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Thank you very much for joining us today for the Medicaid/SCHIP Webinar, remote disease challenges. We have more attendees joining, so we will get some of the housekeeping things out of the way and move to our presenters.

We will have two presenters today: Dr. Lee Goldberg, Associate Professor of Medicine, and Dr. Thomas Klein. As the presentation goes along, make note of questions you have and towards the end you may, or during the presentations, you may use the chat box to note your questions and we will sort through, have a question and answer period at the end.

If you have trouble, feel free to raise your hand, if you registered appropriately for the Webinar, we might be able to do that, no guarantees, but thank you for joining us.

Today our two presenters will go in the order their slides are on the screen. First I would like to introduce Dr. Lee Goldberg, of the Heart Transplant/Heart Failure Ambulatory Center, and the program at the University of Pennsylvania.

He has a significant interest in this remote monitoring issue, and certainly in the electronic medical record realm. He is the Governance Chair of the EMR Committee for the Cardiovascular Division and is a member of the system-wide EMR Operations Committee. Dr. Goldberg is board certified in internal medicine and cardiovascular disease. He is the Principle Investigator of an AHRQ sponsored RO1 grant evaluating the impact of different technology models on heart failure disease management.

We would like to welcome Dr. Goldberg, and Lee, I will turn the ball over to you.

This afternoon, briefly, I will go over some of the background, some of the lingering questions from a political and research standpoint, trying to point out what we know and don't from some of the studies that have come before us. To give background, my definition of remote monitoring, how I will use it in this context is: a system designed to collect physiological or behavioral data to deliver to clinicians to improve ultimately the outcomes. Depends on how you define outcomes, I will get into that. Most remote technologies we are talking about typically involve using two-way communication between the subject and the clinician, but not just automated reminder calls. We are looking specifically to have two-way communication between the subject, in the home, community and a clinician located somewhere else.

Examples of the types of technology used up to now include glucometers, scales used in the heart failure world, medication compliance devices used in heart failure, Coumadin monitoring, questionnaires to fill out online, device in the home. And technologies using

video virtual visits to do things like wound care, vascular, and some pediatric visits for patients that need geographically to get to a specialized center.

I will give the background on the many different ways of doing remote monitoring. These have significant implications in terms of cost, efficacy, complexity, what you can expect to get out of them. One thing we are learning, the more complex the technology, doesn't necessarily translate into improved outcomes. Sometimes an improved solution gives us the most bang for the buck. There's the telephone only, the remote monitor, patients call back and forth. Devices like on the previous slide, connected to a phone line, data transmitted to a triage computer, the data are highlighted as red, yellow, or green, the red generate alerts. Clinicians can follow up, a third-party who may not be directly involved in the care of the patient can validate, send on. For cardiovascular disease and coming along for diabetes to have active or passive data from the sensor located within the patient to the clinician in their office. The big question mark is, how do we integrate all of this volume of data we are drowning in, into our electronic medical systems and how does that fit from a policy perspective, in terms of initiatives coming forth? How do we make sure the technologies we are using are translated into doable and not overwhelming? Looking at telephone only, a tremendous amount of education goes on, we do this as part of our heart failure discharge guidelines, JHACO discharge instructions for the subject to know when to call their clinician. Some self-monitoring, weighing, weight is up two pounds, call, or glucose above a certain amount. Then they generate a phone call to the clinician's office and lastly, the possibility of the clinician calling the subject by protocol. There are studies where a pharmacist calls, nurses, as well as clinic-based nurses that call subjects, third-party payers, protocols where their case managers will call out to subjects, protocols by weeks, medications, et cetera. These are, in a sense, a form of remote monitoring, although relatively primitive in terms of the physiologic outcomes.

You connect to the patient's phone line, raw data sent over the phone line, clinician, or systems that fax summaries or alerts to the clinician's office, which is reviewed. The phone is still part of the equation, the clinician communicates back, changes interaction via the telephone. You have a two-way system between the device, clinician and the clinician and patient via phone. There are certainly devices that can also collect symptoms, asking the patient a series of questions: are you short of breath, blood sugar out of control, which would indicate a hyperglycemic episode.

The more complex model is where we actually add into that same information some type of validation. Certainly clinicians who use this technology will tell you there are a lot of false positives in this technology. Having some type of filter between the clinician and patient in their home can be very helpful. There are two models out there now. One is a system we were testing in my H R2 grant, triaging computer system to try to triage or rank the importance of the physiologic data, sending alert information to clinicians to act upon them. The other model, also used in the grant, is having a third-party, call center, vendors that provide this, sometimes payers that provide a nurse call center that actually screens the data coming back from the devices in the patient's home; then provides the conduit for information out to the clinician. But by the time the clinician is seeing the

information the data has been filtered and validated, then the clinician, then, can contact the subject by telephone, they interact, make changes. Occasionally the third-party will interact to validate before passing things on to the clinician. There is data, that that third-party vendor system or clinician system is very effective. Only so many subjects can be monitored by each individual person. The most complex, but one that actually has some advantages, although cost is a big disadvantage, the implantable devices. Far and away the heart failure world, but other devices for diabetes and others that will be available in the future. We have monitors, volume sensors, devices that can passively send data to a box in the patient's home, via Bluetooth or wireless technology, that device transmits over the phone line, computer system, and ultimately to the clinician. The advantage of implantable sensors, recording information continuously. Huge disadvantage of the devices is they are recording information continuously. We don't know what to do with all that data, make it actionable, an area of research from industry, as well as researchers to understand how to use the data. Can be transmitted very much the same way, through a computer system triage or another clinician, ultimately to the main clinician's office who is monitoring the patient.

