug. This process allows us don't have to collect two blood samples.
Total of the 12 patients.

Who received?
Actually, just 11 patients received the TXA.
So what is a physiological based pharmacodynamic model?
Physiological based pharmacodynamic model is a really interesting thing. The pharmacists have come up with were basic. What they do is they plug in all the information they know about a drug into a computer program.
And everything that's known about the position and component of the program, and they're able to predict if I give a drug here like to the lung, it should get absorbed and change over this period of time.
So what's really cool about this is that then you just need to get one or two doses. Confirm the model instead of getting all the doses to create the model, you already have the model there and just need to confirm that those samples are landing in the same spot as your model predicts.
This decreases the number of samples you need to do to predict Pharmac, which is really important pediatric studies because it's very hard. In order to get blood samples from kids. As we all know.
So we have a really smart pharmacist, kashia lopetti, who's been able to work up this model.
He's predicted how many drugs and what's the absorptions and inhaled properties and how the inhaled drug actually you know how much stays on the surface and how much gets into the bloodstream, which tells us the side effects of what's important for the FDA to know. But it also.
Gives us the fewest number of samples. This is a really cool graphic how pbk models are really working.
Pediatrics you start with the child.
You look at the transporter and all the different data component.
You think about the age-related.
Parameters you can plug in the model.
The drug related parameters.
You can plug into the computer model you pick in the trial design, you do the modeling.
You put the sample, you predict your plasma and drug concentrations.
You confirm the model from the plasma compensations and then you can get the application much quicker.
This is a very exciting technology and it's allow us to advance more drugs for kids as

we move along with less blood samples.
Then we also want exploratory objectives. Of course we're going to use just a standard faces pain scale for all the kids.
Hey, you got txa. Do you feel a little better?
Do you feel a little bit worse?
You know, how is this improving your overall pain?
But we also want to know what was his parents and child's anxiety. So they came in bleeding.
The bleeding stopped or didn't stop.
Are they more anxious? They didn't get surgery or they less anxious. They didn't get surgery.
And so this really kind of tells us a patient centered outcome for our actual application.
Here's a timeline of the study after long periods of regulatory review and component. So as I come in the room's room, they get enrolled to randomize C txa or normal saline.
We won't know what the randomization is.
It's blinded.
We'll attempt to give 3 nebulizations over the first hour.
We'll then draw blood draw within about 60 minutes of that. Just sort of get it 1 sample. We'll watch them for 24 hours, which is routine practice for all hemorrhages.
We try to admit them to the hospital over the period of time.
Sorry for this extra little thing here and then we'll get another blood draw and then we'll get discharged. And at that time, we'll say, hey, is your pain better or worse?
Did you get surgery?
Did you not get surgery?
How is you know?
Did you rebleen?
What's your anxiety? Say we'll follow them for seven days and around seven days 7.
We'll call them.
Hey, did you go back to the emergency room?
Have you had more pain?
Do not more pain do you feel better that you didn't get surgery or not get surgery and then the FDA wanted to make sure at 30 days that we call them again, made sure they didn't have any adverse events.

