



Journey to a Miracle

— Freedom From Insulin —



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Journey to a Miracle Freedom from Insulin

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Documentary distribution

Journey to a Miracle: Freedom from Insulin is an independent documentary produced by Laurie and Mike Jaffe, Chicago and TMK Productions, Northfield, IL. The award-winning film premiered on PBS Chicago station WTTW in 2015. It has shown in film festivals throughout the world and is now available to public television stations nationwide. *Journey to a Miracle* is available on DVD.

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Film site

<http://www.Journeytoamiraclemovie.com>

Facebook

www.Facebook.com/Journeytoamiracle

IMDb

www.imdb.com/title/tt2083236

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Genre - Documentary

Running time - 57 minutes

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Background

As many as a half million Americans with diabetes are taking insulin and don't need to. What these patients and their doctors don't know is that they actually have the wrong diagnosis.

For decades, scientists throughout the world have worked diligently to find a cure and discover critical pieces to a complex diabetes puzzle. In recent years, scientists confirmed what they had long suspected: there are *genetic forms* of diabetes – *different from* either type 1 or type 2. These newly understood forms are called “monogenic diabetes” and the best way to treat many of them is not with insulin.

With the right diagnosis - using genetic testing - many people can radically change their diabetes treatment. Rather than insulin shots, they can be successfully treated with an inexpensive and commonly used diabetes drug, a sulfonylurea. It allows the body to make and secrete its own insulin.

According to the Centers for Disease Control, more than 25 million Americans (347 million worldwide) suffer with various forms of diabetes. It is a chronic disease in which the body cannot control blood sugars resulting in serious, and sometimes deadly, health consequences including blindness, heart disease, amputation and kidney disease.

Up to 95 percent of people with monogenic diabetes are misdiagnosed. This is because neither they nor their medical providers are *even aware of the possibility* of another diagnosis and treatment. Producers of *Journey to a Miracle: Freedom from Insulin* hope to raise awareness and encourage both doctors and patients to consider exploring an alternative diagnosis.

Up to a half million Americans with diabetes have the wrong diagnosis.

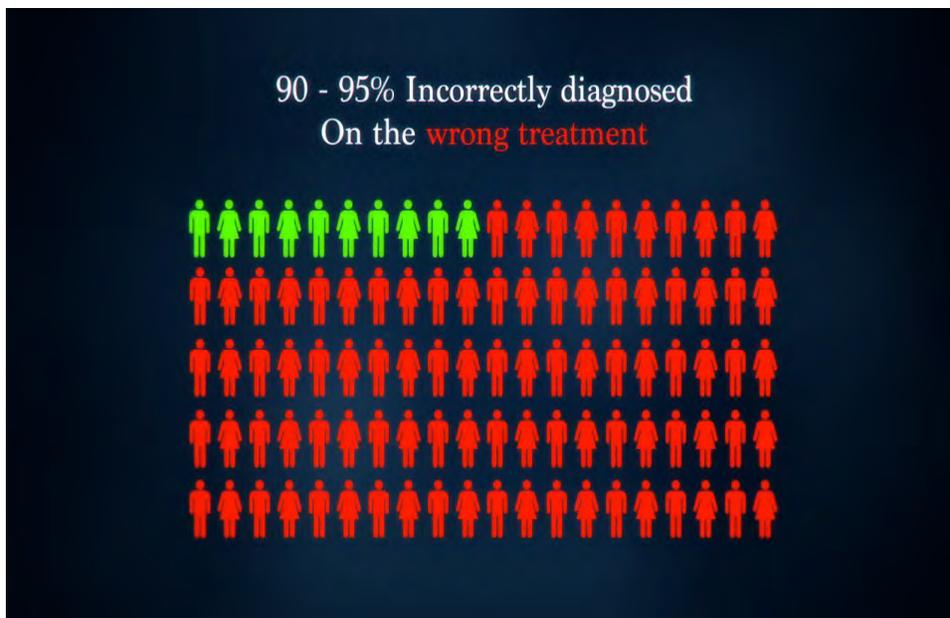
“While there are far fewer people with this form of diabetes than have type 1 or type 2 diabetes, there's still an enormous number of people in the United States alone that have one of these forms of diabetes. We estimate somewhere between 250,000 and 500,000 people in the United States and upward of 5 million people throughout the world have one of these forms of diabetes.” (Scene 8)

Dr. Louis Philipson
Director, the University of Chicago Kovler Diabetes Center

Most people with monogenic diabetes are on the wrong treatment.

