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Session: Data Decisions and Quantitative Analysis in a Study Investigating the Impact of Remote ICU Monitoring in VA Hospitals

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Linda Kok: Hello! This is Linda Kok from VIReC, the VA Information Resource Center. And welcome to VIReC's Good Data Practices Cyberseminar miniseries. In four sessions, last week and this, our presenters focused on the interaction between research design and data decisions. But before we begin, I'd like to tell you a little about the miniseries. The learning objectives of the Good Data Practices series this year will touch upon one or more of the objectives, excuse me, shown on this screen. Today's speakers will present a case study of one of their research projects, and they'll highlight data challenges they faced in the VA's changing data environment. And they, each of the four researchers that have presented last week and this, will talk about some of the learning objectives that you see here on the screen. We're going to have a brief poll, so not including today's sessions, how many of the previous two sessions in this year's Good Data Practices did you attend? None, one, or two?

Heidi: And we'll give everyone just a few more moments to respond before we go through the results here. Responses are coming in nicely, but I know people are just joining the session and getting situated, so we are just looking to see how many sessions you have attended in this year's Good Data Practices. Not looking at previous years, just looking at this year's sessions. How many have you attended? It looks like we have slowed down. So what we are seeing is 39% of the audience saying that this is their first session. They did not attend either of the sessions last week. Fifty-two percent of the audience has attended one session, and 10% attended both sessions last week. Thank you, everyone!

Linda Kok: Right. Well, I'm glad we have so many returnees, and I hope you'll all join us on Thursday for our capstone discussion session in which all our speakers will be joining our discussion. Excuse me. Neil Jordan. Pardon me. Today's session is entitled Study Design and Data Decisions in a Study of Intensive Care Unit Telemedicine Monitoring. I want to thank CIDER very much for providing technical and promotional support for this series. Today we're pleased to welcome Dr. Mary Vaughan-Sarrazin and Dr. Amy O'Shea from Iowa VA Medical Center. Dr. Vaughan-Sarrazin is a core investigator in the Iowa City VA Center for Access and Delivery Research and Evaluation, or CADRE, an associate professor in the Department of Internal Medicine at the University of Iowa. She also directs the data analysis and biostatistic services for CADRE. She has served as principal investigator on multiple grants from the VA HSR&D, AHRQ, and NIH that employed a variety of study designs and statistical methods, particularly methods for addressing confounding and observational data.

Dr. Amy O'Shea will follow Dr. Vaughan-Sarrazin. She is a biostatistician and assistant research professor based out of Iowa City Veterans Affairs Healthcare System and the University of Iowa, Carver College of Medicine. She is adept in prepping VA administrative data and the application of statistical theory to address research questions in many topic areas. To date, her published work includes research related to neurological impairment and driving ability amongst elderly populations, observation care in the VHA healthcare system, and military sexual trauma. We'll monitor your questions during the talk and present them to the speakers at the end of this session. You can enter them at any time. I'm pleased to welcome today's first speaker, Dr. Mary Vaughan-Sarrazin. Mary?

Dr. Mary Vaughan-Sarrazin: Yes, thank you for that introduction. That was very nice. So I want to just give a little bit of background. So I picked this study. When we were asked to present a study, I picked this study in part because this is a study that, this is a topic that we've been investigating for a number of years. The initial proposal, I think, was submitted to HSR&D back in 2010. And during that time, the VA had gone a number of modifications in terms of data availability and data structure, and so I thought that this was kind of an interesting project to present because you'll be able to see how some of those changes have impacted our work. Anyway, the study, so we're talking about the study design and data decisions in a study of intensive care unit telemonitoring. I'd like to start off with a poll question. So the question is can you, to essentially assess your use of MedSAS datasets. Have you ever used National Patient Care datasets, also known as the Medical SAS datasets? And if so, could you indicate whether you've used them for less than a year; more than one but less than three years; more than three but less than seven; more than seven, less than 10; and 10 years or more.

Heidi: And responses are coming in. We will give everyone just a few more moments to respond, and I'll go through the results here. I will say it looks like we are definitely skewed in one direction here. So unless we get a lot of responses in another direction...

Dr. Mary Vaughan-Sarrazin: Okay.

Heidi: Looks like we have come to a slowdown here, so I'm going to close it out. And we have 84% of the audience saying that they have one year or less experience with the National Patient Care Database; 8% saying more than one year, less than three; 3% saying at least 7, less than 10 years; and 5% 10 years or more. Thank you, everyone.

Dr. Mary Vaughan-Sarrazin: Okay. Alright. Well, that's very useful to know. It'll kind of maybe impact what I say about the MedSAS datasets. So the learning objectives for this session are, number one, we want to describe intensive care telemedicine and its role in the VA. Now when I say intensive care telemedicine, you might also hear me say remote ICU monitoring. You might also hear me shorten it just to TICU or telemedicine ICU. I just want to clarify those terms.