So this is how the study would go.
Of course, we need statistical analysis. As I said, we had phase three, we wanted to target the phase three trial enrollment.
So hypothesis txa would decrease surgery.
We we predicted a very small conservative 15% interest. We use a Fischer exact test with 80% power gives a total size of 324 patients.
That tells us what is our prediction and how many patients enroll per month in our feasibility trial and that was .6 patients per site per month.
So we enroll .6 patients per month, we're doing well.
So the next part is the regulatory.
So now that I have and funding now that I have designed the trial, the question is how do we get this?
This is doctor Collins.
He recently retired from the NIH. He is most famous for discovering all the genes that led to the Human Genome Project with adna instruction book, and he wrote the financial burning of running large scale randomized trials immense up to 100 and millions of dollars. The regulator is.
Can be equally daunting, yet these are the best ways for us to make decisions.
So, undaunted, I pressed on.
And one of the most important parts is how to get funding. So during this process, we've done multiple different funding.
Oh, I'm sorry it's been multi wrong. Multiple different funding agencies and one of the ones that was most positive and successful is right here at home. The long school Medicine Pilot Project award, which we won and provide 75,000 year for two years.
So that we can.
Start going and why do I need this?
I need to hire people to help me get this through the regulatory process.
And then at the same time I'm applying for a multi institutional award.
Prove the NHLBI clinical trial published studies, which is an R34 and that provides 225 or $450,000 for two years in order to develop your study. Small amounts of money but start working so a little.
Early success. Some of you know, last year I was awarded the pilot TRANSMIC for pediatric postonsolectomy hemorrhage award along with Doctor Solis Herrera.
Let's give the 75,000 a year for two years, which we've used aggressively to move our process forward.

And during that process, we've used those funds that were kind of develop RB and also develop the buddy for the two year thirty budget. So one of the reason I put this up is how complicated it is to fund the funding for A2 year grant budget with.
A small amount of money you can see.
Hear me as a principal investigator, I've got a pay doctor early. Got a pay doctor Schwartz.
Sorry, I put the name wrong.
There are Schwartz apologize, research coordinator.
I have to pay the investigational pharmacy we have to buy the USENIX box.
We have to pay for the data.
Data study monitoring board.
Then each of my different sight leads need some money. Each of the coordinators need some money, and then of course each of the pharmacy fee.
So the money goes very quickly.
Also, every time a patient gets enrolled, you have to pay the the coordinators who do all that extra hour to come to the hospital and enroll the patient.
Take all the blood samples of things you have to pay for their additional time, specially if they come in the middle of the night.
Participant payment also, we want to encourage the patients to participate in the trial and that's completely reasonable to pay them a little money for their time and efforts.
Received the phone calls and do the things we had to ship and store the samples and drugs for pharmacinetics.
And what's most important that we want to order is that we have a data coordinating center, a data coordinating center is a group of physician, a group of people in one area who run these trials consistently. And so we have a a dedicated bio prosthetician that gives a.
Project Manager, a biostatian and clinical data manager, and all of them cost a great deal of money.
Also, we do a central IRB review and they store all the data in a secure facility.
So this the money goes very, very quickly, even though it seems like a lot.
And originally we had supplement from the PECARN was really nice.
They could give US infrastructure funds.
That sense has gone away.
We've had to reduce our budget, but they have been very supportive in trying to

improve that and the last bit was paying cash. The our pharmacist in order to process the samples. And then I was actually able to figure out from the US Army how we could act.
Process the samples there with me things and then how do we package and package the sailing?
All this costs a certain amount of money.
All right, so I have my little pilot award now. I need to get it approved.
Just 'cause I have the trial written and the FDA approval on that done.
So luckily the 75,000 was allowed me to hire a certain percentage effort of our emergency medicine research coordinators.
Really wonderful.
Doctor Miss Perez is terrific down in the room, and Alex Nunnery is a great research associate.
And when you're thinking about how to get a trail to approval, this is the algorithm on the website of utusca IRB of how clinical trial steps to get approval.
And yes, does it look daunting?
It is daunting, but let me kind of break it down for you in brief periods of steps.
The first step is that of course you do need some kind of money or, you know, regulation of how you're going to run the trial.
And that's the office of Sponsored programs. They give you an initial grant.
All right.
Next part is it goes to the Institutional Review Board.
Now if you'll notice, I call these all the three letter acronyms because you have to get through all these three letter acronyms before you can actually get your study approved.
So you go into reward. They're really wonderful.
They have something called urms electronic research data management.
You upload your protocol related documents consent forms.
Most of those are written.
On IRB they review them.
The RB meets.
I'm on the rbfm questions. I'm going to discuss the human interactions of the study, and that's all they they reviewed to say, is this going to be safe for humans to get?
And that's interviewing board because the clinical Research Implementation Office that is a group that's only two.

