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Moderator: I just want to welcome everybody to today’s health economics cyberseminar. Today we have two presenters: Christine Pal Chee and Donna Zulman are going to be talking about the ImPACT Project, which is a Randomized Controlled Trial of an Intensive Management for Patient Aligned Care Teams for these very high-extensive patients.

Donna is a Career Development Awardee and clinician here in Palo Alto and Christine is one of Health Economists here at Palo Alto and we are happy to have them.

Christine Pal Chee: Thank you Todd. I am Christine Pal Chee and as Todd mentioned I am a health economist at a health economics resource center and I will let Donna briefly introduce herself.

Donna Zulman: I am Donna Zulman, I am a general internist and health services researcher here at the VA Palo Alto.

Christine Pal Chee: Donna and I today will be presenting results, actually we will first be describing this intensive management patient aligned care team piloted here at Palo Alto and we will also discuss results from the evaluation. Donna and I are actually going to tag team the presentation to keep things lively. I will be discussing elements of the study design and results from the evaluation and Donna.

Donna Zulman: I am going to be first describing what we learned about some of the high-cost patients in the VA nationally and describing the program as it developed and how we developed it. Then talking a little bit about the implementation challenges and some now ongoing work nationally in this area.

But before we begin, we thought it actually would be very helpful just to get a sense of why people are here today, what you are most interested in. I will ask Heidi to help us put up the poll. What is your primary reason for joining today’s discussion? You can select the first option – I would like to develop a clinical program for high I would like to develop a clinical program for high-risk VA patients. The second - I am interested in studying interventions for high-risk VA patients. C the third - I am in a leadership position and I want to learn about effective interventions for high-risk VA patients. And D the last one - I just find the topic interesting.

Heidi: Unfortunately I have a character limit there so the responses on the screen are a little bit shorter than what you just heard but responses are coming in nicely. We will give you all just a few more seconds before I close the poll question out and go through the results. I will close that out here. We are seeing seven percent saying developing a clinical program for high-risk VA patients. Forty-one percent are interested in studying interventions for high-risk VA patients. Eleven percent in a leadership position and want to learn about intervention. Forty-one percent just find the topic interesting. Thank you everyone.

Donna Zulman: Okay great. Just to start off it has been shown across the range of healthcare settings and populations that five percent of patients account for approximately fifty percent of healthcare costs. This slide shows the distribution of healthcare spending for the VA and similar patterns have been observed within the general population and within Medicaid populations and a slightly attenuated fashion within the Medicare population. As many as forty percent of patients in the top five percent were persistent with the most costly bracket the following year, that has been shown outside the VA. As a result there is a lot of interest in identifying effective interventions to optimize and streamline care for these patients.

A group of us here at Palo Alto had an opportunity to explore some of the characteristics and healthcare utilization patterns of the most costly five percent of the patients in Fiscal Year 2010. I am sure you can see the breakdown of costs for these patients, the mean total cost of this cohort was seventy-three thousand; the median was fifty-three thousand. You can see that in aggregate approximately half of the costs were generated in the inpatient setting in orange, but close to a third were generated in the outpatient setting in blue. Half of these patients had one or two hospitalizations in the year that we looked at and sixteen percent had three or more hospitalizations. Thirty-seven percent had one or two ER visits and twenty-nine percent had three or more ER visits.

When we compare the VA’s most costly patients on the left to the remaining population on the right, you can see that a disproportionate number are between the ages of forty-five and sixty-four. That mortality was high during the year of investigation. Fourteen percent were homeless suggesting that many of these patients have important needs outside of their immediate medical care and a lower proportion of patients in the top five percent are married so many of these patients likely have needs for social support as well.

Here you can see the most common chronic conditions and mental health conditions among the top five percent on the left compared to the remaining population on the right. You see high rates of common conditions such as hypertension and diabetes and disproportionally high rates of costly conditions such as chronic renal failure and heart failure. Then forty-seven percent of the patients have a mental health condition and again you see disproportionate rates of complex and costly conditions such as substance abuse and schizophrenia.

When we look at multimorbidity or the presence of multiple chronic conditions we can see here that seventy-six percent of the patients in the top five percent have three or more chronic conditions; forty-two percent have five or more chronic conditions. Then when we group those conditions into body systems, you can see that sixty-five percent have conditions affecting three or more different body systems. For example cardiovascular disease as well as pulmonary disease and a mental health condition, and nineteen percent of the patients have conditions affecting five or more body systems.

Just to summarize some of these early findings, this is an exploratory study of patients who are high-cost for a single year in the VA system. Again, we see frequent hospitalizations and ER visits, high volume of outpatient primary and specialty care, high rates of multimorbidity with seventy-six percent of the patients having three or more chronic conditions. High rates of mental health conditions and homelessness and likely many of these patients also have insufficient social support.

Here is a quick overview of some of the characteristics of the VA’s high cost patients. We then turn to thinking about interventions and at this point the VA had rolled out this extensive patient centered medical home program where every patient in the VA system had access to a PACT Team or Patient Aligned Care Team for their primary care. Our question was – How do we build on the existing VA primary care system to better meet the needs of these highly complex and high cost patients?