Second, we're going to define key variables and data resources to evaluate TICU, and this one calls, and these, this includes some challenges we encountered in the research design, especially facility matching, which was one of the goals of our analysis, and also to understand how we evaluated alternative data sources that were available to us. We want to illustrate the transition to the VINCI environment. This is something we did sort of mid way through our analysis, and we had to, in order to do that, we had to, number one, overcome our fear of the unknown. I, myself, have been in the VA for about 18 years now and had been using the MedSAS datasets for that entire time and available to an older system which we called the Austin Automation Center where we could download data directly to our desktop. So transitioning to VINCI was, for me, a bit of a leap of faith, and I'm pleased to say it was not nearly as bad as I expected. And then also we want to explain the limitations of data collected for clinical purposes.

Okay, so this is just a brief outline of what we're going to be going through. I'm going to talk a little bit about the background of the project, or evolution and goals. Then I'm going to talk about goal one, and goal one was essentially to evaluate the impact of TICU or remote monitoring on patient outcomes, outcomes such as mortality, length of stay, and some other intermediate outcomes. I'll review the key variables and data sources that we used. I'll talk about some of the challenges that we encountered. I'm going to present, briefly present some results, and then I'm going to talk a little bit about how the project evolved and how we updated our analysis plan based on various things that were happening, including changes in the intervention and changes in data sources. Then I'll turn the talk over to Amy O'Shea, who is going to talk about goal two, which was to evaluate the actual utilization of the TICU units. So I'll talk about the impact of TICU on outcomes, and Amy will talk about how it was actually used.

Okay. First let's talk about the background of the project. So in 2012, VISN 23 started implementing tele-remote monitoring in ICUs, and they announced the plans to implement TICU roughly in about 2010. And at that time, Dr. Peter Cram, who is a physician here in Iowa City, submitted an investigator-initiated research proposal to HSR&D and it was funded to evaluate the impact of these TICU units on outcomes in intensive care units in VISN 23. Subsequently, Dr. Heather Reisinger, who was a co-investigator on the original project, also submitted a proposal to the Office of Rural Health to obtain additional funding as TICU was essentially expanding around the country.

So I'm going to give you a little bit of background here on sort of the geography of what we're looking at, and then I'll tell you a little bit exactly about TICU and how it's used. So this map shows VA VISNs at the time of TICU implementation, and the number of beds, number of ICU beds per 100,000 unique patients. VISN 23 is right smack in the middle of the country if you see there that turquoise color. It basically encompasses Minnesota, Iowa, Nebraska, North and South Dakota, and parts of Missouri. So there's a lot of rural areas and some urban areas. Now subsequently VISN 10, which is roughly the state of Ohio, also implemented tele-remote monitoring, and then even later, in about 2014, VISNs 7 and 15 also started implementing TICU. So I'll discuss a little bit later how this expanded implementation of TICU impacted our work.

Alright, so this is just a little overview of what I'm talking about when I refer to remote ICU monitoring. On the right-hand side is, you see the actual physical ICU team. These are the nurses and physicians who are at the patient's bedside, and they provide the direct monitoring and the actual patient interventions. Then on the left side of this graph you see the IC team that's located at the communications hub. In VISN 23, the communications hub was in Minneapolis, and this is essentially a room with a series of monitors, and the monitors are hooked up to patients in the remote sites. And the room is staffed by, the remote monitoring room is staffed by intensivists and ICU nurses. So there are sort of intensivist specialists staffing the room, observing, watching the monitors, and they are in communication with the people actually at the bedside.

I should note that communication between the central room monitoring system and the bedside can be initiated at either location. So clinicians at the bedside who require consultation or assistance can contact the remote monitoring center for assistance, and similarly, nurses and intensivists who are at the remote monitoring center may see a potential problem on the monitors and then contact the local site. I also would note that when initially implemented in VISN 23, the actual use of this system very dramatically across hospitals. We had one facility that actually incorporated the remote monitoring personnel into their daily rounds. So for that facility, the remote clinicians were actively included in activities on a daily basis. Other systems, other facilities either used the systems partially, sort of on an as-needed basis, or in, you know, at least one facility, they used it very rarely. So we had a separate piece of the project that was actually evaluating, you know, sort of physician acceptance of the intervention, but I'm not going to talk about that. Amy and I are focusing strictly on the quantitative analysis of secondary data.

So, as I mentioned, we are going to be talking about two goals here. I am presenting part one, which is assessing the impact of remote ICU monitoring on patient outcomes, and then Dr. O'Shea will be discussing the nature of the interaction between local staff and the ICU monitoring center.

Okay, so let's move on to goal one, looking at the impact of TICU on patient outcomes. So our primary goal was to evaluate outcomes in facilities that implemented remote monitoring, or TICU, on an intensive care unit compared to the outcomes in facilities that didn't. Our initial analytic strategy was to evaluate the change in outcomes from the six months before implementation to the six months after TICU implementation relative to changes that occurred in matched facilities outside of VISN 23 that did not implement TICU. So you might call this a difference-in-differences approach where we evaluated whether it's the change that occurred in TICU facilities differed from the change that occurred in non-TICU facilities. I would note that TICU was implemented in VISN 23 in a staggered manner between August 2011 through February 2012. So that's our definition of before and after isn't the same for all facilities, and it depends on the date of implementation.