People stuck in this island and that Miss Rohand over VPR, they really help you with the clinical research implementation. They communicate with the FDA to get your study set up.
They register a clinicaltrials.gov.
Oops, sorry, they do the start up and support.
I went back too far.
And so once that's then really just to help you, that goes to the clinical Trials Office, they figure out, OK.
Well, how much is this study going to cost?
What's going to be impacting the nurses?
What's going to be the component?
How are we going to get paid?
Are we going to have much management? And since I had very small amount of money, this was very quick. Then you go to the Office of Clinical Research.
Does everyone have their appropriate training?
And they have all their city training. Is everyone up to date?
Study components are going to be risk and the last step is to go to the research administration quality, which we met with last October.
Who does?
Sort of a mock audit to see if the study's gonna prove for the FDA component. And that's one of our our last step that we're stuck on.
The other thing is that here at UT course, UHS is a different institution than UT, so you have to go through UHS approval.
A lot of people ask me why do I have to go through UHS approval?
Well, because it holds its own license for the studies. It does not that IRB approval. A lot of people go well. The IRB approval is always. Remember the IRB just says that it's safe to go inpatients.
It doesn't say that the institution is willing.
To take the risk of the study, and so it has to go through UHS approval.
That's why you get a lot of strange questions there.
Approved concurrently though, which is one of the things I improve being on the committee since 2013, is that we did concurrent approval. So they do work at the same time as the IR BS going through.
They just take a little longer and that's because they're asking all the nurses and all the people in this institution. This study is coming.

Is it going to impact your workflow and how you do work and what you need to do?
And I'll just be happy to say we finally got UHS approval.
And a contract as of yesterday, which is exciting.
So we've had some challenges as we move through the study.
One of them is.
One of them is just that patients opportunity to have late at night.
So you can see what time of day on postoperative day, how many people come overnight and you can see the majority of patients come overnight.
This means that I need to pay the coordinators a certain percentage.
That's why at 30% and actually pay for the time to drive in the middle of the night and enroll these patients.
And so that was one challenge. So we got over.
The sponsor and investigator being the same is rare. Most times industry sponsors study writes, the whole protocol helps the physician goes through the FDA process and sent the study on this case.
I've done all those steps and so sometimes I get different questions on are you the sponsor?
Are you the investigator at this point of time?
Last Pharmac samples we had to get approval that our Ed coordinators could draw samples from.
Established ID lines in the emergency department.
All pace to put in the last bit is that we wanted to keep the surgeons kind of out of the study a little bit because they're making a decision. We don't want to influence their decision as they're going to go to the operating room or not. So these.
Are some challenges that we dealt.
The other challenges is technology, so.
One of the things that I've been trying to work is make everything digital, because as you know, paper can cause significant amounts of problem.
But digital records have new rules and new regulations that have kind of slowed us down.
And one of them is, even though we have this wonderful thing called Redcap research, electronic data capture database, it is not up to speed. The 21 CFR part 11 compliance for the FDA.
So we have to ask for a waiver.
Also, the data retrieval is from EPIC for uhss fee for service.