Before continuing we have a second poll now that will help us guide the next part of the discussion. Our question now is – Are you familiar with the structure of PACT Teams in the VA? Yes or No.

Heidi: We will give everyone just a few moments to respond there and we will close the poll question out and go through the results. Just waiting for the responses to slow down and it looks like we are good there. We are seeing fifty-eight percent saying yes and forty-two percent saying no. Thank you everyone.

Donna Zulman: Okay. For those of you who are not familiar with the PACT Team, every patient in the VA has access to a team of providers and this includes a physician or nurse practitioner as their primary care provider; a care manager, a nurse; and then a clinical associate typically an LPN or MA and then there is the clerk. Each patient and caregiver has access to that team and all of the teams have a hub of their team members who can provide additional services – clinical pharmacy services, social work, nutrition, case manager as behavioral health and so forth. This means that all the patients already have access to a fairly comprehensive primary care system.

Again the question in thinking about interventions is – How do we build up the existing infrastructure to better meet the needs of these high-risk patients. That led to this idea of ImPACT or Intensive management PACT.

To give you some background about this idea of the intensive primary care, many of you may recognize this picture it is from a 2011 *New Yorker* article by Atul Gawande entitled *The Hot Spotters*. The article profiles the Camden Coalition Clinic in Camden, New Jersey. The clinic founded by Dr. Jeffrey Brenner was one of the first to innovate around this idea of intensive primary care. The idea of these programs is to identify individuals with the highest rates of healthcare utilization so these are often patients who have very frequent ER visits and hospital readmissions then provided those patients with exceptional individualized care. For example they offer frequent in-person and often after hours contact. They help coordinate primary and specialty care. They provide support to patients during transitions form hospital to home. They facilitate access to social and community resources, for some patients this may involve assisting with housing and other critical needs. Through this type of effort the Camden Coalition was able to dramatically cut ER visits and hospital stays among a small group of extremely high-cost patients.

There are a number of other examples of programs that focus on complex high-risk patients in a variety of settings especially in the geriatric literature and also in both private and safety net settings outside the VA. While there have been few randomized controlled trials with these programs, the observational studies suggest that this type of model may hold promise for improving care while reducing costs for these patients.

Unidentified Male: Donna quick question for you.

Donna Zulman: Sure.

Unidentified Male: That have come in, for the PACT Teams and possibly you can speak about this more broadly, there is a question about the ratio of patients to teams so you said twelve hundred to one. How is that defined for VA and is that consistent across other providers?

Donna Zulman: Again I think it may vary a little bit by facility but the team typically has approximately a thousand twelve hundred patients that they are responsible for. Are you asking about how many care managers for example would take care of those patients?

Unidentified Male: How is the number twelve hundred approximately identified? Is that just from history?

Donna Zulman: I am actually not sure.

Unidentified Male: Okay. And is that panel size typical for non-VA as well when you get into these other programs or is that highly variable?

Donna Zulman: These are panel sizes for VA’s patient centered medical home. I think it may vary quite a bit outside the VA. For these intensive management programs, the panel typically much much smaller. It may be anywhere from maybe a hundred patients per case manager, health coach depending on who the point of contact is and typically just a few hundred for the entire program. Again I think there is quite a range depending on the environment. The other important piece here is that these programs are very heterogeneous in terms of the patients that they are serving. Some of the programs, the Camden County Program for example is serving high-risk Medicaid patients who typically have substantial mental health issues, substance use and other programs are focusing on TDGH Programs are focusing more typically on employed patients. The needs of the patients vary quite a lot, but what the programs all have in common is that they are taking the highest risk patients within any given setting and they are trying site services for those patients.

Unidentified Male: Okay and we actually just had two other people who chimed in, listeners. One person said the PACT handbook outlines the panel sizes and then another person says the panel sizes are quite typical for managed care plans in this arena.

Donna Zulman: Great, thank you. Approximately two years ago the Palo Alto VA decided to implement this intensive management program and the framework for the program was adopted from Ed Wagner’s Chronic Care Model. The goal was to transform the care in each of the domains at the top so for example by engaging patients and community resources, providing them with self-management support and redesigning care for example through afterhours services and case management. Ultimately the goal is to empower patients and their caregivers with necessary resources and to facilitate productive interactions between the patients and the multidisciplinary teams. The outcomes at the bottom are the outcomes that we are looking at in the evaluation. Our goal was to assess whether this program improved utilization patterns, decreasing needs of the ER and hospital admissions and improved patient centered outcomes.

Before implementing the program we had an opportunity to interview some of the high-cost patients at the Palo Alto facility to learn about the challenges that they face. We heard things like – “for someone who has many conditions and a condition that could kill me at any time, I should be monitored all the time.” “I never know when I am going to have to go to the ER. I cannot finish programs and I do not know why.” “I wish someone would help me navigate the system, I do not know what resources or programs are available to me.” The other themes that came up were – continuity and communication challenges so patients talked about lack of provider continuity, having a lot of different specialists difficulties coordinating multiple providers. Many of the patient had needs for social support and social services. Many of the patients expressed interest in having after hours contact and access for example because of unstable health conditions or anxiety or isolation that generated need to talk to providers in the evenings and on weekends.