Alright, now I'm going to talk about our key variables and data sources. First of all, so for the next, oh, thank you. For the next three slides I'm going to talk about patient level outcomes, the covariates that we used for risk adjustment, and the patient level data sources.

So for this goal we were primarily interested in evaluating the impact of TICU on patient outcomes, which included mortality, which we defined three ways. We defined it as death in the ICU, death in the hospital, any unit in the hospital, or death within 30 days, which could be in or out of the hospital. We also wanted to look at re-admissions to the hospital within 30 days and also length of stay. And by length of stay, I mean both days in the ICU and also days in the overall hospital. And we had defined as well a number of intermediate outcomes, and these are outcomes that reflect processes or quality of care such as ventilator-acquired pneumonia, catheter-related bloodstream infections, or VTE prophylaxis, which VTE is venous thromboembolism, so essentially prophylaxis given to prevent blood clots. And we called these intermediate outcomes because they represent essentially quality of care measures.

Okay, so in order to adequately evaluate patient outcomes, we had to consider the patient, the severity in comorbidity in patients at the time of admission so we could adjust for this. Specific patient characteristics we considered were demographic variables such as age, sex, and race, the primary diagnosis from the ICU bed section record. And the primary diagnosis was defined based on ICD-9 codes. Now there's about 16,000 different ICD-9 codes, so in order to make those a more manageable variable, we collapsed those into 200 meaningful clinical categories. We did that using the Agency for Healthcare Research and Quality Clinical Classification Software, and this is a software that's available through the AHRQ website. We also defined about 30 different comorbid conditions, and these are essentially based on secondary diagnosis codes available in the patient discharge record. And again, for that we used an algorithm that's available through the Agency for Healthcare Research and Quality, or AHRQ. Some people might call these Elikshouser [phonetic] conditions that were originally developed by an investigator named Ann Elikshouser.

Finally, one of the biggest considerations we had was how to measure admission severity. And so an admission severity reflects the patient's status at the time of admission. So what was their heart rate at the time of admission? Could they breathe? Were they conscious at the time of the admission? These are really key variables that are often hard to get in typical administrative data. The beauty of the VA data is that we have access to a lot of other variables. And some of the variables that we considered were laboratory values, so lab values collected within plus or minus 24 hours of admission, such as albumin, creatinine, bilirubin; vital signs such as heart rate, respiration, temperature, blood pressure, use of mechanical ventilation which would tend to indicate someone, you know, is having a hard time breathing. We also considered using something called the APACHE score. The APACHE score, that stands for Acute Physiology, Age, Chronic Health Evaluation score. And this is a widely known measure developed to measure severity in ICU patients, and it essentially encompasses all of these things, various vital signs, lab values, comorbidities, age. At the time, some of the variables that we needed for that were available through VINCI, and we were not yet on the VINCI data system, so we ended up not going with the full APACHE score. We did lab values, but I'll get into that a little bit later.

So this is our patient level data sources. So, again, in the VA there's a variety of data sources that we considered patient level data. Now I will talk a little bit here about VINCI. One thing to bear in mind is we started this analysis right around 2012, 2013. The VINCI platform was fairly new at the time and people were just sort of starting to transition and do a little bit more with VINCI. Now here in Iowa City we had a lot of experience using the MedSAS patient level data, and these were datasets that you could download, you know, once you obtained appropriate permission, you could download these from the Austin Automation Center. They came to us as task datasets. They were fairly well organized, and all of our analysts had a lot of experience using these. So, and the VINCI platform I should say also has inpatient records. At the time they didn't have the MedSAS data available. They do now. At the time they didn't, but they had other inpatient data available through Corporate Data Warehouse.

At any rate, we opted to use the MedSAS dataset. So our main dataset for identifying our cohort of ICU patients was the VA Patient Treatment File. So this is essentially the inpatient data in the collection dataset called the MedSAS dataset. And this provides information on bed section such as, by bed section I mean the unit of stay so we could track patients in the ICU, in the observation unit, in other acute care units. And it also included the various ICD-9 diagnosis.

Heidi: It looks like we may have lost our presenter's audio. Let me see if I can. I apologize for this. Occasionally technical issues do pop up. Let me see if I can get their attention here. My apologies. I'm still not getting a response from them here. I'm not sure if their whole network cut out or what happened here.

Dr. Mary Vaughan-Sarrazin: Hello?

Heidi: Hi! It's Heidi. Do we, it looks like, did you guys call back in?

Dr. Mary Vaughan-Sarrazin: Yeah. Can you hear us now.

Heidi: I can hear you now, yeah.

Dr. Mary Vaughan-Sarrazin: Okay. I'm not sure what happened.

Heidi: Technical issues pop up every once in a while. I'm just glad we were able to get you back on and we can edit out that little bit of dead spot in the recording and we can just continue on. Thank you for calling back in and we can just go forward.

Dr. Mary Vaughan-Sarrazin: Sure. Where would you like me to pick up?

Heidi: I am really...

