

<opening credits>

Announcer: dLife TV, the only show for your diabetes life, packed with information, insights, cooking and real stories about real people. dLife brings it all together to help you live a healthy diabetes life.

<montage of previous episodes>

<Card: dLife for your diabetes life>

<shots of upcoming show>

**Mother Love:** Today on dLife making sense of diabetes research. Dr. Eva Feldman talks to us about clinical trials and how they may advance the search for better treatments and a cure. Also, the latest in prevention and cure-based research and we'll see what's happening with diabetes intervention in the Latino community. And now, please welcome your hosts, people living with diabetes just like you, Nicole Johnson Baker, J. Anthony Brown, Jim Turner and me, Mother Love.

<applause>

**Mother Love:** Welcome to dLife everyone.

<Card: Mother Love, Author and TV Personality>

**Mother Love:** You know most of the diabetes drugs and the treatments you're using today were tested at some point in a clinical trial. What's a clinical trial? You'll find out later in the show from Dr. Eva Feldman. Nicole, I know that you're in a clinical trial now. What's that? What's going on with that?

**Nicole Johnson Baker:** I am. I am.

<Card: Nicole Johnson Baker, Author, Miss America 1999>

**Nicole Johnson Baker:** Actually very exciting results. It relates to the pregnancy.

<shot of audience>

<shot back to Nicole>

**Nicole Johnson Baker:** I've been in a trial of type I women with diabetes who become pregnant to see what happens with their bodies and how they make and generate and regenerate insulin.

<Card: Clinical trials are vital in bringing new treatments to patients.>

**Nicole Johnson Baker:** And they found that 20 to 25 percent of type I women actually start making their own insulin during pregnancy and it will go away at delivery, which is the only bad part, but I'm making about 30 percent of the insulin that I need on a daily basis naturally.

<Card: Research shows pregnancy hormones may stop beta cell destruction.>

**Nicole Johnson Baker:** So, this baby's been a blessing.

**J. Anthony Brown:** So, you're doing pretty good huh? All right, okay.

**Mother Love:** I mean that is so amazing. You got to be really excited about that.

**J. Anthony Brown:** Yeah.

**Nicole Johnson Baker:** Ah!

**Mother Love:** You know there is some other amazing research that's going on. Islet cell transplantation is one of the most interesting and promising areas of research but there are also limits and it's the topic of today's story. Jim, what's the story today?

**Jim Turner:** Well, this letter is from Rita Hart [ph?] from Port St. Lucie, Florida.

<begin video clip of Rita>

**Jim Turner:** I have had three islet cell transplants and my experience shows both the promise and the limitations of what the surgery can do.

<Card: Islets are clusters of insulin-producing beta cells>

**Jim Turner:** After 41 years of diabetes I was desperate to explore the possibility of life without insulin injections. With my family's support I began participating in a cutting edge islet cell transplant program. Since then, I spent a total of 18 months completely insulin free with normal blood sugars. I consider this nothing short of a medical miracle. Alas, now I am back on insulin as the transplants proved not to be permanent for me. Still, my experience reaffirms my belief that we must do everything to see that research continues until a cure or long-term treatment is found. I am enthusiastic about my involvement with this protocol and what it means to the future of diabetes research.

<Card: Islet transplants are still in trials and considered experimental>

**Jim Turner:** If the research done on me allows people with diabetes to live an easier and longer life in the future, my efforts are justified. Well, thank you very much Rita for sharing that with us.

**Mother Love:** Wow, Rita's brave going through this procedure.

**J. Anthony Brown:** Right, 18 months with nothing, oh.

**Mother Love:** That's a benefit to people, everybody with diabetes.

<Card: For more info on clinical trials visit [dLife.com](http://dLife.com)>

**Mother Love:** I would like to see future generations not even have to deal with diabetes.

**J. Anthony Brown:** Okay, well one thing we can do is we test, don't guess!

<Card: TEST! DON'T GUESS.>

**Nicole Johnson Baker:** Don't guess.

**J. Anthony Brown:** All right, so it's time to test everybody.

**Mother Love:** Testing. Coming up, Jim Turner talks with Dr. Eva Feldman about the world of clinical trials and how people just like you play a part in testing new diabetes drugs and treatments. We'll be right back.

<pause for commercial break>

<applause>

**Jim Turner:** The subject today is clinical trials and research studies.

<Card: Jim Turner, Actor, Bewitched and HBO's Arliss>

**Jim Turner:** With me is Dr. Eva Feldman, a professor of neurology from the University of Michigan and director of the JDRF Center for the Study of Complications in Diabetes.