That's the backgrounds of the types of devices we are talking about, how complex or simple they can be.

One question that comes up in designing clinical trials, trying to decide what to do within our health care system, what is improved outcome. Perspective is important, I am working on grants with research staff, whose perspective and what will the outcome be. Lots of competing interests in the persons involved. Yet the goals of the patient may be different than the payer or health care system or society as a whole. Cost, is cost the right outcome to look at? Only reduction in cost or cost-effectiveness, total cost or keeping the patient out of the hospital. We have shown studies where hospitalizations have gone down, but pharmacy costs have gone up significantly. Maybe the total cost isn't down, but it's cost-effective. The concept of quality of life, the costs the same or increase, patients do better, feel better over time. Is it improved outcome, having patients on the monitoring system, others involved, case managers, et cetera, do we prod the primary physicians to keep patients on the best medicines we have? The VA found their costs went up significantly, but evidence-based medicine went up, treating lipids issue, diabetes they found when trying to focus on the heart failure.

Safety, is that a desired outcome? Do we hurt people? Important to have improved safety or not make things worse? System performance, does the technology perform as designed or intended, and lastly, we have one study, literature showing remote monitoring, we improve survival, but had no impact on hospitalizations or cost. Is that a reasonable outcome to study with these technologies? Certainly, from the research side there's a lot of perspectives to think about.

To give one example, the vast majority of my research, why is it a good target for disease management or remote monitoring? The criteria we think about, common chronic disease, direct and indirect, impact on patient's quality of life, high mortality, research to guide therapies, therapies we know can extend life, improve symptoms, but managing

these therapies can be challenging in a high-risk population and some technologies available to monitor them. In this case scales, monitors, what have you, but there's a way to monitor patients and try to help get them on the right therapy. You could choose another disease state, COPD or asthma, diabetes, episode of pregnancy, for instance, all those may have more or less some of the factors in play. The idea is you want a disease state that's a relatively good target.

What are the factors we have learned have been successful for implementation of such a system? Number one, you need prompt, consistent response to receive subject data to provide feedback. If the fax machine rings, computer beeps, or phone rings, someone is on the other end of that transmission to respond to that data. The sensor can work appropriately, computer triage, call center, but if the clinicians are not prepared to act upon, respond, receive the data, then the system will fail.

We certainly had excellent examples of how that portion of our system does not work very well and can be a reason a clinical trial or project fails. We need clinical algorithms that include action plans, avert negative consequences, admission to hospital or ER visit. We have to know what to do with an alert system and there can be controversy among clinicians. The subject has to have some trust of the system and its clinicians; it's like me lecturing, I have to have faith that people are listening. Patients in this case have to have some faith. We need a reliable, easy to use technology. And we have to notify our clinicians when the patients are not using the technology. That's usually a symptom something has gone awry. Using a missed data collection is something very important to recognize as a marker of something we want to track over time and act upon.

What are the barriers to successful implementation? Number one is reimbursement. In the real world we have had very little reimbursement for these systems and as such, there's a tremendous amount of effort clinicians put in, but don't reap the benefit. Might be good for the payer, patient, but the clinician, reviewing hours, logging in, doing what they should, don't get paid a penny. We got tremendous feedback from practices all over the country telling us they are doing a lot of work and we are not paying them enough. We included a monthly fee, and still the amount of time is significant. Having the same clinician to manage the data, know what to do when the data comes in. Have mechanisms set up in the office. If there's an alert Christmas morning, but no one assigned to look at the alert until Monday, we missed the opportunities. We didn't reap the benefit of responding to the data. You need a neck mechanism for that, to monitor the data and respond appropriately.

We need appropriate algorithms and there's a lot of debate, how to respond in a way that includes outcomes. Legal medical liability is a problem, what happens if they get an alert on a Saturday night, don't have anyone checking until Sunday, the patient has an adverse event, [are] they medically legally responsible, can that be used in a malpractice suit? How do we know it's HIPAA compliant?

We have the issue of professional license, call centers, my example, nurses in Montana, managing patients in Pennsylvania, Kentucky, Arizona, Montana, and Wyoming. How do

we address that they are not licensed in all those states? We licensed them in all states, but need a national policy. The type and frequency of continuous data sounds wonderful in a research conference, but impossible to understand, we have never had that available. It's all in the CCU, people at rest, not driving cars, at work. We are getting alerts for numbers that are high, but don't know what the normal numbers should be.