“We’ve done studies throughout the world and they’ve all suggested that only between five and 10 percent of patients with monogenic diabetes are correctly diagnosed and that really matters because they’re on the wrong treatment and if we can find them and diagnose them, then we can get them on the right treatment which would be better for them and better for everyone.” (Scene 26)

Dr. Andrew Hattersley
University of Exeter Medical School, UK



Synopsis

Journey to a Miracle: Freedom from Insulin tells of a breathtaking cure for diabetes and the lives that were changed forever. It is an inspiring journey that spans the globe.

Journey to a Miracle is a rich story about scientific perseverance that has taken decades to write. Through painstaking research, collaboration and heart, an international team of scientists assembled pieces and eventually solved an intricate diabetes puzzle. This work resulted in a monumental breakthrough for many with genetic forms of diabetes. The bold journey made medical history, but more importantly it created life-changing miracles for those who have been able to break free from insulin dependence.

This breakthrough has deeply affected everyone whose lives it has touched. The film weaves together the lives and stories of scientists and grateful families who hoped and prayed for a diabetes cure, but never in their wildest dreams imagined it would come in the form of a simple pill. Families shared the devastating diagnosis of what doctors only knew to call type 1 diabetes. But thanks to the work of brilliant researchers, they now share a new diagnosis and with it a switch in treatment from insulin shots to taking pills. It's a heartwarming story that blends science and humanity with authenticity.

“Being part of something bigger than one’s self. That’s what this story is about. It’s not centered on a single person, event or discovery. It’s about all of these things. These lives and moments beautifully joined to form a life-changing journey...with science and humanity blending the way that they should. Changing one’s treatment from insulin injections to pills... Medical experts call it a ‘transition.’ Families call it ‘life changing.’ But everyone touched by this discovery calls it a ‘miracle!’” (Scene 53, narrator)

Production Notes

- Travel and filming in three countries (US, Canada and England)
- In-depth interviews with 10 of the world’s leading experts in the discovery and treatment of monogenic diabetes
- In-depth interviews and interaction with dozens of families from across the U.S., Puerto Rico, Canada, Argentina, Australia, Venezuela and the UK
- Interaction with 25 researchers and physicians from 8 countries including Japan, England, Germany, France, Italy, Holland, Norway and the U.S.
- Film completed in five years

Featured families and highlights

Those who have made the transition from insulin to pills come from all walks of life and every corner of the world. Some were babies and others as old as 65 when they embraced their miracles. The film features touching vignettes and in-depth stories of these special families.



The Neighbours-Matthews family, pictured left to right, Emma, Paul and Jack in front

The Neighbours-Matthews family – Essex, England

Jack is from Essex, England. He has a form of monogenic diabetes that also causes developmental delays and cognitive challenges. His parents were thrilled when he was able to go off insulin. But, in the weeks following his transition to pills, his mother Emma witnessed a second and unexpected miracle. The new treatment that helped Jack's body produce insulin also fueled a stunning developmental breakthrough.