Dr. Mary Vaughan-Sarrazin: Can I just talk and start with patient level data sources?

Heidi: Yeah, you can definitely do that. That's where we, about where we were. So that's fine, yeah.

Dr. Mary Vaughan-Sarrazin: Okay. Alright. So anyway, I mentioned there were a variety of data sources that we considered for patient level data, and one thing to bear in mind is that we were initiating this project in 2012 to '13, roughly around the time that VINCI was just, that people were just kind of starting to use VINCI, and we weren't really quite there yet. We had been using the MedSAS data for a number of years, so we opted to use the MedSAS data, which, and the MedSAS data includes, you know, a variety of information, the units of stay so we identify ICU patients. It included the ICD-9 diagnosis and procedure codes, the various demographics, and so on. We also used the VA Vital Status File, which provides dates of death for VA users. And we opted to use the Decision Support Services Laboratory Files. Now again, the DSS data at the time were available for download through the Austin Automation Center. They were available through fiscal year 2012, so they're not available any more that way, but at the time we opted to keep things local.

And then for the Vital Signs File, I mentioned that the vital signs, now that file contains things like blood pressure, temperature, pulse that can be good measures of patient acuity at the time of admission. That file was only available through VINCI, at least to our knowledge. We didn't, for our initial analysis, we didn't obtain access to the Vital Signs File. We had sort of a previously established algorithm for measuring patient acuity and looking at labs collected during the first 24 hours of admission, and so we opted to use that measure of acuity that only included labs from the Decision Support Services Lab File.

Finally, we had hoped to obtain information about intermediate outcomes from the Inpatient Evaluation Center. I'll touch on that a bit later on. Oh, I think I'm going to have to share my file again now. Am I sharing it?

Unidentified Female: Yeah, you are.

Dr. Mary Vaughan-Sarrazin: Okay.

Unidentified Female: Just click in there again.

Dr. Mary Vaughan-Sarrazin: It's not letting me. Oh, there, okay. Sorry. Okay. Facility, so for these next two slides I'm going to talk briefly about facility characteristics. So the facility characteristics are important because in this initial analytic design we had eight ICUs in VISN 23 that we wanted to match to eight similar ICUs outside of VISN 23 that did not implement tele-ICU. So that's why we wanted the facility characteristics, and some of the characteristics we considered were number one ICU type. There's medical ICUs, surgical ICUs, and then there's mixed ICUs. We also considered ICU complexity. This is the score ranges from four to one and essentially represents the services that are available through the ICU. So the most basic ICUs might have continuous monitoring and maybe airway management, and the most complex ICUs also have services to, you know, other, you know, maybe emergency service or, sorry, emergency surgery, intraaortic balloon pumps, and other sort of more invasive services. We also wanted to measure bed size, intensivist staffing, and this was really critical. So intensivist staffing basically reflects whether they have an intensivist at the local unit. Intensivist is essentially a physician who specializes in care in the ICU unit. And by, when we say intensivist staffing open and close, a closed unit means only intensivists treat patients in the unit whereas an open model means that non-intensivists also see patients in the ICU unit.

We also wanted to include patient volume in the ICU, patient characteristics such as, let's say for example, mean patient severity marker and also baseline patient outcomes. And then the other features that we considered are the area around the ICU or around the facility. We thought that population density or rural location were key variables as they also may reflect services available in the ICU.

So in terms of facility level data, there were a few sources. Number one, the VA Healthcare Analysis and Information Group, also called HAIG, does periodic surveys of organizational characteristics of facilities. So they had done a survey on VA intensive care units that provided information such as number of beds, type of staffing, and so on. So we used information from that survey to measure characteristics of ICUs. We also used the MedSAS Inpatient Files to summarize patient level data at the level of the ICUs. So we counted the number of patients per year at an ICU, mean ICU length of stay, mean mortality in the ICU. And finally, it was our goal to also obtain data from the VA Inpatient Evaluation Center, also called IPEC, and that includes a variety of measures reflecting, essentially process measures such as VTE prophylaxis, intermediate outcomes such as ventilator-associated pneumonia, catheter-related bloodstream infections, and so on.

Okay, challenges. So we did have a number of challenges I will talk about briefly. Number one, our initial analyst left. Her husband got a job out east. She's still with the VA, but she left Iowa City. So we had an analyst turnover. Not long after that, we also had an investigator turnover, the original PI, Dr. Peter Cram, left Iowa City; in fact, left the country. So anyway, so we had an investigator turnover. And then also there were issues with the actual implementation of ICU. It was delayed a little bit beyond our original planned date to start these activities. And as I mentioned when I showed you the map, it also expanded considerably over the duration of our study. In terms of data management, we, you know, our analytic plan called for matching the eight VISN 23 ICUs to eight ICUs without telecommunications, tele-ICU, and that was an excruciatingly painful task. That was very challenging, more challenging than we anticipated, and I'll show you some of the results pertaining to that.