<Card: Eva Feldman, MD, PhD, Director, JDFF Center for the Study of Complications in Diabetes>

**Jim Turner:** Welcome, Dr. Feldman.

**Eva Feldman:** Thank you.

**Jim Turner:** First off what is a clinical trial?

**Eva Feldman:** A clinical trial is a scientific study that tries to understand the effectiveness of a particular medical approach, treatment or protocol on patients, on human beings.

<Card: Clinical trials are regulated by te NIH and U.S. FDA>

**Eva Feldman:** And for diabetes and its complications there are five types of clinical trials. We do clinical trials trying to better understand screening, prevention, diagnosis, treatment, and understanding quality of life. And then in those trials that are focused on treatment those trials have evolved after, you know, very long, very periodic well thought out research trials in the laboratory before we then begin a treatment trial in a person.

**Jim Turner:** Right.

**Eva Feldman:** Or in patients and then the treatment trials that actually are done on patients those too are done in a very systematic fashion until you reach what's known as a Phase 3 trial which is the last trial that's done before you understand whether a treatment will be approved by the Food and Drug Administration for use in diabetes.

<Card: Phase 3 trials test drug safety in a large patient population>

**Jim Turner:** And what's a double blind, random something?

**Eva Feldman:** So, a double blind randomized control trial.

**Jim Turner:** Yes.

**Eva Feldman:** So, okay good, so those are trials where neither the researcher or the participant knows whether or not they're taking the active drug and half the patients aren't taking the active drug. They're taking what's known as a placebo.

**Jim Turner:** Right.

**Eva Feldman:** Which is an inactive pill and those trials are by far the best way to get the most rigorous effective answers.

**Jim Turner:** Why would somebody participate in one of those, especially if you were, you know, stuck in the placebo group?

**Eva Feldman:** Well, for many reasons. One is you're taking active control of your diabetes and its complications and active control of your own health.

<Card: More than 390 diabetes-related clinical trials are in progress in the U.S.>

**Eva Feldman:** And what is well known is if you enter a clinical trial there's almost always better control of your diabetes, so that's one reason. Secondly, you have access to potentially a new treatment before-- before it's available more broadly. Thirdly, you're helping medical research and helping us gain more medical knowledge. And, if you do get the inactive pill you're still probably better controlling your diabetes and helping medical research.

**Jim Turner:** Well what are the risks?

**Eva Feldman:** There can be some adverse effects of taking a medication, some unpleasant side effects.

<Card: Researchers are required to disclose rules and benefits to study subjects>

**Eva Feldman:** Frequently, you know, maybe a little nausea or vomiting. Sometimes there are unanticipated life threatening side effects but that's very, that's very rare. And then the other maybe you would call "risk" is that you may not be getting the medication if you're in a placebo controlled trial.

**Jim Turner:** Yeah. So the bottom line it is safe to do these trials?

**Eva Feldman:** There are governmental regulations and, you know, individual institutional regulations and boards that review these trials.

**Jim Turner:** Uh huh.

**Eva Feldman:** Each trial has a safety committee, a data safety monitoring board that reviews all the patients and how they're doing and then when you're in a trial, you know, you get to routinely see the researchers...

**Jim Turner:** Right.

**Eva Feldman:** ...who monitor not only your health but the safety and effectiveness of the drug.

**Jim Turner:** Uh huh. Say I was in one of these trials and I'm testing a new product or a new drug and then the trial's over and I'm really doing well on this product and they say it's over and it hasn't been approved for use in the U.S. Do I still get to take it?

**Eva Feldman:** Right, what happens, what happens? Well, in some trials yes. Some trials have what's known as an open label extension so at the end of the trial you get the active drug whether you were in the active or placebo group. But in other trials not but you would know that before you started the trial. You would be informed of that.

**Jim Turner:** Could you maybe give us a couple-- some examples of some trials that maybe are going on?

**Eva Feldman:** One very interesting type 2 trial is currently going on. It's called the ACCORD trial, very large trial, still entering patients where they're looking at the effect of better controlling your blood pressure and your lipids along with controlling your blood glucose in terms of long-term complications such as heart attack and stroke.

<Card: The ACCORD Study is examining ways to lower cardiovascular risk in diabetes>

**Eva Feldman:** So that's one trial. There's also another large trial looking at a medication that increases your sensitivity to the normal insulin that you produce as a type 2 diabetic.