Taking some of what we learned from the quantitative work that we did early on with the high-cost patients and then this qualitative, the interviews with the patients, we developed a program that we felt was a good fit for the VA. This slide shows the core elements of the ImPACT Program and the ImPACT Team Members on the right including Jonathan Shaw our physician, Katie Holloway our recreation therapist, Terry Rodgers on the bottom left who is the coordinator for the program, Miriam Trigrive [ph] who is the social worker and Deborah Hummel who is the nurse practitioner. A really fantastic group that I want to make sure to acknowledge they are really the heart of this program. It is a multidisciplinary team, again their role really is to provide the exceptional individualized care that is based on the patients goals and challenges and needs. They do a comprehensive intake and provide frequent in-person contact and telephone contact with the patient. They offer intensive case management for chronic conditions. They help coordinate the primary specialty care and this often involves going to specialists with the patients to help them navigate the care they need and potentially help deescalate care that they do not need. They are able to rapidly respond if a patient’s health deteriorates. They provide support during transition from hospital to home, they are able to go visit the patient in the hospital to help work with the patient team around the discharge plan and then follow up with the patient after discharge. Then another key part of this program is they provide access to social and community resources. This involves getting patients engaged in community programs, Tai Chi classes and cooking classes and their community pool, which has helped with patient’s quality of life and also has helped engage them in the program and build their trust in the VA.

In terms of our evaluation because this was a pilot we wanted to study its effectiveness but also understand the implementation process and barriers. We conducted what is called a Type I Hybrid Trial, which allowed us to test the clinical intervention while also gathering information about delivery and implementation. I want to mention that this evaluation involved a very close partnership with facility leadership at the VA Palo Alto. A critical piece was that ImPACT was implemented as a quality improvement pilot so the facility wanted to find out whether intensive management team would be a valuable addition to PACT in Palo Alto. Because they really wanted to understand the effects of the program, they agreed to offer it to a random sample of patients initially. That allowed health services researchers to work with them to evaluate it in a pretty rigorous way. We ended up with a hundred and fifty patients who were randomly assigned to participate in ImPACT during the pilot period and then the remaining eligible patients continued to receive usual care through PACT.

Now I am going to turn it over to Christine, she is going to describe our methods in a bit more detail.

Christine Pal Chee: Thank you Donna. Donna had mentioned that patients were randomly selected for the ImPACT program. I wanted to highlight that that the fact that patients were randomly selected for the program, really facilitated our evaluation. It made our jobs as researchers much easier in terms of establishing the causal effect of this program. Donna will discuss in a little bit some results that support that there was true randomization or successful randomization.

In this evaluation we wanted to estimate the effect of the program on healthcare costs and utilization and there we used data from the DSS office. Our question was - What effect did ImPACT have on health care costs and utilization? In our primary analysis we estimated the Intention- to-treat a fact within a difference-in-differences framework. Where we compared pre and post treatment outcomes across the control and treatment groups. I will talk a little bit more about this. Here. We estimate the average treatment effect in the population that was eligible for treatment. But because not everyone who was eligible for treatment actually received treatment, not everyone who was randomly selected for ImPACT actually enrolled and received ImPACT services. And because we believe that those who engaged with the program they differ from those that did not engage in the program in ways that might affect their costs or utilization. We used instrumental variables analysis with randomization as instrument. And we believe randomization here is a valid instrument because one – it is relevant. Randomization whether or not you are randomized to receive ImPACT determines or affects whether or not you actually engage in ImPACT. We find that most patients who are randomized who receive ImPACT actually enrolled. Second, randomization we believe is exogenous. So it is unrelated to other factors that might affect a person’s costs or utilization and particularly they are unrelated to these factors that might be correlated with whether or not someone actually chooses to engage in the program.

In the instrumental variables analysis we estimate the effect of treatment on the treated. That is we estimate the effect of the program among those who actually engaged in the program. Here we define engagement or treatment to be having completed intake and having at least three encounters. And to evaluate whether the program affects different across different groups of patients we also stratified analyses by key characteristics. Here we looked at patients who are over and under the age of sixty-five; patients who have mental health conditions; patients who had chronic heart failure, diabetes, COPD and those who had a recent hospitalization. I will share more about the results from our evaluation in a little bit after Donna shares more about the program and some initial lessons learned.

Donna Zulman: Okay, great. This is the timeline for the intervention and evaluation. Starting at the left, we identified patients using data from a nine month period. We selected patients who are either high-cost or at high-risk for hospitalization. It then took a few months to hire the staff and refine the program so we had a pre-period of sixteen months. The red line February, 2013 indicates when we started enrolling new patients and it then took about nine months to enroll all of the patients who ultimately participated. We reached what we call the study state at the end of August, 2013 and then today we are going to present analyses for the first full seventeen months of the intervention period so comparing that post-period to the pre-period.