“I know Jack is going to be a happy, healthy young man, which is something that we couldn't have dreamed of when he was on insulin. He's got his difficulties; he's got his challenges but for him, being off insulin means he will be able to have some kind of independence and a life we never thought that he would have. Our lives are completely changed and I just want to say thank you to everybody that was involved in this from the bottom of my heart because you cannot express what a miracle it is. And it is a miracle. There's no other word for it. It is a miracle.” (Scene 1)

Emma Mathews, Jack's mum



The Jaffe family, left to right - Mike, Charlotte, Lilly, Nathan, Laurie and Goldie and Sweet Pea

The Jaffe family – Chicago

Insulin was Lilly Jaffe's lifeline from the time she was a one-month-old baby. She was diagnosed with diabetes during a routine visit to her pediatrician. Lilly made medical history and headlines in the US when she disconnected her insulin pump for the last time on August 23, 2006, the week before she started first grade. The news of her story began on the front page of the *Chicago Tribune* and spread throughout the world leading many others to seek a different diagnosis. Her parents have been strong advocates for raising public awareness about monogenic diabetes. Laurie and Michael are executive producers of *Journey to a Miracle*.



“I think really a very clear example of how patients have made a difference is Lilly Jaffe. Suddenly her story spread and had far more impact than anything that could be done in the conferences or lectures. I think to see how things have spread and how rapidly America has moved to the very forefront of research in neonatal diabetes and properly treating these patients is an outstanding example of why patients matter.” (Scene 33)

Dr. Andrew Hattersley

“I've always been a person of strong faith, and have felt that God had a plan for my life. I saw through this experience with Lilly, from her diagnosis, which was devastating, until the day that we saw her unplug her insulin pump for the last time, that God does indeed have a plan.” (Scene 1)

Laurie Jaffe, Lilly's mother

The Moynihan family pictured back row left to right, Ann, Tom, Stephanie and baby Jameson, Scott in front and McKaela in center



The Moynihan family – Toronto, Canada

This three-generation Canadian family shares a heredity link to monogenic diabetes. Four-year-old McKaela and her father Scott were both diagnosed with type 1 diabetes as babies. Grandfather Tom was also diagnosed with type 1, but as a 21-year-old young man. Incredibly, all three were found to have monogenic diabetes and were able to transition from insulin to oral medication. Had it not been for their “angel,” baby McKaela, doctors would never have thought to consider genetic testing and a different diagnosis for her father and grandfather.

“When I found out I could transition off insulin, I almost kind of didn’t even believe it. It was like yeah---It just seemed crazy to me, you know. I mean it was all I’d known. I’ve never known anything else other than being a type 1 diabetic. I mean its defined parts of my life, so the whole idea of not being on insulin was just very foreign to me. I was excited though.” (Scene 42)

Scott Moynihan, McKaela’s father

“To have this gift handed to you at 65 years old is just absolutely phenomenal and to be able to, you know, look at life so differently going forward, and knowing that you know, you aren’t going to run into the side effects of diabetes, which is really the big worry for every diabetic. Obviously for Scott and McKaela, well, I mean they’ve been given a clean slate for their life, and wow, that’s pretty important.” (Scene 43)

Tom Moynihan, McKaela’s grandfather

Featured scientists and highlights

Leading scientists, physicians and researchers from around the world share their stories and unique contributions to the monogenic diabetes miracle. These four doctors served as invaluable scientific advisers to the producers. Here are highlights from their interviews in the movie.



Research Professor -- Department of Physiology, Anatomy and Genetics Oxford University, UK

Frances Ashcroft, FRS, Ph.D.

“I have been extraordinarily fortunate as a scientist because amazingly our work has turned out to have an effect on people’s lives... in my lifetime! Now, as a scientist working in a medical area, you always hope that your work will have some benefit, but you never actually imagine it ever will - and in most cases it never does - so I have been immensely privileged that it has done so and I think I’ve been even more privileged to have met the people it’s helped. (Scene 45)

“...The most extraordinary thing is to have people come up to you, fling their arms around you and say, ‘I just have to hug you. You saved my child’s life.’ (Scene 46)



“I was even visited once by Lilly, the wonderful Lilly who came to the lab and left behind on my board this marvelous piece of writing that says, ‘thank you, Love Lilly.’ I haven’t ever had the heart to wipe it off because this is so emotionally important to me and when...when experiments don’t work and things go wrong, I can just turn and look and see that, you know, this supports me further on.” (Scene 47)