<Card: Questions to ask: What is the purpose of the study: What is required of me? Who will the study benefit? For more FAQs visit [dLife.com](http://dLife.com)>

**Eva Feldman:** So an insulin sensitizing drug and that too is being done in many centers, so there are many websites you can go to to look at the number of trials that are available, lots of exciting research being done right now in clinical trials that will not only benefit you as a patient but, as I said, benefit all patients with diabetes.

**Jim Turner:** Well, thank you very much Dr. Feldman for a very informative and interesting look at clinical trials.

**Eva Feldman:** You're very welcome.

**Jim Turner:** To find out more about clinical trials or to see if there are any that you might want to participate in go to our website at dLife.com. We'll be right back.

<Card: To find out about participating in clinical trials visit dLife.com>

<pause for commercial break>

<Card: Nicole Johnson Baker, Author, Miss America 1999>

**Nicole Johnson Baker:** dLife wanted to look at the current state of diabetes research in terms we all could understand, so today we're pleased to have "TIME" magazine health journalist Christine Gorman join Dr. Eva Feldman to give us a layperson's update on the latest advances in diabetes treatment, prevention and cure-based research. Perhaps one of the most controversial things out there in medicine right now is stem cell research. Can you tell us from your perspective what does this mean to a person with diabetes?

<Card: Christine Gorman, Health Journalist, TIME Magazine>

**Christine Gorman:** Right. When I think about how to describe what stem cells are I call them starter kits and it turns out our body has all kinds of starter kits throughout the body to make different kinds of tissue. And where you get those starter kits from makes a big difference into, you know, what you can end up with.

<Card: Stem cells are "blank" cells that can be programmed to function as other cells>

**Christine Gorman:** So, we've heard of embryonic stem cells, the ones that are the most controversial. Those are probably going to be the most-- you can change from one tissue type to another. There are also adult stem cells in our bodies and what in terms of diabetes you're trying to do is to create the insulin-producing cells or the beta cells.

<Card: Stem cells have many sources, bone marrow, embryos and umbilical cords>

**Christine Gorman:** I have to interject there though that, you know, there's a lot of controversy. There's a lot of promise but the reality is, is we're at the very beginning of stem cell research so not to expect a lot of application in the lab, in the clinic right away.

**Nicole Johnson Baker:** A lot of times in the media we see, you know, stem cells linked to cure and it raises false hope.

**Christine Gorman:** Right.

**Nicole Johnson Baker:** And we certainly don't want to do that for patients and their families.

**Christine Gorman:** When I write articles I'm always trying to keep in mind that there's somebody reading that so we're even very careful about writing about pure research because when you're desperate, when somebody you love is ill, you don't want to hear this isn't ready for another five or ten years.

**Nicole Johnson Baker:** I want to make sure that we define exactly what embryonic stem cell research is. Can you do that for us, Dr. Feldman?

<Card: Eva Feldman, MD, PhD, Director, JDRF, Center for the Study of Complications in Diabetes>

**Eva Feldman:** It really is taking an embryo, so a cell that has just been fertilized and, you know, either at that very early fertilization step or once after multiple divisions and using one of those single cells to perform research.

**Nicole Johnson Baker:** And now then the adult stem cells that you were mentioning that are being used in research right now, those are taken from where?

<Card: Adult stem cells are found in mature tissues or organs>

**Christine Gorman:** From an adult so, you know, in the same way that, you know, there are stem cells in our bodies right now in the bone marrow, for example, that give rise to red blood cells.

**Eva Feldman:** So, the idea maybe you could take a cell from your own spleen and then turn it into an insulin-producing cell and then give it back to the person, you know, who you took the cell from.

<Card: Adult stem cells may be limited in the types of tissues they can become>

**Nicole Johnson Baker:** Right.

**Eva Feldman:** So that's very exciting.

**Nicole Johnson Baker:** Oh, absolutely. Well another field of research that is so interesting and exciting right now is the islet cell transplantation work. Can you give us your perspective on that?

**Christine Gorman:** Well there's been a lot of progress there. What you're doing is you're taking probably several pancreas transplants. Usually it doesn't take with just one, although there are technical improvements there.

<Card: An average adult transplant requires up to one million islets from several donors>

**Christine Gorman:** And it doesn't seem to work forever.

**Nicole Johnson Baker:** Right.

**Christine Gorman:** So, but on the other hand, you know, for 18 months or for, you know, some length of time someone can be insulin free, I mean not dependent on taking insulin and then, you know, later on they don't need as much insulin as they did before.

**Nicole Johnson Baker:** Then the success rate is a little bit over 50 percent right now?

**Eva Feldman:** Yeah, the success rate I would say is at least 50 percent. Some of it depends on how, you know, an individual patient responds to the transplant and also how the patient tolerates the drugs that are needed so the patient doesn't reject the transplant.