Here you can see how patients were selected for the pilot. We started again with about the five thousand patients who were either in the top five percent of the facility based on their total costs to the VA care or were in the top five percent based on their risk of hospitalization over the next year. To identify risk we used the care assessment needs score which is a score that has been developed within the VA and can help predict patients who are likely to be hospitalized. In our case we used their risk of hospitalization over the following year. We excluded patients who died before we started the program and also excluded patients who were already enrolled in intensive management type of program, through home-based primary care, through palliative care or through mental health intensive case management MHICM. We also excluded patients who had a length of stay of over fifty percent of the baseline period. This was because we really wanted to focus on patients who are primarily in the outpatient setting. We then ended up with about four thousand patients who met our inclusion criteria. We funneled that down to patients who had one of fourteen providers who were part of pilot intervention. These PACT providers were either physicians or nurse practitioners and they were all attending, not residents. We excluded patients then who had low cost or were at low risk and ended up with our five hundred and eighty-three patients. Again randomly identified a hundred and fifty to invite to participate for the pilot.

Unidentified Male: Donna.

Donna Zulman: Yes.

Unidentified Male: This is Todd. Can you go back one slide? We have a question from the audience, which is that the hundred and fifty assigned to ImPACT Is considerably smaller than the twelve hundred we talked about earlier. Is that because of it being a research study or is that just because the clinic is just much harder to manage this group of high use patients?

Donna Zulman: The PACT panel is very heterogeneous in terms of needs so there are a lot of patients who are receiving care through PACT who have very few needs throughout the year. Some of them for example may get a lot of their primary care outside of the VA system and only come to the VA to get medications. Others may just have hypertension or one condition that needs some following. The idea of ImPACT is to take the very highest risk patients from the PACT teams and consolidate them and give them these additional resources. The patients are still continuing to get some care from their PACT and they can still work with their primary care provider, but ImPACT kind of provides this layer of additional services on top of what they are getting through PACT. It is an intentionally small panel because some of these patients may need daily or weekly contact; they might require home visits, they are in and out of the hospital a lot and we anticipate that the team will only be able to manage a small number. It is still not clear what the right number is for these programs. And I am going to, towards the end of this presentation, talk about some other work that is being done in the VA nationally that we are trying to figure out what the right balance in terms of numbers and patients. And how many of those patients need the very intensive management versus just more keeping an eye on them and intervening when necessary. That is part of where we arrived at the number. We also arriving at the hundred and fifty we also extrapolated from what we were learning outside of the VA in terms of the appropriate size for these really intensive management programs.

Unidentified Male: Great, thank you.

Donna Zulman: Thanks. This is just to show that our randomization worked for key variables including age, sex, urban versus rural location, presence of non-VA insurance. Indication of any homelessness during the nine month baseline period. Number of chronic conditions and frequency of hospitalization and ER use during the baseline period. Here you can see rates of chronic conditions and again they were well balanced across the two groups. We looked at forty conditions in total and you can see there were slightly more patients in ImPACT with coronary artery disease; slightly more patients in the control group with cancer but for the most part the two groups were well balanced.

Now we are going to turn to some of our findings from the evaluation. What did we learn? First approximately two-thirds of the patients who we invited to participate actually engaged in the program. As Christine mentioned, we defined engagement as completing the ImPACT in at least three additional encounters with the team. Here you can see there were some important differences between the patients who engaged and those who did not. The patients who engaged were older, were more likely to live in an urban location, were more likely to have non-VA insurance, most of this was accounted for by Medicare and reflects the older patients in the engaged group. But the other characteristics were similar across the two groups. Then we look at chronic conditions among the engaged and non-engaged patients we can see differences in the number of patients with liver disease or Hepatitis B, certain mental health conditions so patients who engaged had lower rates of drug use, alcohol use, and schizophrenia. All of the other conditions were similar across the two groups.

Our next finding was among the patients who engaged in the program most thought that it was extremely valuable. We conducted pre/post surveys with the ImPACT patients, only with the ImPACT patients not with the control patients receiving usual care.

We had about a sixty percent response rate to the follow up survey among the program participants. Ninety-three percent of these respondents that they would recommend ImPACT to others. We heard things like – “The ImPACT program helps me keep track of my health and well-being and medical care.” “Knowing that someone has your back means a lot, I do not have to go to the ER for minor things.” “Having a liaison between myself, my doctor, hospital or pharmacy is so very crucial to me and ImPACT fits the bill.” “Not to sound like a TV commercial but one call does it all.” You can see there were very high satisfaction rates with the medical care, social work, recreation therapy and community services and afterhours care that patients were receiving through the program.

We also saw that among the surveyed respondents there was an increase in general satisfaction with the VA overall. The percentage of patients who agreed that care at Palo Alto VA is just about perfect increased and there was also an increase in communication satisfaction so the percentage of patients who disagreed that doctors at Palo Alto VA often ignore what I tell them also increased.

Now I am going to turn it back to Christine to present some additional findings.