Frances Ashcroft, FRS, Ph.D. - continued

“I feel loved... I feel loved by all these people and it’s just wonderful. And another thing is, I don’t have any kids of my own, which I would have liked to have had. And in some funny way I see these children here as part of my family, even though they’re nothing to do with me. But I kind of hope that in some way I have touched their lives a little and it’s just wonderful.” (Scene 48)



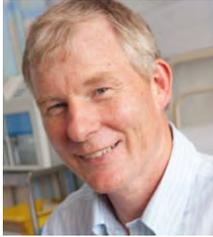
Louis Block Distinguished Service Professor of Medicine and Human Genetics, Director, Diabetes Research and Training Center, University of Chicago.

Graeme Bell, Ph.D.

“The work that I’ve done in the area of neonatal diabetes has affected me directly because not only am I involved in the area of scientific discovery, but I’ve had the opportunity to meet the patients as they’ve come to the University of Chicago for their care and treatment. And that has changed my whole view of genetics of diabetes. When I saw the miracle unfolding for these patients, it actually caused me to sort of re-double my efforts and to try to find cures for other forms of diabetes.” (Scene 49)



“When I began my research career many years ago I had no imagination that I would reach the point that I am today where the work that we do has a direct impact on individual lives. It not only changes the life of the child that is switched from insulin to pills for the treatment of their diabetes. It changes the life of the family and it also changes the life of the investigative team and not only myself, but the students, fellows and technicians that work with me their lives have been changed as well.” (Scene 50)



*Professor of Molecular Medicine, University of Exeter
Medical School, Exeter, UK*

Andrew Hattersley MA, MRCP, DM, FRCP



“I remember when Jack’s result came through. I wanted to ring his mum straightaway and decided to go out into the field because it would be quieter there. I was looking out over the hill around as I was explaining to her that we had indeed found the mutation and that Jack was going to be able to change his treatment. Both of us cried. It was a very emotional moment. (Scene 14)

“I’m a very fortunate man because I have a fantastic combination of work. I do work where I am a diabetes doctor and look after patients and I do other work where I work with patients to make scientific discovery. The lovely thing is when those two bits come together and when the scientific discovery starts to move over to helping patients, I think is one of the most exciting and most enjoyable things that you can be involved in. I just feel very happy to be able to do that.” (Scene 51)

“I think for everybody in Exeter there is an enormous feeling of being part of something bigger. To have had the opportunity to make a change in people’s lives is something we never expected, but to be involved in that has been quite simply the best thing that we’ve ever been involved with.” (Scene 1)





Professor of Medicine and Pediatrics Director, Kovler Diabetes Center, University of Chicago; Lilly Jaffe's doctor who tested her for monogenic diabetes and managed her transition off insulin.

Louis Philipson M.D., Ph.D., FACP

“I was discussing the recent events in science which related to type 1 diabetes, and I mentioned in passing, more than anything else that it was clear to us that the genetics of type 1 diabetes was very important especially in extremely early onset diabetes. And again, I had never seen a case, nor at that point had I even heard of a doctor who had seen a case other than Hattersley himself. And after giving that lecture, a gentleman came up to me and said I'm Mike Jaffe and I'm a member of the JDRF here and my daughter had diabetes at about one month of age. I can still feel the electricity that went up and down, because I never expected anyone to say that really, because of the rareness of the disease. “ (Scene 31)



Producers



TMK Productions

Ted Kay is president and owner of TMK Productions. He has been producing powerful and moving documentaries for public television since 1991. Kay is the recipient of two Emmy Awards for the internationally acclaimed documentary *Choosing One's Way: Resistance in Auschwitz*, hosted by Academy Award Winner Ellen Burstyn. Many of his documentaries have focused on major health care issues, including Alzheimer's, attention deficit disorder, congenital heart disease, autism and mental health.