**Nicole Johnson Baker:** And that's the hard part.

**Eva Feldman:** It can make people feel very ill.

<Card: Currently, a transplant must be followed by a lifetime of anti-rejection drugs>

**Eva Feldman:** So they're immunosuppressive drugs. They, you know, depress your immune system so you're more likely to get an infection or to get sores in your mouth. So, you can feel ill from the drug itself.

**Nicole Johnson Baker:** Well there's one other field of research that I want to discuss briefly. It's what's happening with the Lee Iacocca Foundation...

<Card: The Iacocca Foundation raises money to research a cure for diabetes>

**Nicole Johnson Baker:** ...and Dr. Denise Faustman, the animal studies, can you share a little bit about that with us?

<Card: Dr. Faustman is a researcher at Harvard University>

**Christine Gorman:** Sure. She has cured diabetes in mice by changing the autoimmune reaction. This is obviously type 1 diabetes, so she has kept the body from attacking the beta cells.

<Card: In Type 1, the immune system destroys insulin-producing beta cells>

**Nicole Johnson Baker:** So basically these mice are now creating their own insulin again. Is that accurate?

**Christine Gorman:** Well what it turns out is that they were creating it all along but that the body because of the autoimmune reaction was killing those cells.

<Card: Dr. Faustman's lab has reversed the defect in the immune system in mice>

**Christine Gorman:** So if you can stop the body--

**Nicole Johnson Baker:** So it's not killing them anymore.

**Christine Gorman:** Anymore so then you have-- you can make enough of your own insulin.

**Nicole Johnson Baker:** So where does it go next? To human trials?

<Card: Dr. Faustman's clinical trial is scheduled to begin in 2007>

**Christine Gorman:** Right, that's what they're looking at and as I say time and again it makes such great sense as a story but as a journalist I know it's very easy to be seduced by a good story.

<Card: The three phases of the trial will cost \$70 million and take six years>

**Christine Gorman:** And so, you need the science. You need the testing and you need it to be replicated by other laboratories.

**Nicole Johnson Baker:** Dr. Feldman, what else is happening that you know of that you can share with us?

**Eva Feldman:** So many things. There's a group of researchers that have formed a consortium known as Trial Net and it's multiple centers in the country and for patients who are newly diagnosed with type 1, they have a protocol where they're giving medication to see if they can preserve beta cell function. So, immunosuppressive medication. And so that's very exciting to allow type 1's to keep making their own insulin much longer. And for patients with pre-diabetes, okay, so patients who may later develop type 2 diabetes, there is some very nice work now showing that diet and exercise, 30 minutes, okay, five times a week and really just losing about five to seven percent of your body mass prevents you either from either developing diabetes or developing the complications, two I think very exciting pieces of work.

**Nicole Johnson Baker:** Oh, absolutely.

**Christine Gorman:** And what's really nice about that work too is that it gives you a sense of control.

**Eva Feldman:** That's right.

**Christine Gorman:** And when you talk about losing weight it's also important to realize that you're not necessarily, if you're overweight, you don't have to go all the way back to normal weight. We're talking on average about 15 pounds.

**Eva Feldman:** Right.

**Nicole Johnson Baker:** Uh huh.

**Christine Gorman:** And for most people that's doable.

**Nicole Johnson Baker:** Well another fascinating aspect of research though comes with the funding because you can't do research without the money and there's a lot of politics involved. Now you're in the thick of it as a researcher.

**Eva Feldman:** Yes, I am. Because of wonderful lobbying from patients and patient advocates, the Diabetes Institute received an extra \$700 million towards type 1 research within the last three years. The Juvenile Diabetes Foundation is very focused on funding type 1 research and gives \$100 million a year towards type 1 research. And the American Diabetes Association is very focused on funding both type 1 and type 2 research and both of those organizations have, you know, personal and political missions but they're all towards the same goal.

**Nicole Johnson Baker:** Right.

**Eva Feldman:** And that's, you know, why do we get diabetes and how can we cure it and how can we cure the complications?

**Nicole Johnson Baker:** Exactly and it benefits, no matter what form of diabetes they're researching, it benefits everybody.

**Eva Feldman:** Yes, that's true. That's true.

**Nicole Johnson Baker:** Well thank you both so much for helping shed some light on what is a difficult subject to understand and it's so wonderful to be able to understand more so about what's being done to prevent, treat and cure this disease. Coming up, how one woman is making a difference in the ever increasing problem of diabetes in the Latino community.