So according to HS, to pull that data out manually, there's no way to pay them for the component.
We couldn't use the Wi-Fi service, so we had to buy a hotspot downstairs and and and having no sponsor means we had to build all our own.
Own processes and technology, so it takes much more time than initial component.
So current state of affairs the pilot has given us, we've had funding for about a year.
We've got an IRB approval, we got new HS approval. We're currently waiting to get final approval from the F.
To enroll on our redcap.
So we hope to start enrolling in the next month or two.
The we at the same time, we've already submitted our multi institute grant.
We got a score of 38. We've resubmitted and our study section is going to meet in February 2025.
We figured out a method to.
Vials of exactly the same txa vials, which was something tips, and just this month, Doctor Schwartz is publishing a paper showing this is still a significant problem that requires us to do this trial with still 60% of ent's choosing surgery instead of any other options even.
Though they increase txa period of time, so last thing is David 2nd and I love this quote. Half of what you'll learn in Med school, we showed it to be either dead wrong or out of date within five years of graduation.
And we do not have txa nebulization. When I went through medicine.
And randomized controls are expensive, time consuming logistic.
But they're still the best way.
And this is the way we have to move forward in order to change things.
And he was known as the father of evidence based medicine. He passed away in 2015.
So I'm finishing with about 10 minutes ago, which is perfectly on time. What I was hoping.
So I just wanted to end with a large number of people acquires just to run a small little pilot trial where I'm only going to enroll 22 patients at three sites over a period of time.
So you can see here at UT health and university, we have five of us.
We have me doctor, early Doctor Schwartz, Stephanie Perez. Alex. That doesn't count all the wonderful RPS and nurses that have been involved, including Gina.

I'm a Silva like Candace at UC Davis.
We have them.
We have three people there.
They have me and T Daniel Machine and Marie Morris.
Who's our coordinator at UT Health University of Health.
And we have the Biostatician and Kash and the last we have at Spark, Thomas, John and Jan Grabowski.
So I don't mean to dissuade someone from running a clinical trial, but I do also want them to realize when they're walking into this large regulatory.
Man, industry that you need help.
There are people to help you out along and it is possible with hard work and determination, and we're hoping that this feasibility trial will move on.
We move on to a larger randomized efficacy trial and this will become standard care saving. Hopefully thousands of children from ever having to get surgery again for Poston selection hemorrhage.
Thank you very much for your time.
I hope this was informative.

Kamat, Deepak M 53:51
Thank you, Doctor Mayer.
This. That was wonderful.
Very informative indeed.
Let's see if anybody has any questions, comments.

Meyer, Andrew D 53:58
Oh, sorry.

Kamat, Deepak M 53:59
Doctor Wood is saying wonderful presentation.
Thank you.
Andrew, I have a question.
So you when you do your formatric formatric studies, you should.
The particle size is about 6 microns, if I understood right, so very little goes into lung.

Meyer, Andrew D 54:15
Correct.

Kamat, Deepak M 54:19
So you said from lung into the bloodstream?

Meyer, Andrew D 54:19
Right. So.

Kamat, Deepak M 54:21
So how can you correlate that I mean.

Meyer, Andrew D 54:22
Some.
Right. You you can't.
You can't correlate exactly where you get that position.
All we can record is how much gets into the bloodstream and that can tell us how much got absorbed and stayed on the lung tissue site.
So it really sort of tells us what the absorption area is throughout.
It does not tell us how much goes on the distal area into the lung or how much goes into the tracheal area, but what it does tell us is that we know most of the particle probably end up on the site of bleeding in the trachea.
Because of the particle size, so we think most of it actually goes to the actual site that needs to to get to the prevent the fibroids from occurring. The most important part of the fibrokinetics is that the high dose of txa that we're we're planning to give is.

Kamat, Deepak M 54:53
Yeah.

Meyer, Andrew D 55:07
Not going to cause a high dose in the bloodstream for a later side effect, so not so much important that wear gets absorbed, but more important that we're not causing additional side effects later on.

Kamat, Deepak M 55:13
OK.

Meyer, Andrew D 55:17
But it does give us interesting that we could redo.
Redo the formulation of the txa to treat different patients over a period of time and then something we are working on just as slowly. It is a big molecule and I will finish by telling you because I know this because the RTS come to us and say this.
Clogs our our our nebulizers and even on the ventilators all the time. So we know it's a big molecule and it's probably not going to the idea, but that's a great question.
So I see a question.

Kamat, Deepak M 55:44
OK.