Larissa Woodward joined TMK Productions three years ago as editor. She is a graduate of Grand Valley State University with a degree in film and video production. Larissa previously worked with WGUV, a PBS affiliate in Grand Rapids, Michigan where she was producer, director and editor for a variety of news and entertainment programs.

Executive Producers



Laurie and Michael Jaffe of suburban Chicago are the driving force behind *Journey to a Miracle*. They were inspired to produce the film after their daughter Lilly, who was diagnosed with diabetes as a baby, was able to disconnect her insulin pump for good after doctors discovered that she did not actually have type 1. In June 2006, Mike attended a JDRF meeting where Dr. Louis Philipson of the University of Chicago Kovler Diabetes Center spoke of an upcoming study in the *New England Journal of Medicine* involving children diagnosed with diabetes as babies. Dr. Philipson explained that most of the children did not actually have type 1 diabetes, but rather a newly understood genetic form that is best treated with oral medication, not insulin shots. The rest is history. The Jaffes made a forever friend in Dr. Philipson who became Lilly's doctor and helped her transition from insulin to oral medication.

Moved by their family's miracle and the potential of reaching thousands more, the Jaffes are passionate about helping to raise global awareness of monogenic diabetes. They initiated monogenicdiabetes.org, an authoritative website now administered by the Kovler Diabetes Center. Laurie also began and moderated an online discussion/support group for parents whose children were also able to switch their treatment from insulin shots to oral medication. The close-knit group grew as parents contacted Laurie after hearing about their family's story. The group eventually met in person in 2010 and 2013 at "Celebrating the Miracles" conferences hosted by the Kovler Diabetes Center to bring scientists and families together.

Laurie is a founding Leadership Board member of the University of Chicago Kovler Diabetes Center. Her professional background is in communications, strategic planning,

Laurie and Michael Jaffe - continued

and public affairs for national nonprofit organizations. She is a graduate of Asbury University and Wheaton College Graduate School.

Mike is president of the Jaffe Companies, a Chicago-based commercial real estate development firm. He is the developer/owner of the Arboretum of South Barrington. Mike served for six years on the executive committee of JDRF Illinois and is now a sustaining member. He is a graduate of the University of Illinois and Loyola Law School.

Host and narrator



Lia Mortensen is a Chicago-based stage and screen actress.

Lia Mortensen

Monogenic diabetes at a glance



Who

More than 25 million Americans – 347 million worldwide – suffer with diabetes. Between 2 and 3 percent have not been correctly diagnosed and actually have a genetic form called monogenic diabetes.

Monogenic Diabetes

These newly understood genetic forms are different from types 1 and 2 and affect up to 500,000 Americans and 5,000,000 worldwide. Most of these patients and their physicians are unaware of the historic breakthrough in monogenic diabetes that could lead to a different diagnosis and a life-changing new treatment.

Life-Changing

With genetic testing and the correct diagnosis, those with monogenic diabetes may be able to radically change their diabetes treatment from insulin shots to oral medication.

Monogenic diabetes facts

- Monogenic diabetes results from a change - or a mutation - in a single gene that controls the body's ability to make insulin.
It is a newly understood form of diabetes that has been misdiagnosed as type 1 or type 2 because most doctors aren't aware of it.
- Between 250,000 and 500,000 Americans have a form of monogenic diabetes and don't know it.
- Up to 95 percent of people with monogenic diabetes are misdiagnosed
As type 1 or type 2 because neither they nor their physicians know about the possibility of a different diagnosis and treatment.
- There are more than 20 genes associated with monogenic diabetes.
- It is not an autoimmune disease like type 1 diabetes.
People with type 1 do not produce insulin because their bodies destroy the insulin-producing cells. Most with monogenic diabetes are negative when tested for autoimmune antibodies, which is routinely done when the person is first diagnosed with diabetes.
- It is not like type 2 diabetes
where the body doesn't produce enough insulin for various reasons.
- Most with monogenic diabetes have healthy insulin-producing cells
but a key channel won't open and close because of the genetic mutation. Scientists discovered that an oral medication (a sulfonylurea), fixes the channel allowing the body to make and secrete insulin on its own. Imagine a gate that is stuck in one position. When fixed, it is able to open and close normally.
- The many forms of monogenic diabetes can present at differing ages. They are grouped based on the age of the person when they were first diagnosed, regardless of current age.
 1. "Neonatal diabetes" affects children diagnosed typically at six months or younger and is almost always due to a form of monogenic diabetes.
 2. "MODY" - maturity onset diabetes of the young - affects children with diabetes at a very early age into early adulthood.