Christine Pal Chee: Thank you Donna. The third thing we learned was that there was no program effect on mortality. Here we present results graphically and what we do here is plot on the Y axis the percentage of patients alive in each group in each month. On the X axis we plot months since the start of the ImPACT program. The blue line is the percent of patients in the usual care that delayed control group who are alive in each month. On the red line plots the percent of patients in the ImPACT group who are alive in each month. You can see here that there is no discernible difference in mortality across the two groups. These two basically track each other so we see no effect here and this is the same when we run regressions the results are the same. We find no difference in mortality between the two groups.

The first thing we find was that the intervention was cost natural.

Here we start off with graphical results again although I will discuss more specific results and numbers in just a little bit. Here what we do on the Y axis we plot average VA Palo Alto monthly costs and this includes ImPACT costs. On the X axis we plot months during the study period. The dark vertical red line on February, 2013, marks the beginning of ImPACT and the thin red line corresponds to the end of August or September, 2013 marks when the last patient who participated was enrolled in the program. So after that everyone who participated was enrolled. The dotted blue line plots the average VA Palo Alto monthly cost among the usual pairs of control group of each month. The red line plots the average VA Palo Alto monthly cost in each month for the ImPACT of the treatment group. We can see here one really interesting and important thing to see here is that for both groups average cost to client over time. In general patients do not have high-cost versus indefinitely. It is very difficult for a patient to basically sustain high-cost over an extended period of time.

The fact that both groups see this decline in cost actually highlights the importance of the control group in our analysis and the value of the difference-in-differences framework. So without the control group if we were to only look at the red line at the treatment group, we would see that the average post-monthly cost are actually lower than the pre-monthly costs. So there is a reduction in costs across the post-time period. We might attribute that cost reduction to the program. But we see here that cost in the ImPACT group did not decline any more than it did in the control group. At the same time the program also did not appear to increase costs in the ImPACT group and that is despite the fact that ImPACT is providing intensive care to these patients.

Another way to look at this which highlights the difference-in-differences results is the totaling figure. Here what we do is each of the bars here corresponds to the average monthly costs in each of the pre or post time period for the control and treatment group. I will start with the dark blue bar on the left. This bar here shows us that the average monthly cost in the pre- ImPACT period with the usual care of the control group was about fifty-eight hundred dollars per month. In the post period the average costs declined to about forty-six hundred dollars so there was a decline of about twelve hundred dollars between the pre and the post periods for the usual care patients. The dark orange bar shows us that the average monthly cost in the pre- ImPACT period for the ImPACT patients, this is our treatment group, was about eleven hundred dollars in the pre-intervention period. In the post-intervention period average monthly costs were about forty-eight hundred dollars. In the treatment group, there was a change of about twelve hundred and ninety dollars. The assumption here in difference-in-differences is that in the absence of treatment what would have happened in the treatment group is what did happen in the control group. In the absence of treatment we would expect costs in the treatment group to decline by twelve hundred dollars. Instead we incurred a decline of twelve hundred and ninety dollars, which gives us if we take the difference of those two we get the difference-in-differences, which is about eighty-six dollars. We can see here that costs decline by about eighty-six dollars more in the ImPACT group than it did in the control group. I should mention that these are just raw costs, these numbers are just not from our regressions, they are raw costs. We decided to show this for simplicity, we will talk a little bit more I will show our actual regression results in a little bit and they are actually very similar to these numbers. We see here that the decline of costs of eighty-six dollars is very small and we will see later in regression results that the estimated program effect on costs is small and statistically insignificant.

Unidentified Male: We have a few questions and I want to make sure that I am interpreting it correctly, Christine. One is - because you are looking at monthly costs if inpatient stay crosses the month you just allocate the cost proportionate length of stay in the month – right.

Christine Pal Chee: Yes that is correct.

Unidentified Male: Does the cost that you are looking at here include the program costs of developing and running this ImPACT program?

Christine Pal Chee: Yes, it includes the cost of any care received through the ImPACT program.

Unidentified Male: The additional staff that you hired and so forth is built into this.

Christine Pal Chee: We did discuss how we should include ImPACT costs and one option was to include the cost of the staff that were hired for this. Another option was to include the cost of the encounters or the services that were provided for ImPACT. Here what we did was we included the cost of the encounters, the ImPACT encounters.

Unidentified Male: Okay thank you.

Christine Pal Chee: Our fifth finding was that the intervention could potentially have an effect for certain subgroups of patients. We found that on average or for the entire group of treated patients the estimated program effect was quite small and it was statistically insignificant. For some patients the program might be beneficial as we see here.

These are regression results. Here I am going to start off with results for all patients. Here we report the intention-to-treat, the difference-in-differences with estimates. Here we see that ImPACT led to a one hundred dollar decrease in monthly costs but that as a fact was not statistically insignificant, we see that there is a much larger standard error.

I mentioned earlier that because not all patients who were offered the program actually participated in the program. We wanted to also evaluate the effect of the program among patients who actually did participate. In our last two columns here results from the instrumental variable analysis. We see here that ImPACT reduced costs by about a hundred and thirty dollars a month among patients who actually did participate in the program. Again, here the results the effect is small, it is statistically insignificant.