Some clinicians feel their work is being replaced. An office where a physician is not interested in the technology, choose not to use it, the system will not work. We add cost without much benefit. The lingering questions are what type of technology should we be using in terms of intensity. In our practice we have begun to think about testing simple things against the more complex. Going head to head. Again, the concept of having too much data, hurt people by responding too quickly, research studies need to have two-tailed tests to be sure no harm is being done. We always assume it is beneficial. Daily monitoring or some disease states at twice a week to simplify the review.

Duration, once you are on a system, do you stay on it forever? Get 6 months we pay for, then stop, reassess? Withdrawal effect, patients learn to self-manage, don't need it, can auto manage themselves, know to call us. Or, do they decay in some way after the device is removed and really do need it, and we certainly have data for withdrawal effects. We were surprised. About 800 patients, find there's a withdrawal effect, we have a bump in admissions, adverse effects in the 90 days after we remove the technology, suggesting they don't get it over time and decay back to control over 6 to 12 months.

In a perfect world, daily monitoring would lead to improved quality and outcomes and savings and we would take that and apply to [indistinguishable] but the trouble is, when we have gone, done studies on this, one of the limitations of our field of research, that all of us have come up with some hypothesis like patient with disease X, treated with technology Y will have improvement of Z. Several studies met the hypothesis, several failed, for a number of good reasons, but very little focus on the mechanisms of changes and outcomes, like what is specifically driving the outcomes, maybe we could distill it to something more simple. Monitoring actually impacts outcomes and self-management, we always assume the impact will be positive. The IRB considers these to be low-risk, you are not giving a drug, but several studies have shown increased cost and a few have shown harm, to the hospital with low potassium, renal insufficiency. We include the patient’s want to know or need to know the data, we have data that they don't, but -- how to responded to the data, data are actionable, reliable and systems are in place to quickly, easily incorporate the data, not just looking at a bunch of peak flows, but a bunch of peak flows in the context of patient's medication list, who follows, other medical problems that patient may have, not just logging into the vendor’s system, seeing the peak flows. It's the flows and context of the patient; many systems do a really bad job, have to access two or three systems to really manage the patient. We are looking for ways to incorporate this data into the work flow.

The reality of our studies, many have shown improvements to quality of life, survival. These have been difficult to duplicate outside the confines of a single center or research center, because they are driven by individual humans. A nurse, a clinician dedicated to

technology uses it, champions it. They are able to do it in the local microcosm. The variety of areas has been really a challenge. It's important to remember some studies show increased cost in utilization, improved access, care, but some show no impact at all.

Centers involved with the risk, access to care seems to drive the outcome. We have begun to restratify the populations and recognize the highest-risk population, no matter what we do for them, they will still have events. Perhaps this form of remote monitoring is not for them, they need something more intense. The low-risk won't have events, no matter what. The moderate-risk patients are where we feel you can have the biggest impact. They will have adverse events, but they are not so sick you can't abort the event and get good outcomes, change the natural history of their disease. Very few studies tried to restratify the population, understand how the technology may apply to a broader population. Then, managing the data, incorporating into the practice is a real challenge people haven't started talking about yet. As we go more and more to EMRs there will be a bigger demand for that. What could be going on outside the technology?

Oftentimes the technology is given credit for the better outcome, but it may just be patients have improved access to care in general. By having the device, someone looking in, calling them, saying, oh, by the way, I ran out of my inhalers, get access to a prescription. May get better adherence, because we are reminding them, identifying other barriers to care. Oftentimes in trials we keep an incident database, find that patients have financial, psychosocial or co-morbiditiy issues. If their pressures change on implantable monitor, you find out they've run out of the prescription because they lost their job or -- didn't have the money. Sometimes the novelty of the technology gets people to be more compliant. Whether we are listening on the other end of the line or not is irrelevant, the device itself acts as a reminder. To have a red flashing light, every morning it flashes, compare to electronic system, sending data, see whether compliance and outcomes are different. Maybe they just need a daily reminder. Lastly, the concept of regular human contact. From our call center studies, vendors that do the work, patients become attached to the fact that somebody who knows them is calling them. We have had patients answer yes yes yes to generate contact to clinician, to talk to them, have interaction, maybe it's we are taking better care, especially for patients living alone, not to do with technology, but human contact. We need to collect data about some of these factors, what I call the mechanism of action, whether it's the technology itself or some[thing] that technology helps.

There are lots of other issues I want to touch on. Vendor issues, technical problems with servers, phone lines, troubleshooting installations, equipment issues, devices that require batteries are major cost barrier, can't afford to change four double A batteries a week. Vendors providing technologies, support staff, on off-hours, Christmas morning, no one there until Monday, do we miss monitoring the patient for four days?

Other vendor considerations, too. There are lots of issues regarding privacy, beaming a lot of information about the patients around, over the Web, fax, et cetera, we need to be careful about having agreements in place for HIPAA, we [need to be] careful about how the data is beaming around. Is it anyone's business who is being monitored or not? Is

there a service guarantee, to make sure the servers are active, equipment approved by regulatory agencies, we found several examples where they were not, the vendors didn't know they needed approval for this stuff. Support hours, interface issues to subject and clinician. Fax, e-mail, text messaging, pager, cell phone—how does that technology work? Reliable? Et cetera? Lastly, integration concept, can you get information into an electronic medical record automatically, use the alert systems within the EMR to help people move forward.