We also dealt with missing data from the labs. The Decision Support System files, and it was known at the time that there were issues with those files having to do, I believe, having to do with just the way the data are captured. We had roughly 20% of patients missing any given lab. And we had eight labs that we were looking at. And then also there was the transition to VINCI that was occurring right around that time. So around that time, the VA decided to retire the Decision Support System files that were available through the Austin Automation Center, meaning we couldn't download data beyond fiscal year 2012 unless, you know, we had to go to VINCI for that. Same thing for the MedSAS datasets. They were eventually retired in about 2015, not retired completely but they were no longer available through the Austin Automation Center. So all of these things sort of converged. You know, we had kind of an interruption of the project with the loss of an analyst, the loss of the PI, changes in the way the data were being accessed that really prompted sort of what I would call a second phase of analysis where we really transitioned the way we did everything. What I'm showing you is the first phase of analysis where we did everything locally, and then I will show you a little bit how we transitioned and the pluses and minuses of that. The other challenge is that we were actually never able to get IPEC data. So some of those intermediate outcomes we have not, we still have not evaluated.

Alright. I'll show you the results. So here are characteristics of, well, we had eight pairs of intervention and matched control ICUs. I'm just showing you a sample of three. So I already mentioned matching facilities was very difficult. Can you still hear me, by the way?

Heidi: Yes, we can.

Dr. Mary Vaughan-Sarrazin: Alright, I'm just, I'm a little paranoid. So I just wanted to make sure you can all still hear me. As I mentioned, matching facilities was very difficult. We started off with about 10 key facility level variables, and we tried to prioritize and come up with some algorithm for matching, and admittedly it was somewhat arbitrary. We had talked about using, you know, some type of a propensity algorithm, but we thought that, well, the propensity algorithm approach had statistical appeal. We thought that matching on actual facility characteristics had a certain intuitive appeal to the audience that we were interested in and other sort of non-research-type individuals who might be interested in the project. So we wanted to directly match on certain key facility level characteristics.

Ultimately, we ended up using five facility level variables that we thought were most important. The ICU type, which you see here, mixed, so there was mixed, surgical, and MICU. The management, and that reflects the degree to which intensivists are involved at the local level. Open facilities means essentially that the ICUs can be staffed by non-intensivists. ICU level, again that's the complexity with one being the most complex, four being the least complex. And then the patient volume, and then also the percent white, which is kind of, also reflects a little bit of urbanicity and also just the makeup of the hospital.

You can see here the first match. This is a great match. We had one TICU unit, mixed, open staffing model, level three, with about 146 patients on average, 94% white. We matched it to a facility without TICU, also mixed, open, also level three, roughly comparable patient volumes, and roughly comparable percent white. If we go down here to the second one, we had a facility that had a staffing model open with intensivist consults, means care might be provided with, you know, by non-intensivist physicians but intensivists were nevertheless available for consults. ICU level two, patient volume 300, 94% white. And we matched that to a facility that was strictly open, with or without intensivist patient consults, and then you can see there's somewhat of a difference here in patient volume, roughly 33% more patient volume in the matched non-TICU facility. And again, if we go down here to the last example, you see we were not able for this facility with TICU, again, we searched through all the available other ICUs outside of VISN 23 and this was essentially what we felt was the best match we could come up with. This was an intensive care unit that was a level four. So level three and four are the two least complex levels, but level four is more uncomplex, less complex. And also they had roughly half the volume. Now in general, these are both small volume facilities. So we, you know, that's a reasonable match, although you can see that it's not perfect.

So anyway, so we finally, though, identified our eight intervention facilities in VISN 23, our eight non-intervention facilities that were matched, and then this just summarizes our analytical design. So in the TICU facilities, the eight VISN 23 intensive care units, there were 1,708 patients admitted to the ICU during the six months before TICU implementation. And in the matched non-TICU facilities, there were 1,664 patients admitted before the implementation date. And when I talk about implementation date in non-TICU facilities, I'm talking about the date at which their matched facility implemented TICU. So if Iowa City was, say for example, is matched to Tulsa, Oklahoma, and ICU implements, you know, tele-communications on February 1st, then the implementation for Tulsa, Oklahoma, which didn't have TICU, is also February 1st. And again, these are the number of admissions afterward. So essentially we're comparing the change that occurred before to after in TICU facilities to the change that occurred before to after in non-TICU facilities.

This is just some patient characteristics. In the interests of time, I won't spend, I won't go through this too much. We had age, race, mechanical ventilation, some comorbid conditions. And essentially what you can see is that they're relatively stable over time.

This is an example of a lab, one of the labs that we looked at, creatinine. So we had identified eight lab tests that were sort of good measures of patient acuity, and these eight lab tests we identified because they are lab tests that are included in the APACHE score that I mentioned previously. And you can see that we were missing anywhere from 18 to, I'm sorry, from 15 to 20% of serum creatinine, and these are labs identified. Basically we took the most abnormal lab value identified within plus or minus 24 hours of admission as a measure of patient acuity. But, you know, roughly 20% of patients didn't have a lab value within 24 hours of admission. Or if they did have it, it just didn't show up in the DSS data. So we ended up using imputation to fill in those missing values, and this is the distribution of creatinine essentially. These are normal labs, 0.5 to 1.4 I believe is normal. So most patients are normal.