Meyer, Andrew D 55:45
How expensive? Txa. It's dirt cheap.
This is a great drug.
We're talking less. It's off patent.
It's made by Pfizer under a label called Lyseda.
And yes, there have been several studies. Mr. Doctor Lipshit on should be given provincially, and actually several studies in Poston, selective hemorrhage patients where they gave it in the operating room and those did not show any kind of improvement in secondary post tonsil hemorrhage which he thought was.
Really interesting.
It is been shown to be improvement in patients with cardiac surgery and orthopaedic surgery. We've had significant improvements.
And decrease in bleeding for those patients over a period of time.
I actually think it should be sprayed on everything for bleeding, but I'm kind of a zealot so.
Don't don't really think. But Doctor Schwartz has, and we've had some bleeding patients, at least in the ICU. And I can ask her.
She's on the call in the IC US. Sometimes we spray txa on gods or wounds where bleeding from ECMO sites, and that seems to improve the bleeding component.

So, but you know there is always a risk. There was a case report recently of a patient who got bronchoscopy.
Received a larger dose of txa during the bronchoscopy and had a seizure later, so we are concerned about the side effects of the dosing regimen and that's always a risk component and we want to make sure that we avoid that.
Great question.
Any other questions?

Kamat, Deepak M 57:10
O what are the side effects of nebulized txa?

Meyer, Andrew D 57:13
Very low as far as we can tell.
We need a larger efficacy study and really to determine all the side effects from different patients and the reason why we think it's very low is because we know that the drug doesn't act not all the drug gets absorbed to the bloodstream. Most of the side effects have.

Kamat, Deepak M 57:27
Wait a little.

Meyer, Andrew D 57:30
Been done by intravenous studies, not.
And then we ended up large topical studies.
They've had very low, if any side effect consistently.

Kamat, Deepak M 57:39
Thank you.
Any other questions?

Meyer, Andrew D 57:40
Good question.

Kamat, Deepak M 57:41

Comments for Doctor Maya.
Doctor source.

Meyer, Andrew D 57:44
Hope everyone enjoyed.
Yes, thank you Kosh.
This is a clinical trial. We have not started yet.
We're hoping to start soon.
I want to thank this is not a project that's done just by me.
I know I'm the only one talking.
Doctor Schwartz has been amazing.
I just everyone thank her every day for being here. Coming back to UT after being a resident before going out for a fellowship.
We love that she's in the emergency department. Also, I want to invite.
All of the faculty at UT the emergency department is very excited about doing clinical trials.
Studies Doctor Schwartz student and I do not want this to be the only study in the Ed. If you have ideas come to us, we will help you.
We want to get it involved.
We want to get it funded.
We want to get it up and running.
They are working to hire 24/7, Ed resident research coordinator coverage in the Ed, which is terrific.
So it's going to be seen, we now have 33 pediatric, 3 three or four pediatric.
Attendings.
Three. But you have to unmute yourself, Doctor Schwartz.

Kamat, Deepak M 58:44
Yeah, you're muted. Yeah, yeah.

Wroe Schwarz, Whitney 58:49
4/4 essentially 4 essentially.

Meyer, Andrew D 58:51
Or essentially would.

Wroe Schwarz, Whitney 58:52

And we're hiring.

Meyer, Andrew D 58:54

That is amazing, guys.

We have to all collaborate down in the University Hospital that we're getting 4 pediatric trained emergency physicians which is terrific.

Please, when you see them when they call, say thank you for being here. Do not leave.

Anybody out?

Any other wonderful questions?

Kamat, Deepak M 59:09

OK.

Any other questions or comments for Doctor Mayer? Hello.

I don't see any doctor Mayer.

Thank you very much, Doctor Swars.

Thank you very much for attending this morning's grand rounds.

I'm going to conclude and we'll see you next Friday for another grant. Thank you all.

Meyer, Andrew D 59:34

Thank you.

Kamat, Deepak M stopped transcription