We have written a manuscript about implementation issues with home IT, giving a list of variables that raise some safety issues for us. Then, talking a little about what the options are. You can ship the device, then have a visiting nurse install. You can deliver, install by a health provider. Ship the device to the patient, have a technology company, we used the alarm companies, because they are bonded, to set up the service in the patient's home, plug into the phone system. But that adds cost, complexity to getting the device to the patient. Concepts of transmitting data, ability to validate software, encryption standards, cellular technologies, how you get stuff to the provider, store, archive data, assure that the devices are HIPAA compliant, reliable, clean, tested, recycled devices, the vendor has a mechanism for doing that; whether the payer is leasing or what the support is like. Lastly, how we feed back information to vendors, regulatory agencies about concerns for the technology, validity. We tested home-based skills, found tremendously variable. Impacting a clinical trial. The pharmaceutical industry and vendors have very little oversight. There's a call for regulation to compare, make sure their quality is appropriate outside of the clinical issues.

What about provider resistance? We have certainly had a number of issues I already covered, but we certainly have begun to do education with providers on how, when to respond appropriately. Really, the clinicians that are comfortable adjusting medications over the phone, having the physiological data without seeing the patient, those folks have no trouble adding to the system. If you have a doctor writing a prescription without seeing the patient, we have to overcome that barrier. One problem we had with practices on nights, weekends, they tended to [indiscernible] no matter what, increases utilization, the learning curve for most clinicians, practices, at the beginning generated a lot of visits, ER visits, over time that goes down as people become more comfortable with [what] the alerts mean. In the beginning no one wants to miss anything and are terrified this information is life or death. Send to ER if it's after hours, increase in costs initially, so training and education around that will be key.

In the Medicaid population, Indian Health Service, a lot of issues, having access to a home phone line is critical, not just cell line or voice over Internet. Does the patient have a stable home life, if not, that can be a problem. Ability to install equipment, hear, see well enough to use the equipment, and the ability to stand on the scale, or operate the equipment. If you have really bad vision or above the weight of the scale or dexterity to use the glucometer, it will fail. Understanding the population is really important for people to know what culture, what language, what environment the technology will be used [in]. Finally, in conclusion, several challenges to home monitoring. They are provider, vendor, subject matter, and payers. We need to do studies to understand what

drives change and outcomes. Studies need to be performed on best practice for alerts, interfaces and we need some vendor regulation, standardization, certification, so we know exactly what we are testing and our subjects are getting. I will stop there, move on, answer questions.

Thank you very much for such an incredibly extensive overview. For those on the line, these slides will be made available on the Web, as well. I am not sure what point, for you to review again. There are so many applications we can reflect on, think about applications within our own states, area. Here in the state of Nebraska we deal with a population area that covers 77,000 square miles, and so remote monitoring takes on a different perspective for us. From that perspective, I am very happy we are actually going to be talking now with Dr. Thomas Klein from the Iowa Foundation for Medical Care. He's going to do a presentation, a little closer, I guess we call them Midwest folks. Dr. Klein serves as medical director for the IME and pharmacy services, more than 16 years of extensive service with managed care, medical quality assurance, committee chairmanship, and support, expertise for authorizations, appeal hearings, recommendations for coverage, policies, meets with policies, providers, meets with Medicare carriers, and is certified in family practice. Dr. Klein, welcome, we will let you take over the presentation.

Dr. Klein: Thank you very much, and thank you for giving me the opportunity to relate Iowa's experience in remote disease monitoring. The first slide indicated I am Medical Director for the Iowa Foundation for Medical Care. I was contracted to the Department of Health and Human Services to oversee services for Medicaid programs. It was the beginning of a new way of managing medical services for Medicaid members in Iowa. Prior to 2005 Medicaid programs essentially were the payer of claims; that is, they did it with sole oversight on some medical services, minor authorizations. In July 1 of 2005 we switched to the management of Medicaid for our members, necessary to improve the overall quality of care to members and improve the health of Iowa members with Medicaid, and be cost-effective.

As part of the transition it was important for us to develop a chronic disease management strategy. The majority of care, money spent in the Medicare world, as in probably most payers, is in the area of management of chronic diseases. In 2006 it was noted that approximately 125 million people in the United States had at least one chronic disease. It's expected to go to 160 million in the year 2020. That increase is occurring in Iowa as it is across the United States.

With that increase in the chronic disease burden, it will be an increased number on the Medicaid roles, and Medicaid is rather unique at being the safety net for all members in the state of Iowa that need medical care. We have to be very good stewards of the taxpayer's money. We have to be sure the medical care provided to members is the best quality and the most cost-effective. We have a lot of budget issues, resource issues. In order to give good care we need a definitive strategy.

We elected to develop the Center for Health Care Strategy for the management of chronic disease. They did a nationwide search of the 51 Medicaid programs. In the process they defined six key components of the various programs that were successful or they felt would be a pathway to success.