And this is sort of the money slide. These are our results. I'll just go through one, you know, one example here. So looking at ICU mortality, this is death in the ICU, this is the post- versus pre-ICU mortality in our eight intervention ICUs. And this is estimated using logistic regression with random effects for facilities. So we had, the odds ratio is 1.07 with a P value of 0.82, essentially indicating no change in ICU mortality in our intervention facilities. In our control facilities, post versus pre, we had an odds ratio of 0.88 with a P value of 0.65, again indicating no significant change in ICU mortality in the control facilities. And then the ratio of this, the ratio of 1.07 to 0.88 is 1.21. And that's essentially the interaction term in the logistic regression model. But this is the relative magnitude of change in the intervention versus control ICUs, and as you can see, not statistically significant.

So essentially we found in this analysis really no significant impact of the tele-ICU on outcomes. A modest suggestion that maybe tele-ICU increased length of stay a little bit in the intervention units. You can see not, this is relative length of stay. So, and I believe this was, this may have been estimated with the Poisson model. I don't remember, actually. Anyway, the relative length of stay, 1.11, suggests roughly 11% higher length of stay in intervention versus control ICUs, P of .05. And there was some notion that having the tele-ICU might enable the smaller hospitals to keep patients locally rather than having to transfer them out. So it's possible that that might account for the reason why tele-ICU units experienced an increase in length of stay relative to control.

Alright, I'm just going to talk briefly about the project evolution. I just have about three more slides, and then I'm going to turn it over to Amy for the part two, four more slides. So a couple things happened that I briefly touched on. One is the Decision Support System data were no longer available through the Austin Automation Center. So in order to measure patient acuity in subsequent analysis, we needed to move our project to VINCI. In addition, we really wanted to incorporate the full APACHE score rather than just the lab values. In the full APACHE score, that incorporated the vital signs such as blood pressure, temperature, and so on. And those are only available through VINCI.

So number one, we made a decision to move our project to VINCI. And it was a good time to do that because, you know, because we also had this interruption in our analyst, the interruption in our principal investigator. Second thing that happened is I mentioned that the TICUs, the use of tele-communications expanded. Started off in VISN 23, then VISN 10 started implementing TICU with their own remote, with their own monitoring center, and then they also expanded services by, also were monitoring beds in VISN 7, and also VISN 15 now is also part of the remote monitoring center. And then finally, as part of that, as part of these changes, we also changed our analytic strategy so that we didn't have to go through this painful and perhaps somewhat arbitrary process of trying to match facilities. So we decided to use the whole country and change our analytic approach using the whole country.

So in subsequent analyses, and these analyses actually are sort of ongoing in which we're expanding to different outcomes and to other, you know, to the expanded ICU. Right now we're looking at 566,000 admissions to VA ICUs that occurred from October of 2009 through September of 2015. These are also identified in the MedSAS inpatient data. However, they are identified in the MedSAS inpatient data that's available through VINCI. So we've moved the entire data, the entire analysis project to VINCI. Now I should note VINCI also has other inpatient data available, but given our history with MedSAS, we're sort of sticking with the MedSAS structure. Of those, about 90, close to 98,000 were admitted to units that implemented tele-ICU during that period of '09 through '15. And that includes units in VISNs 10, 15, 10, 7, 10, 15, and 23. So for each, and for each facility that implemented tele-ICU, we have their implementation date. So we were able to identify admits before the implementation date and admits after the implementation date in each of those sort of intervention facilities. So we had roughly almost 63,000 patients admitted to the TICU units in VISNs 10, 7, 10, 15, and 23 that were implemented after the implementation date and 35,000 implemented before the implementation date.

Some of the variables we used, many of them were very similar to what we had done previously. But as I mentioned, we also wanted to use the actual full-blown APACHE score which includes the vital signs. And then instead of pulling our lab tests from the DSS data, we went, we started pulling our lab report tests from a different source also available through VINCI, which was the Corporate Data Warehouse.

Now I will mention there's pros and cons of the DSS and the CDW. The DSS data, which is also still available through VINCI, the nice thing about that is if you want to pull a lab value, let's say creatinine, there's a nice table with a nice set of codes. So I might find that creatinine is identified by code 51, for example. I pull all labs with code 51 and there you have it. I have my creatinine. Problem is, as you saw in my previous slides, there's a lot of missingness. Now when we went to pull the labs from Corporate Data Warehouse, our proportion of missingness dropped substantially. We were down to, for creatinine, for example, we were down to 5% missing, which was, you know, it was about 20% with the DSS. So we had a lot less missingness.

But the Corporate Data Warehouse lab data are very messy. There's no such thing as a nice tidy code that you can go to to pull a particular lab. The labs can be identified, you know, through a variety of other different indicators, but again, they're messy. Sometimes you have to actually, and we played around with a lot of different ways. So, for example, if you're identifying them through tech strings, you might be looking at, you know, creatinine might be coded as serum creatinine. It might be creatinine. It might be just CR, or it might be creatinine with a typo. So it's a lot more messy, but from our perspective, it was useful. And moreover, we used these labs for a variety of projects. So now we have an algorithm to identify them that is useful for us in, you know, in that project outside of this one. We also looked at an additional outcome in this new analysis, which was we wanted to look at whether the TICU impacted the extent to which patients were being transferred out of the hospital.