<Card: Menachem Baegin and Anwar Sadat shared the 1979 Nobel Peace Prize. Both also had diabetes>

<pause for commercial>

**Mother Love:** The numbers are eye opening, 10.2 percent of all Latino Americans have diabetes and the rate of type 2 diabetes is two times higher in Latino than non-Latino Caucasians.

<Card: Mother Love, Author and TV Personality>

**Mother Love:** Our next feature is about a woman on a mission to make a difference in this epidemic. "TIME" magazine named her one of the 25 most influential Latinos in America. Meet Dr. Aida Giachello.

**Dr. Aida Giachello (english subtitles):** You know that diabetes is substantially high in the Latino population.

<card>

AIDA GIACHELLO, PhD,  
Director, Midwest Latino Health  
Research, Training & Policy Center

</card>

**Dr. Aida Giachello:** My name is Aida Giachello and I'm the founder and director of the Midwest Latino Health Research Training and Policy Center. I am trying to make a difference, an impact in people's lives. The reason why we established this center was helping the community to come together and taking charge of what to do about their problems as it related to health and human services.

<Card: More than 10% of Mexican Americans 20 years or older have diabetes>

**Dr. Aida Giachello:** Make time for regular physical activity. Visit your healthcare provider regularly and use medication as directed. Research indicates that when you are an immigrant before you come here if you come from a small town in Mexico or Puerto Rico you don't have the kind of technology that you have here.

**Hispanic Woman (subtitles):** Over there <Mexico> we walk all the time. But here we eat, we watch TV, we drive in cars and there is no exercise. We burn more calories in Mexico than here.

**Dr. Aida Giachello:** And so there's a drastic change in behavior once they come here. We have one of the highest overweight and obesity in the country.

<Card: 22% of Hispanic males and 27.5% of Hispanic females are obese>

**Aida Giachello:** Now as a result of that condition and the lack of physical activity, we are finding the diabetes type 2 is emerging among Latino children and adolescents. Diabetes is actually two and a half times higher among Latino compared to white, non-Hispanic. One of the modules is knowing your body. They have to say where's the heart or where's the kidney? Where's the pancreas? What is the relationship between the heart and diabetes? Everything that we do is getting them immediately moving around the room doing exercise, doing things that would allow them to be alert, to be an active participant and we have found that that kind of approach helped them to increase their understanding, their knowledge.

**Woman 2:** With this program that came to the YMCA they taught us how to manage our sugar and bring our A1C down.

<Card: In Puerto Ricans and Mexican Americans age of onset is 30 to 50 years>

**Woman 3:** One of the goals for the class is not only for you to come and learn about diabetes but also to pass the information around. Those that we love and not only family members but also people that are around in our community that don't have the opportunity to come to this place and sit like you.

**Aida Giachello:** This whole idea about community empowerment as not only as a philosophy but as a process, as an outcome is very much embedded in everything we do. <Speaking Spanish> Our Latino who are of low levels of education and income, you need to provide the information very simplistic using a lot of visuals so they could be able to understand the message and that has worked for us.

**Mother Love:** Kudos to you, Dr. Giachello for creating a model for other communities to live and learn by. It is inspiring to see how much we all can do to help in this important battle against the epidemic of diabetes in the U.S.

<Card: Learn more about how diabetes affects communities at dLife.com>

**Mother Love:** When we come back a tip from Dr. Richard Bernstein.

<pause for commercial>

**Richard Bernstein**, MD, Diabetologist: Many diabetics has gastro paresis or impaired stomach emptying. This can lead to very erratic blood sugars. One of the many little tricks for alleviating this condition is to chew gum after each meal, preferably sugar free gum.

<Card: Chewing gum "tricks" the digestive system to keep moving.>

**Mother Love:** Well that's all the time we have for this week. Thanks for tuning in and thanks to our guests, Dr. Eva Feldman, Christine Gorman, and Dr. Aida Giachello. And, remember it's your dLife. You are responsible for your diabetes life.

<Card: To order a copy of any episode of dLifeTV visit [www.dlife.com/orderdlifetv](http://www.dlife.com/orderdlifetv)>

**Mother Love:** We will see you next week.

<Card: dLife TV is produced by LifeMed Media and does not represent the views or opinions of CNBC, Inc.>

<closing credits>

**Mother Love:** Remember, we're not role models. We're people living with diabetes just like you. What we do and how we manage may work for us but everyone is different and you have to work with your diabetes care team to find out what's best for you. Remember, it's your dLife and there's no substitute for getting control of it.

#### End of Episode 125 ####