We adapted that strategy, implemented those steps in develop[ing] our program. First is identity of target population. It's important to figure out exactly what you're aiming at and trying to accomplish. Unfortunately, in the Medicaid world, it's unlikely if someone has one chronic condition they are only going to have one, again being the safety net, the incidence of multiple chronic conditions is far greater than probably in the general population. So we felt that this population really needed our attention.

The second step or guideline is to the use of guidelines and measures. The guidelines we followed in the management of our congestive heart failure patients were the American College of Cardiology, and we used Johns Hopkins data sets, a number of measures to evaluate the program, including the Minnesota Living with Heart Failure evaluation, given early on in the intervention and given more toward the end of our intervention to give an idea of how successful we were.

We also used the Disease Management Association, helped in development of measures, along with the University of Iowa public policy area. They helped us define how we would be able to determine from a financial perspective that we were successful.

The next step or guideline is information technology. There's a lot of variation in what we can adapt. As we looked around, checked with our partners, we settled on a system provided by Phaseris Innovations, a monitoring technology that worked very well for us. The care management area, we felt in addition to having this remote monitoring it was important to have a live person. Again, Dr. Goldberg alluded to the impact of having a live person. We felt our nurse care managers would help facilitate the program, direct our members. We did not want to deal with one isolated problem, i.e., congestive heart failure. We looked at the total person, all the conditions, not all medical, but managed, because to ensure success we felt like we had to deal with the entire medical spectrum.

Incentives, financing was an important part or step. Unfortunately, we were not in a position to provide incentive for participation, had to rely on the fact that we were the member's health insurance and the providers were taxpayers and they wanted to make sure they had the most cost-effective care for Medicaid members. Lastly, and I think the Foundation for Care and Intervention was the activation of members and their participation and care. I will speak more to this later, but it was important to educate them, direct them in a self-management direction.

I spoke to the fact initially we are limited by budget, resources. We felt in order to be able to reach the vast, greater population, to have a more extensive comprehensive program, we had to develop partnerships. The Iowa Medicaid Enterprise was the base of our program you might say, where the day-to-day management, nurse care managers, administration occurred. We worked closely with the Iowa Chronic Care Consortium.

Prior to us implementing this telemedicine program, the Iowa Chronic Care Consortium had concerns in other areas, mostly commercial, never addressed a Medicare population, understood it would be a challenge, somewhat different than commercial carriers.

We also partnered with the University of Iowa research program, which helped us design the measures to determine how successful we were. Des Moines University helped with the day-to-day, week-to-week, month-to-month administration, and to help find return on investment.

The Iowa Foundation for Medical Care, our parent company, had the overall administration for the programs, Magellan Health Services, selecting a target population, it was brought to our attention by our partner Ferris, you have to define patients that suffered a concurrent depression, significant clinical depression. What we did, partnered with behavioral health vendor, partner, and diagnose, identification of people with significant clinical depression, referred them on for ongoing depression therapy while monitoring the congestive heart failure.

And without them, comparable to the example Dr. Goldberg mentioned in his presentation, I will go into greater depth, describe the process, how it worked well for us.

The overall goals for the program were to provide effective health care for all of Iowans in both urban and rural settings. For those who may not be familiar with Iowa geographically, there are five to seven population centers, mostly centered on the east and west borders, the Mississippi River, the capital in the center, where the bulk of the population is, but north and south of Des Moines, very rural setting. In those areas, important to have access to the same type of care that somebody in an urban area might receive.

Our next goal was to maximize the efficient utilization of the state resources. At the same time we developed this program, the state Medicaid program, as well as all programs had budgetary issues. We felt it important to target a population that would implement saving and improvement. Reducing the cost of caring for chronically ill people, and to improve the health of all Medicaid members. Prior to 2005 they really didn't have attention, this was the first program we had in the area of disease and/or care management, remote as it was, and we wanted it to be successful.

Our target population, we chose congestive heart failure. There are lots of reasons it's a good target: a chronic, progressive disease, a lot of high costs, it significantly affects a person's quality of life. Anyone familiar with someone with progressive congestive heart failure knows it leads to a cycle of failure, doctor/ER visits, hospitalization, instability. It's very important to intervene at the appropriate time to provide the best care; within the management of congestive heart failure there are a number of things that are avoidable or preventable. Oftentimes admissions are, certainly readmissions and emergency room and hospitalization certainly can be. That was our goal to try to impact, keep people out of the hospital, in their home setting, and reduce the overall cost of health care.

We thought that this target population would adapt well to the strategy we were developing. I spoke a little about the screening for depression. As I said, it was brought to our attention that a member with depression is much less likely to have a successful intervention than someone that is not depressed. So, it was important for us to screen every member that we enrolled in our congestive heart failure program for depression. We used a scale above which we felt with significant depression it is necessitated -- a number of people with mild depression, set up a policy. Moderate to severe depression were referred on, kept close tabs in terms of congestive heart failure and response to the depressive therapy. Unfortunately, we had an extreme of depression, one episode where someone was contemplating suicide at time of the call, we had a protocol for that intervention, worked successfully, that patient was enrolled in our program, subsequently improved in their physical condition and has done well since.