Here we look at results for patients, we focus on the group of patients with heart failure or diabetes or COPD. We find here that the estimated program effect is actually a reduction of about seven hundred and fifty dollars per month among the entire group of patients with those conditions. That number is larger but it is also statistically insignificant. Among patients who actually received treatment, the estimated program effect was a reduction of about one thousand one hundred dollars per month. Again, we did not have precision to reject \_\_\_\_\_ [00:38:51] that the program had zero effect on cost.

We also look at patients who have a mental health condition and do not have a mental health condition. Again the results are qualitatively similar to what we found for all patients. Now we focus on patients who are under the age of sixty-five as opposed to over the age of sixty-five. The interesting thing here so the results here again, not statistically significant, but qualitatively the results are actually quite interesting. So among patients who are under the age of sixty-five it looks like an ImPACT might have reduced their costs. But for patients who are over the age of sixty-five it looks like ImPACT actually increased their costs. We think this is because patients over the age of sixty-five might be shifting their care from Medicare to the VA. We also focused on patients who are high-cost at baseline compared to high-risk or having a high-risk of hospitalization at baseline. Here we find the program did not seem to have an effect on their costs. We also looked at patients who are hospitalized in the six months prior to enrollment, again, similar results. Finally we look at patients who are at high-risk of hospitalization and who are hospitalized in the pre-period. We find a somewhat larger effects but also statistically insignificant. What these results suggest although we do not have much precision they suggest that the program might be beneficial to certain subgroups of patients. With that I will hand it back to Donna.

Donna Zulman: Okay. I am actually going to move pretty quickly through this next piece to make sure we have enough time for questions. As I mentioned this was a hybrid trial, we wanted to learn about implementation, the process of putting implementation and barriers and facilitators as well as the effectiveness. So we conducted interviews, Jessica Breland one of our staff lead interviews with all the ImPACT Team Members, facility leadership and some other providers who contracted with ImPACT using the CFIR Facility to Framework for Implementation Research Framework to develop interview questions. And the goal again was to identify barriers/facilitators to implementation and to understand the strength of the program and also opportunities for improvement.

Some of the facilitators that we heard about again and again were the proactive and creative approach of the ImPACT Staff. We heard a lot about how the team really would jump in when providers asked for support and how they had a lot of creative ideas to try to help patients who were in and out of the ER. The adaptability of ImPACT’s design, so the program really evolved over time as the team understood more and more about the patients’ needs and also about the resources at the VA. The fact that it was adaptable was very helpful. In terms of the local environment people spoke a lot about how engaged the leadership was with this program and how helpful that was. Also how there has been a culture of innovation at this VA Palo Alto which helps get buy-in form all the different stakeholders in trying something new like this.

Barriers included the complexity of the patient population these patients needs are very heterogeneous in terms of their conditions and their social needs. A staff member said “ImPACT at its core, is trying to address 100 or 200 patient's’ individual needs and goals.” I think mental health, the patients who have serious mental illnesses were a particularly challenging group before the team two engaged. They did not have a mental health provider on the original team, they worked very closely with the mental health care services at Palo Alto VA but I think they felt it would have been helpful to have someone with that expertise. It was difficult to reach the rotating hospital staff and to collaborate with them. They also noted that because this was a pilot and we were evaluating it there was quite of lot of pressure and they did not know how long the program would be in existence so that created some challenges for them in people moving quickly and having some uncertainty about the future.

Finally I think one of the most important lessons we learned from this project was that this rigorous evaluation of this type of model is really important. As Christine said, a lot of these programs have been looked at just with pre/post results and potentially that could be misleading because of the regression to mean effect that can occur in patients who are very high-cost at baseline. We also found as Christine mentioned in our subgroup analyses that there are potential groups of patients who may be that \_\_\_\_\_ [00:43:49] program. So we think that there is still a lot to learn about patient selection for these programs and that appropriate mix of services some of the staffing issues that came up in our earlier conversation.

We are fortunate in that the VA has invested in a national demonstration project to look at other types of models of intensive management for high-risk patients. Here the programs in yellow – San Francisco; Milwaukee; Cleveland; Salisbury and Atlanta are all in the process of enrolling patients now. Palo Alto and Los Angeles are collaborating a national evaluation of all five programs. The VA has adopted the partnered research approach that we use for ImPACT, which is wonderful so that all five of these programs are enrolling random samples of patients, which will allow us to do a really rigorous evaluation of all five programs in a central way. That is exciting and we hope to learn more over the next few years.

I just want to mention that each of the programs if really bringing unique elements to the table. For example San Francisco is focusing on older adults and Milwaukee is focusing on the transition from hospital to home, they are enrolling patients during the hospitalization. Cleveland is engaging military medics and really emphasizing peer support and trying to support the PACT Team to prevent provider burn out. Salisbury is unique because the PIM program is actually to assume total care for the patients whereas all the other programs layer on top of the PACT program. Then Atlanta has a lot rural patients and so involving a lot of telehealth and it is emphasizing patient activation. We are hoping to learn a lot from each of these.