Our analysis methods. We still used a logistic regression model to control for patient characteristics and treating facilities as random. And the models also included three flags, one flag for facilities that ever implemented the TICU, one flag representing admissions before or after TICU implementation in those facilities, and one flag that was the interaction between those two.

And so here's our sort of the punch line of those analyses. We have, again, the tele-ICU pre to post. This is the odds ratio for the tele-ICU pre to post. Overall we have, you know, based on this logistic regression model that I just mentioned, odds ratio of 1.1, 95% confidence interval, and the P value of 0.28. For non-tele-ICU we have an odds ratio of 1.1, with a larger P value, which could simply reflect the fact that there were more non-TICU patients. But this is pre to post in tele-ICU, I'm sorry, post to pre in tele-ICU, post to pre in non-tele-ICU, and the relative change is 1. There was essentially no change in the likelihood of patients being transferred out of the hospital in ICU versus, I'm sorry, in units with remote monitoring and units without remote monitoring. We also looked at it by APACHE quartile, but I'm not going to go through that in detail in the interests of time.

So that's it for my talk. I'm going to turn it over now to Amy to talk about goal two.

Dr. Amy O'Shea: Okay, so goal two, excuse me, was all about...

Heidi: Hold on, Amy. I just want to interrupt for a second here. Just so you know, we have four minutes left in the session.

Dr. Amy O'Shea: Do you want me to just not talk?

Heidi: I'm not sure how much you're going to be able to cover. I don't think we have received, we've only received one question, and so if you want to get through what you can here, but just so you know we're really limited on time at this point.

Dr. Amy O'Shea: Okay. So the goal of this was to look at utilization because the, other researchers had found that tele-ICU can impact patient outcomes while others have found that it doesn't. So the hypothesis was that, well, maybe it has to do with how they are doing it. So we decided to look at the Standardized Clinical Note Template, and now the problem with this template is it was designed for medical and not research purposes. So it's great for doctors, but it has to be manipulated by us in order to actually use it. Now what happened over time, since this project has been going on for a while, is that each VISN 10 now personalized the template. So even though this template started out as the same thing, it is no longer the same thing. So as we are going forward, we have to consider what aspects of the template are the same, and they may not be the same name. So you really have to go back to the people you're working with, the clinicians who are using the template, to say hey, what does this mean.

Now the data is stored in the SQL Health Factors Table, which is also challenging because that table does not have things that are numeric [inaudible 56:59] like numeric things, not text things, so text things change. You can always type things with a typo, and the typo word is a different word than a word without the typo.

So in order to ensure that all the data was sound, we really had to do a search on all things that had to do with tele-ICU. Now on the picture on the bottom here, you can see that as you select things in the template, everything you select becomes its own code in the Health Factor. So you'll have tele-ICU comm initiated as one thing that has been selected and tele-ICU routine interventions. Now those were selected in the same instance, but in the Health Factors Table, they come up as two separate things. So you have to decide well, does that matter? Do I care that I know these happen in the same instance or not? And that really comes down to the question you want to answer with your data. So whenever you're talking about data, you always want to think about what question do I have, what can my data tell me, and what do I have to do to the data? Is there anything I can do to the data to better answer my question?

Okay, I'm not going to go over this because we don't have time. Basically we went from this huge thing with all these different pieces down to something that was more manageable. And the reason for that was because a lot of those smaller categories had very little data in them. And if you only have five things, it's really difficult to say anything about something that's only occurred five times.

Okay. The other complexity with this data, and I apologize that this is super, super fast, is that the two VISNs, VISN 23's hub and the VISN 10 hub, they do not have the same hours of operations. So when we're trying to compare how they're used in the two different locations, you're automatically going to potentially have more utilization in the one that's 24/7 versus the one that only operates at night. So what we had to do was decide how we could consider the patient's exposure to the tele-intensivist. Basically we take and calculate how many times did the tele-intensivist interact with that patient or the bedside staff during that patient's stay based on how much time they're eligible for the tele-intensivist to interact with them. So in the 24/7 one, it's their whole stay, but for the one that only is available at night, we could only consider that the patient's stay was between 7 p.m. and 7 a.m. So what that let us do was more accurately define how tele-intensivist use was going on. So we were considering contacts per week of exposure versus contacts per admission. So it's a more fine-tuned accurate way to consider utilization.

Now ideally what we wanted to do was just compare those two things, but because they were operating on night versus day and we have all this day data that was thrown away, we wanted to utilize everything. So what that meant was we could compare it within the one that operates 24/7. We updated our question to say how is utilization going on during the day versus at night. So, for example, we found that during the daytime in the hub that worked 24/7, we found that doctors tend to contact the tele-intensivist during the day. They very rarely contact them during the night. Now that makes sense, right? Because their tele-intensivist is available at night but your doctor, quite likely, is not. Right? You might have more residents. And we also found that residents tend to contact the tele-intensivist and the tele-ICU hub more frequently than a lot of other staff members.