Initially we thought we would look at all Medicaid members, all parts of the state, urban, rural, any diagnosis of congestive heart failure, in-patient or out-patient diagnosis. Our intent was to use Johns Hopkins data sets to extract members from our database. We did the initial run on that, the number was entirely too high, we felt, for the resources we had. So we entered into exclusion criteria, such as eliminating the program for pregnant women; institutionalized men and women were eliminated from the program. Dual eligibility was also excluded, Medicare and Medicaid eligibility. We had to re-include those ultimately.

After we defined that number, we decided to stratify according to severity of the illness. In this case, congestive heart failure, we like to think of internally as a condition care management program, meaning the instigated condition being congestive heart failure, but the likelihood of elevation, into a stratification level. Consistent with Dr. Goldberg's definition, we stratified to mild, moderate, severe levels of care and had a fourth level, catastrophic, the level alluded to that didn't matter how much intervention you had, you probably weren't going to have much impact, although we still worked with them on a regular basis.

In our member selection process, after we instituted the filters, exclusion criteria, we identified greater than 2,000 members. Because of socioeconomic issues, the ability to get in touch with someone, we next narrowed down to about 600 members. Of that, 348 agreed to participate, and we ultimately ended up with an active group initially of 266 Medicaid members in the state of Iowa from both a rural and urban setting that were going to participate in our congestive heart failure, remote disease monitoring program. We had to identify a matched cohort. So we tried to match up a group of members with the same diagnosis, same age, sex, comorbid conditions, so we could compare to the intervention group at the completion of study.

Next came probably the most difficult part of the program, enrollment. In order to be successful we decided we would have to reach out in as many directions as we could, make enrollment as comprehensive as we possibly could. We solicited members in the newsletter, through societies, any way we could identify a patient to the data sources, hospitals, we try to get them enrolled.

We also sent every member we identified (that would have been the approximate 600 members) a written description of the program, written request for them to participate in the program, and that written request was followed up with a telephone call to also again invite them to participate in the program, let them know the Medicaid program was their health insurance company working for them and we were trying to help them manage their chronic disease. Despite all that, the engagement process was a difficult one. Here today, gone tomorrow, telephone today, gone this afternoon, tomorrow. Lots of social issues that make it impossible for members to participate or to engage, so that's why dramatically our numbers went down. Also, anybody familiar with the Medicaid program knows this population requires a higher level of support, a great deal more care coordination, in other words, to ensure they get the care they need. This is where we were very grateful for the help Ferris Innovations provided us. On their staff they had a track record of very successful engagement techniques. I guess from a disease management perspective, they are greater than the industry standard. They have trained staff, able to train our staff in techniques to help encourage a member to participate in the program. In addition, we had our nurses undergo motivation management; in other words, to help them help the member get involved in the program. Way back in the beginning, the Foundation for the program was an activated patient, one that was motivated to self-management. I like to think without Ferris' expertise the program wouldn't have been as successful.

How does a clinical model work? Dr. Goldberg mentioned a couple of things, types of models. We used this tele-assurance interactive voice response system. That is, once the member was enrolled in the program, and the process occurred by telephone, they were given a 9-digit identification number. This was the number that provided privacy for them, security that their information was safe. We used additional safeguards, or off-site repository for the information. When a member called in on a daily basis, they responded to six different questions. They began by entering their ID number, that number was subsequently verified, given access to the system, responded, asked to respond to five questions. Via "yes" or "no" response, that would correspond to pressing 1 or 2, it was necessary for the [member] to have a touch-tone telephone as opposed to a dial phone. These five questions were essentially clinical questions that would give this interactive system the opportunity to determine or detect any clinical variance in the patient's day-to-day condition.

The sixth inquiry they had was to input on their touch phone their daily weight. It was important on a day-to-day basis to put weight in; if they had a significant weight variance that indicated, triggered a clinical variance, could cause intervention by the nurse care managers. On a daily basis they were able to do that. As soon as they put the information into the system, the interactive system was able, in the case of a clinical variance, was able to project that to the nurse care manager's desktop computer and they were able to see the patient gained 6 pounds overnight, greater shortness of breath, had to use more pillows, that prompted a call. The nurse care manager called as soon as possible, began the process of managing that patient. It occurred in the form of educating them, about diet, educating about activity, where necessary educating about the relationship with a

primary care provider and specialty care provider. The nurse, function of our nurse care manager was to coordinate the care for the member and also to educate the member regarding the self-management of their disease.

At the very beginning of the intervention they set up a treatment plan, goals, and based on the stratification, severity of the illness, the goals were developed, whether daily, weekly, monthly, quarterly, it was the foundation for the management of the member. The self-management educational process was very important.