Just to again say that we have a plan now for national evaluation, these are some of the outcomes that we are going to be looking at. I want to make sure that we have time for questions so I want to leave this slide up to thank the many, many individuals who have been involved. On the left are the individuals who are involved in the high-level analyses that we presented at the very beginning. The ImPACT evaluation team, the ImPACT clinical team and the Palo Alto leadership and the many people who helped advise us in that work. Then all of the PIM sites and the national evaluation center, individuals below who are helping us learn in this next iteration and we listed the many groups that have helped support this work. We are happy to take your questions. Thank you.

Unidentified Male: We are getting some questions in, this is great. One of the questions is just a little bit of clarification. You mentioned early on that a hundred and fifty people were randomized to the ImPACT Program. The question says – it looks like a hundred and forty were used in the analysis. Can you clarify the numbers there?

Donna Zulman: Yes so when we ultimately got all the data together for the analysis, we found that there were some patients who had either died or moved away before the program started. We limited the evaluation to those patients and that is why the numbers dropped a little bit.

Unidentified Male: Okay. The next question I have here is a little bit of a long one so I will see if I can read it maybe break it down. Beyond costs, have you evaluated patient outcomes to see if the patients were more treatment compliant?

Donna Zulman: That is a great question. I think there is still a lot to learn around patient outcomes. We were somewhat limited in looking at patient outcomes because the ImPACT Program was quality improvement and as such we felt that we could only survey and interact with the patients who were in the ImPACT Program. We did not contact the patients in usual care. We therefore could not look at differences between the two groups. What we did look at was the patient satisfaction and some other things around patient experience like their activation level. We are now doing some analyses that we can with the DHR data to try to understand more about patients care and the quality of their care and their experience with the program. For example we are looking among the patients who died and whether they got hospice or they were referred to hospice, how long they were in hospice and whether they died at home or in the inpatient setting. We are looking at how much continuity patients had with their providers whether the balance of inpatient to telephone care that patients had, whether they were contacted closely after discharge within two days after discharge. So some of those metrics we were adapting from the PACT National Evaluation to try to understand whether quality metrics of care might have changed. In terms of adherence I think it is really a terrific and important question and is a challenging one just because again the patients are so heterogeneous in terms of their needs that we did not end up looking at any disease specific measures. In principle it would possible to look at their adherence with all of their medications, but it is sort of beyond the scope of what we could do with this analysis. I think it is really important intermediate measure that would be great to look at at some point.

Unidentified Male: Sounds great. Also you mentioned that there are homeless. What role do you think the specialized PACT Teams can have in addressing social determinants of health or detail or care and address needs that can play in this process. This person gives an example – for example homeless PACTs are incorporating many of these features and putting reducing panel sizes, multidisciplinary providers, walk-in visits. Where do special population PACTs fit into this sort of analysis?

Donna Zulman: That is a great question because I think in particular the homeless patients were a group that the team had a lot of difficulty engaging. It is possible that there are going to be certain subgroups of these high-risk patients that really need a very specialized program and homeless patients may be one of them. Patients with serious mental illness or substance use may be another one. I think that is where in understanding who are the patients who are most likely to engage in these programs and benefit from these programs is very important. I think that the specialized PACTs may be particularly good for patients whose needs resolve very much in one domain and this type of intensive management program may be a better fit for the patients who have multiple chronic conditions and need a lot of coordinated care across a lot of different specialties. In terms of a social determinants of health, I do think that in general that there is an opportunity for these types of programs to help with those issues. Because for the PIM programs many of them are doing home visits and are able to help engage the patients within their communities and build social support for the patients and things like that. There may be also harnessing a lot of existing VA resources by having the time to really take advantage of those resources and get them to the patients.

Unidentified Male: Okay, but the homelessness issue and the social determinants, the more you focus on very specific populations though also reduces not a general liability but the numbers of sites at which this could be used and perhaps increase your costs of finding those patients. If you wanted to do an ImPACT project for homeless patients with blonde hair, blue eyes who are forty-six years old and a birthday in April, I mean I am being totally facetious there but you see my point. It is sometimes very hard to develop a program so specific to that.

Donna Zulman: We were hoping with this to try to avoid creating another silo of care in the VA because sometimes there are so many different programs, and as you say they may be very specific in the population they are helping. I do think again this is not based on evidence, it is sort of me doing a lot of work in this area. That there are going to be populations for whom those types of programs are probably a good fit and there are going to be a lot of other patients who are going to have more diverse needs, they are going to be better suited for a more general program like this one.

Unidentified Male: That is great. The next question I have is for Christine. I know that the difference-in-difference model largely follows the intent-to-treat analyses. Did you do a lot of work with covariates that you were adding to this in sort of a multivariate difference-in-difference model? Or did that not matter?