- Causes of monogenic diabetes
 Scientists do not yet fully understand why genetic mutations occur. They do know that some are inherited and passed down from parents to their children. Other mutations happen spontaneously at conception. These are called “de novo” mutations.

- Genetic testing is the only way to get an accurate diagnosis.
 Because monogenic diabetes is a genetic condition, the only accurate way to diagnose it is through genetic testing. Performed by a number of academic and commercial organizations throughout the world, the patient's DNA is analyzed through either a blood or saliva sample.

- A national Monogenic Diabetes Registry was created in 2007 at the University of Chicago.
 There are currently over 1000 families registered and more than 350 of these have been found to have a form of monogenic diabetes.

- “Lilly’s Law” was established in 2009.
 It requires Illinois physicians to register all children with diabetes onset before 12 months of age with the state department of public health. It is a pilot program to advance understanding of the genetic causes of diabetes.

- Certain types of neonatal diabetes also cause a variety of developmental and cognitive challenges.
 When switched from insulin shots to sulfonylurea drugs, many experience dramatic improvements, such as walking and talking for the first time, and an increase in IQ and motor skills. This is another area that scientists are working to better understand.

- Two studies conducted by researchers at the University of Chicago prove the cost-effectiveness of genetic testing for monogenic diabetes. See Scientific References, *Diabetes Care, 2011 and 2014*

- Hundreds, if not thousands, of children and adults have been able to switch their treatment from insulin to oral medication.
 These individuals take the pills daily and will do so for the rest of their lives. Like everyone, they must maintain a healthy diet and lifestyle, but no longer need to count carbohydrates as they did before. They also don’t need to constantly test their blood sugars, as most are very stable and normal. They also are no longer at risk of the frightening complications that come with insulin and uncontrolled blood sugars.

Who should be tested for monogenic diabetes?

Genetic testing should be considered in one or more of the following settings:

- ✓ Anyone diagnosed with diabetes at or under 12 months of age

- ✓ A diabetes patient who is part of a family with three or more consecutive generations affected by diabetes

- ✓ A diabetes patient with stable, mildly elevated blood sugars, often found incidentally during a routine checkup

- ✓ A type 1 diabetes patient who has negative blood testing for autoantibodies, typically done at the time of diabetes diagnosis (antibodies typically tested include one or more of the following: GAD65, islet cell or ICA, IA-2, insulin, ZnT8)

- ✓ A type 1 diabetes patient who generates a significant amount of insulin years beyond diagnosis (detectable blood levels of c-peptide, proinsulin, and/ or insulin)

- ✓ A type 2 diabetes patient who is normal weight or not significantly overweight and shows no signs of insulin resistance

- ✓ Diabetes paired with pancreatic insufficiency (digestive role of the pancreas is impaired with symptoms like diarrhea and gas)

- ✓ Individual or family history of diabetes paired with developmental kidney disease or abnormalities of the kidney (especially cysts). The urinary system and reproductive organs may also be abnormally formed.