We began enrollment in November of 2006. After this period we had 270 people being managed on a daily basis primarily by nurse care managers. We tried, before we began the program, we decided on how we were going to measure success from both a clinical perspective and a financial perspective. We were assisted in that process by the University Policy Research Center, they work closely with the Medicaid program in Iowa. It was important the blessing of the public policy center be present. It was reviewed by the Disease Management Purchasing Consortium, a nationally recognized disease management association, and it was their feeling our program was meeting the highest standards in terms of disease management programs.

This evaluation was performed by Des Moines University. Another thing we also measured, the Minnesota Living with Heart Failure Questionnaire, we provided, had every member participate in that early on in the enrollment and much later in the intervention to try to get a feel of how successful we were in managing their disease.

I would like to relate some actual measurement results. Again, talking about the 266 members that actively participated in the program, I would like to define matched cohort [as] comparable to the intervention group in terms of age, sex, incidence or frequency of comorbid conditions. It was as like to the intervention group as you can possibly get without any intervention. For the most part, almost exclusively, no one in the matched cohort had any idea the program existed. They were never initially enrolled, disenrolled, brought to their attention about the program. This was an isolated group. We felt that was important in terms of defining the success of our program.

In the beginning some of our goals were that we had a 24% reduction in hospital admissions. At the same time we had a 22% increase in the matched cohort, a very like, similar group, but unmanaged, not participating in the program. A 22% decrease in total bed days: that is, of the people diagnosed with congestive heart failure, those we intervened had a 22% reduction and the matched cohort had a 33% increase. Again, congestive heart failure being a progressive disease, left unmanaged leads to more emergency room visits and hospital visits.

The overall impact on health care or the dollars for health care in the Medicaid program is indicated next. In the intervention group, there was a $3 million reduction in health care utilization, not just related to congestive heart failure. Our nurse care manager wasn't just focusing on congestive heart failure, although it was the basis of intervention. The

matched cohort had a $2 million increase. That's a $5 million swing: instead of paying $2 million more, we paid $3 million less.

As a result of the technology used in this program it was, provided nurses with the ability to manage a significantly larger number of members than they would oared ordinarily have been able to manage. We had our issues initially, overcome, a lot of support.

Lastly, in terms of measurement, we had approximately 300 members, there were 290-some with a screening for depression. Of that group we identified 62 that had clinical depression that were subsequently referred to behavioral health manager for intervention and had an ongoing monitoring of those patients. During the course of our intervention, we had a significant decrease in their depression scores. I didn't mention it before, but we used a PHQ 9 in order to define the level of depression and that was integral to the protocols developed in behavioral health manage[ment]. 62 were defined as having moderate depression, significant enough to be referred to behavioral health care provider, subsequently received the necessary care, and maintained the program. So, we felt so good about that aspect of our program that we have instituted depression monitoring in all of our programs currently. At this time we have probably screened well over 1,000 members with this PH Q 9, identified a significantly greater [number].

How did the members feel about our program? Dr. Goldberg talked about some provider issues. It was important for us in our program, very early on, that we try to identify a medical home or medical provider for every one of the members in the program. We tried to let the providers know what our role was. We were going to help this member understand their disease, manage their care, educate them about the disease, and when necessary get the necessary referral to the provider. I think they felt it eliminated a lot of unnecessary calls to their office.

Some anecdotal stories: 236 customer satisfaction questionnaires, received a 50% return rate, which is in any evaluation a very significant number. 65% were very satisfied or highly satisfied with the program. They felt the Medicaid program was their insurance, somebody was there, cared, was helping them cope and navigate through the disease.

The next statistic or component: the 73% confident or [mostly confident in] self-management. That was one of our primary goals, [to] understand what's causing their issues and what they can do to manage the issues, we felt we were highly successful.

Anecdotally speaking, we had a number of very good success stories. I don't know what people's perception of the Medicaid program is, but unfortunately, people could be inflicted with a very debilitating disease, action, injury and end up on the Medicaid roles because of the high cost of their medical care. People who participated in the program, some were college-educated, very well tuned-in, informed, and they were very grateful someone recognized the need, provided the effort and time to help them get through, to manage their problems.

We had one member who had a significant history of every time he gain[ed] a pound, short of breath, called the ambulance, necessaries necessitated an ER visit. He was fully compliant with lots of things, diet, activity, medications. We were able to get him set up with a primary care provider, a medical home to educate about the disease, get a home health nurse into his home when it was necessary. At the time of the evaluation for the program, where he had a significant number of ER visits and hospitalizations, during the intervention year and at the time of the measurement, he had no ER visits and no hospitalizations.

We had other people in crisis who were noncompliant, weren't doing well because medications weren't being paid for. They engaged with the primary care provider, especially provider when needed, but they educated them about their disease and our satisfaction survey showed they were successful at doing those things. Our nurse care managers didn't restrict activity to a disease, congestive heart failure or any of the chronic diseases, there were numerous ones, they dealt with any issue the member had. It really improved overall success.

What are the next steps? Currently we have continuous enrollment, [indiscernible] the program is ongoing, enrollment dipped down since we lose people through various means, institutionalized people lose eligibility, numbers dropped off. We are at less than 300, but more members currently than at the end of initial enrollment period. We are currently enrolling diabetic patients, and are hoping the programs we are going to have in place with our relationships will help us manage more patients in more rural settings and more effectively. There's some consideration, because of the maternal health needs in the state of Iowa, if we can somehow figure out a way to partner and develop a maternal health program, that might be a next step.