Okay, we'll skip my two plot trends, but I'll tell you that they're both super awesome, so that we can talk about our lessons learned. So one, we learned that the transition to VINCI, even though we were super scared about it, was a lot better and easier than we anticipated. Do we keep running into things on VINCI two years later? Yes, we do. But we just have to keep moving forward and learning things. If you have not gotten on the HSR&D Listserv, you should definitely check that out because it can really help you if you have a specific question. So if you're not on it, I encourage you to check that out and join it.

We also found that the Corporate Data Warehouse data, even though it's messy such as the Health Factors Table, such as things that are lab, or you have to deal with text, even though it's very messy, it can be worth your time to spend going through that, especially if it's something you want to use in multiple projects.

Implementation work is messy. If this were a research project where I could control it, I would have one template for everyone. It would mean the same thing in every single location. Because I don't have control of it, because it's based on clinical need rather than research needs, they get to do whatever they want, and I have to roll with the punches. So if you're dealing with implementation work, be cognizant that that is going to be the case. You don't get to control things the way that you want to and you have to be able to adjust your hypotheses and your questions to what you can do based on what the clinicians require.

Also, as we saw with Mary's project, study design can be really effected by the data that you have. So they found that even though they thought going into it that getting those facilities matched would be really simple, it turned out to actually be really, really hard. And so they had to then later update their question and update their analysis so that they could get over that difficulty.

Now your study design can also really be effected by data you can't obtain. So originally they wanted that IPEC data, and they wanted to be able to look at some of those intermediate outcomes that IPEC strategizes. Not an option. So you just have to move forward. Nothing else you can do.

So study questions ends, take away study questions to be updated based on the data limitations that you have before you. Do what you can. Maximize the data that you have available; there's a plethora of it. And just make sure that you're doing it accurately and well.

Anything else, Mary? Did I summarize my four minutes well?

Dr. Mary Vaughan-Sarrazin: That's awesome!

Dr. Amy O'Shea: Okay. I hope I didn't go over too much. I don't even have a clock.

Heidi: Amy, could you just go through the slides down to your contact information, please?

Dr. Amy O'Shea: Of course! Okay. This is growing really, truly. I'm sorry you guys didn't have time to do this either. It looks so pretty and nice.

Heidi: It's very, just go on, click through them all. I just want to remind people that they can get HSR&D data Listserv link here. And I want to thank Mary and Amy for taking the time to present today's session. To the audience, if your question wasn't addressed, please let us know. I have two questions, very quickly, did you note whether the facilities were teaching hospitals? It looked, one of the questioners thought residents, physicians might have an impact. If you could...

Dr. Mary Vaughan-Sarrazin: It's one of the variables for matching.

Linda Kok: Okay. And would you share with us the algorithm to identify creatinine tests offline. If you could email that to VIReC...

Dr. Mary Vaughan-Sarrazin: Oh, you mean like the, how we did it in CDW, our algorithm for identifying creatinine in CDW?

Linda Kok: I imagine, yes.

Dr. Mary Vaughan-Sarrazin: Okay. Yeah, I'll see if I can. I mean it's just that, I assume it's SQL code because we're pulling it with SQL. We can email our...

Linda Kok: HSR data.

Dr. Mary Vaughan-Sarrazin: What's that?

Linda Kok: Would you be willing to share that up on HSR data?

Dr. Mary Vaughan-Sarrazin: I certainly don't have a problem sharing that, yeah.

Dr. Amy O'Shea: We can talk to Frank.

Dr. Mary Vaughan-Sarrazin: Yeah. I'll talk to the person who pulled that data and see if he knows how to put it up on HSR Data.

Linda Kok: Okay, great. And before we go, I just want to remind you that we have our Capstone session on Thursday, February 23rd, at 1 p.m. Eastern. Dr. Neil Jordan will be joined by Drs. Knight, Reisinger, Vaughan-Sarrazin, and O'Shea in a capstone discussion titled Focusing on the Interaction Between Research Design and Data Decisions, and we really hope you can join us. We consider the four sessions to be a mini-course, and I think we're going to have a great discussion time. Thank you, once again, for attending this session. Heidi will post the evaluation shortly. Please take a minute to answer those questions. They're really helpful for us. And Amy, that was the fastest session I ever heard!

Dr. Amy O'Shea: Well, thank you!

Linda Kok: Thank you both very much. Heidi...

Dr. Mary Vaughan-Sarrazin: Thank you for having us.

Heidi: Yes. Thank you to both of you for presenting today. We really do appreciate it. For the audience, those of you that are still here, thank you for sticking with us. I'm going to be closing the meeting in just a moment here. When I do, you are prompted with a feedback form. Please take a few moments to fill that out. Thank you, everyone, for joining us for today's HSR&D Cyberseminar, and we look forward to seeing you at a future session. Thank you.

[ END OF AUDIO ]