Christine Pal Chee: That is a great question Todd. The thing that we had working on our side was that we had randomization of patients. We saw that patients were actually pretty well balanced on observable characteristics. Because that was true, when we did controls for these observable characteristics, like homelessness, age, gender, chronic conditions, we found that it did not have much of an impact on our estimates of the program effect as we would expect. That said, we did control for person, fixed effects to account for any unobserved differences that do not change over time across patients. Again we did not find that including the sick effect had much impact on our estimates that for comprehensiveness that was the specification we chose.

Unidentified Male: Right. Then you went a step farther which was to use instrumental variables to recognized that there were certain people who are engaged and not engaged in trying to figure out is it the engagement, but that slot did not pan out. At least on a quantitative set you did point out some qualitative differences that you will need some bigger sample sizes.

Christine Pal Chee: Yes, yes. I should just highlight that the intent to treat effect on the treated effect are actually different. The intent-to-treat effect is the average effect of treatment among all patients who were eligible or who were offered the program. The treatment on the treated effect is just the treatment effect among patients who received treatment. These were the patients who engaged. There is a subtle difference there but the two should be capturing different things. As you mentioned we did not find too many large differences between the two estimates.

Unidentified Male: Sounds great. Another question is – did you find that hospitalizations, emergency department visits, time not living at home were reduced in ImPACT patients compared to usual care?

Donna Zulman: Yes, a really important question and I think it did not make the final slide. There was no difference in both groups had a decrease in hospitalization and in ER visits, they were virtually identical. We did not see any difference in the two groups. There were some potential changes in length of stay for certain subgroups. Again none of them were significant, but there was that possibility that for example the patients with the chronic conditions the heart failure, COPD and diabetes had a decrease in their length of stay in long-term care. I also just want to mention that the reason that we focused on those three conditions was that when talking to the team they felt that those were the three chronic conditions where they had the greatest effect. That is why we selected those as a subgroup.

Unidentified Male: Sounds great. Did you assess any other outcomes let us say patient centered outcomes besides satisfaction?

Donna Zulman: We looked at again just in the ImPACT group we looked at changes in functional status, changes in symptom burden and changes in patient activation. I think if somebody is interested in those they could communicate with me afterwards. At the top of my head the functional status in symptom burden in general got worse over the period of time that we looked. We attribute this to the fact that the patients are very sick and many of them are going to be getting sicker. Unfortunately we cannot look at the control group to know whether there was maybe a difference in the rate at which they were having those changes between the two groups. Patient activation we had some patients who had improved activation over the time period. But, it was I think maybe just barely clinically significant.

Unidentified Male: Great. We have one last question and it is probably a great question to end on which is –given the results of this pilot did not \_\_\_\_\_ [00:56:41] cost savings, do you feel this program can be supported by the VA on a larger scale. And will the additional study need to demonstrate cost savings? Will we need to I guess need to demonstrate cost savings for this to work I think is another way of phrasing that.

Donna Zulman: That is a very important question. I think the second part of the question I will have to defer to people who have much greater \_\_\_\_\_ [00:57:08] than I do. I do think that while the findings here were cost neutral we learned a lot about how to build a program like this and the potential groups of patients that may benefit. We are hoping that with the five site demonstration project will have large sample and will learn even more. I do not think we found the right model exactly at this time, but I think that we found some potential opportunities to help these pilot patients. It is a very tough problem that has become very clear and I do not think there is going to be a very simple and fast solution. My hope is that there will be opportunities to continue doing work in this area for enough time that we can really understand what are the challenges and opportunities and is there an opportunity to make a difference. I can tell you that in the consideration there is a lot of interest and of course we would like to see changes in the cost curve and changes in some of the acute care utilization. But there is also a lot of interest and understanding that effects on patient experience and outcomes in other ways. Hopefully we will learn more around those topics too.

Unidentified Male: That sounds great and if I may editorialize just a second, when we are talking about program adoption and evaluating program adoption it probably should not be any less rigorous than defining whether we adopt or approve a new drug. In the FDA world, you need multiple studies to show that the drugs is safe and efficacious before it will be adopted and approved by FDA. In many cases there are multiple trials done and have conflicting results and the FDA and the special panels that review those data have to make determinations. I think that this is a great pilot study but it is clearly a pilot. I think that it is going to be very important to see the additional studies that come out of this.

On the flip side, getting back to your original premise Donna and Christine, this five percent of the population consumes fifty percent, half of all VA spending each year. It is a really critical component that we really need to figure out how to manage and do a better job with that.

I just wanted to thank you both for a great presentation. We are at the top of the hour and I wanted to thank all the listeners out there especially all those that asked questions. Would you like to say any closing remarks?

Donna Zulman: Thank you very much for the opportunity to present today and we are both happy to take additional questions. If you want to email us our information is at the bottom there.

Unidentified Male: Great.

Christine Pal Chee: Thank you.

Unidentified Male: Thank you Donna, thank you Christine, thank you Heidi.

Donna Zulman: Thank you Heidi.

Heidi: Thank you. For the audience when I close this session out you will be prompted with a feedback form. Please take a few moments to fill that out, we really do read through all of your feedback. Thank you everyone for joining us for today’s HSR&D cyberseminar and we hope to see you at a future session. Thank you.

Unidentified Male: Thanks.