What did we learn from this program? Again, our goal was to develop a strategy for managing chronic diseases in the population. First of all, the population is very challenging for lots of reasons. From a clinical perspective, the presence of multicoronary diseases, multiple economic issues, and in some cases we had language barriers to overcome; issues that not only affect the member, but could affect the member's family and ultimately the member, that we had to deal with. We noted that collaboration has a lot of benefits. I noted all the partners in an earlier slide, without which we wouldn't have been as successful as we were. Collaborating with other groups, department of public health, university, external vendor, whatever, it enables us to do more, for more people, more efficiently.

We also noticed technology has its benefits. Dr. Goldberg has much more expertise, spoke about the limits and drawbacks, we felt this population implementation was very simple. To use a touch-tone intervention, weigh themselves, and in cases where they didn't have scales the program was able to provide them with scales, so by simply answering "yes" or "no," weighing themselves, they were able to have a significant impact on their health. We learned that self-management education works. You can see from the reduction in hospitalizations, ER visits, the overall health care savings, the fact

that the members are personally satisfied with the education they received, it works, and did a good job for us.

You can impact a member's health, and we did, feel very good about the fact we improved the health care of members in the state of Iowa with congestive heart failure and hope to continue the program forever. That's about it, thank you very much for your time.

Dr. Klein, thank you very much for your time. I hope the rest of you share the encouragement I have felt listening to Drs. Goldberg and Klein. We are running toward the end of our time here. If you have questions, you can type them in; we have three in the queue now and before Dr. Klein gets too far away I want to address the first two to him. If you have a question, type it in the chat box and we will see if we can address it.

A quick one, someone asked what the Medicaid population was in Iowa.

You are familiar with eligibility, that varies, and referring to the average monthly population in the state of Iowa, that was excluding the Iowa care program, different from the regular Medicaid, approximately 320,000 to 330,000.

Another question, asks about the correlation between improved depression scores and improved congestive heart failure.

The preliminary results show statistically significant intervention. The average age was something like 15.8 on a scale of 1 to 20. Subsequently, at end of intervention, the same subset of the population had an average score of less than 9, almost a 50% reduction, we felt that was significant.

I find that as one of the more exciting outcomes of your study. Both presenters did talk about the remote monitoring; I wanted to reflect on one thing. Whenever you see the ads on TV, On-Star, there's always another person on the other side of the call, not a beep or anything; it's a person, “are you okay? I'm calling somebody.” You feel like somebody cares on the other end, even if it's a nurse coordinator making contact, I think, especially with the remote contact, the elderly who can't make contact, knowing somebody is there is significant. Leading to a question to Dr. Goldberg, have you had a chance to look at that one question in the queue?

Dr. Goldberg: Right, the relatively long one?

Right. Do you want to address that?

Dr. Goldberg: The question asks if patients, monitoring for instance on glucose, it's out of range, they could certainly call the physician's office, why put a piece of technology between the subject and the clinician, why not just have them do it directly. This gets at the very point, maybe I didn't make it as clear as I wanted to, restratifying the population or understanding is key for how technology works. For a patient unbelievably effective at

managing disease, interacting with clinicians, there's very little value to adding the remote monitoring. You add cost and complexity, I agree, you don't get much benefit: the patient is already doing that, reaping the benefits of what makes it work. But, there are many patients with chronic disease who don't do a good job or have the skill set, intellectually or culturally, to communicate effectively with their clinicians, they don't call when their sugars are higher, or don't check or refill insulin, or run into other barriers, leave glucometer at their mother's house. Having the intervention identifies the patients who wouldn't automatically call. That's where disease management can be so powerful. The question asked, compared to usual care, how do these patients do? I have to say it really depends on what the comparative group is. One thing we noticed, interventions done in very effective health care models, where the model is already providing very good access to care and very good guideline care, remote monitoring doesn't add much to the low-risk patients. They are getting good care. It improves access to care. There's a lot of variability, but in a population with high-risk or perceived barriers, remote monitoring can overcome those barriers tremendously.

There's a lot of data outside the trial, really good data if you treat the depression the cardiovascular outcomes improve, patients are more compliant, likely to exercise, translating into better outcomes. Depression is a co-morbidity, major predictor of cardiovascular disease and it ties the behavioral health and clinical medicine together. They are sometimes very difficult to separate. Insurance plans tend to separate them, but if you can bring them together you can be that much more effective.

Thank you very much, as we here in Nebraska face that issue as well, I am sure every state does, bringing the entire person back together to cure comprehensively. We have no more questions in the queue. We have certainly appreciated your attendance at this Webinar.

You see the project information on the screen there, both the Web site and a phone number. If you have suggestions, recommendations for future programming, please send your information to that Web site, and thank you, and thanks again to our presenters for this lively discussion, and good-bye.

Thank you.

[event concluded]