Monogenic diabetes resources



Monogenicdiabetes.org



Diabetesgenes.org



DPAG.ox.ac.uk



Diabetes.niddk.nih.gov



Modyawareness.com

Monogenic diabetes in the news

To view please visit: Journeytoamiraclemovie.com/in-the-news/

Lilly Jaffe's Story on CNN - October 2006



Michael Eizenga MODY Story on CLTV



“Celebrating the Miracles 2010 Conference”

Narrated by former NBC Chicago anchor Warner Saunders



Full articles available at: Journeytoamiraclemovie.com/in-the-news

The London Daily Telegraph, 2004

Old-fashioned Pills Cure Baby Born Diabetic



New York Times, 2006

Some Diabetics Don't Have What They Thought They Had



Chicago Tribune, 2006

Miracle Unfolds for Diabetic Girl



Medicine on the Midway, 2006

Molecular Medicine to the Rescue



JDRF Countdown, 2007

A Significant Breakthrough



Chicago Tribune, 2007

One Girl, One Story Living On Diabetes



People Magazine, 2007

Life-Changing News for Lilly



The London Daily Telegraph, 2009

Boy Can Walk and Talk After Being Given Treatment



Chicago Tribune September 21 2009

'Lilly's Law' Inspiration s Database Kick-starts Diabetes Awareness



The Guardian, 2012

Genetics and Neonatal Diabetes: How Jack was Spared a Life of Injections



The University of Chicago Campaign – Inquiry & Impact, 2014
The New Normal



Diabetes Forecast, May/June 2015

Insulin Independent – Two parents document their daughter’s medical “miracle” with monogenic diabetes

Scientific references

Studies available to read at: Journeytoamiraclemovie.com/scientific-references/

New England Journal of Medicine, 2004

Activating Mutations in the Gene Encoding the ATP-Sensitive Potassium-Channel Subunit Kir6.2 and Permanent Neonatal Diabetes

Diabetes, 2004

Patient Characteristics and Initial Response to Sulfonylurea Therapy

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New Clinical Syndromes, New Scientific Insights and New Therapy

New England Journal of Medicine, 2006

ATP-Sensitive Potassium Channels – Neonatal Diabetes Mellitus

New England Journal of Medicine, 2006

Activating Mutations in the ABCC8 Gene in Neonatal Diabetes Mellitus

New England Journal of Medicine, 2006

Switching from Insulin to Oral Sulfonylureas Patients with Diabetes Due to Kir6.2 Mutations

Clinical Endocrinology News, 2007

Neonatal Diabetes Patients Weaned Off Insulin

Diabetes Care, 2011

The Cost-Effectiveness of Personalized Genetic Medicine

Journal of Diabetes Science and Technology, 2011

Creation of Web-based University of Chicago Monogenic Diabetes Registry

Clinical Endocrinology, 2011

Who Should Have Testing for Mature-onset Diabetes of the Young?

Diabetes Care, 2011 MODY

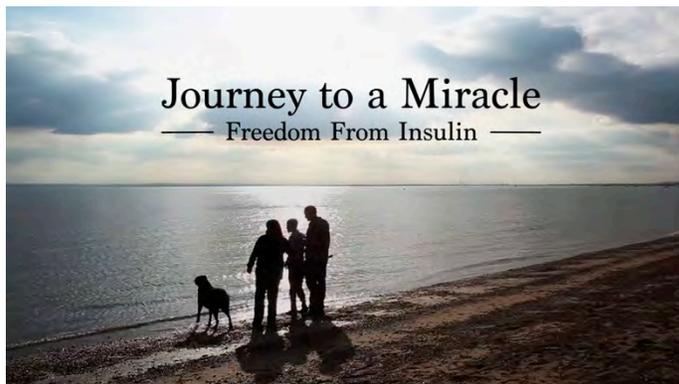
Best Practice & Research Clinical Endocrinology & Metabolism, 2012

The lessons of early-onset monogenic diabetes for the understanding of diabetes pathogenesis

Diabetes Care, 2014

Cost-Effectiveness of MODY Genetic Testing

Title page photos



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Quest Diagnostics is the world's leading provider of diagnostic information services needed to make better health care decisions. The company offers the broadest access to diagnostic testing services through its network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics offers a comprehensive diabetes test offering, including genetic testing for monogenic diabetes. Additional company information is available at QuestDiagnostics.com.

