RESEARCH INTO TYPE 1 DIABETES

Date: 14th June 2019

APPG FOR DIABETES

About the All Party Parliamentary Group for Diabetes

The All-Party Parliamentary Group for Diabetes (APPG Diabetes) is a nonpartisan cross-party interest group of UK parliamentarians who have a shared interest in raising the profile of diabetes, its prevention and improving the quality of treatment and care of people living with diabetes.

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Key diabetes facts

- In the UK an estimated 4.6 million people across the UK are living with diabetes.
- An additional 1.1 million people are expected to have diabetes but undiagnosed, this is primarily Type-2 diabetes.
- Since 1996 the number of people diagnosed with diabetes has doubled, from 1.4 million to 3.8 million.
- Of those 4.5 million in the UK diagnosed with Diabetes it is expected that 10% have Type-1 diabetes and 90% have Type-2.
- When looking at genetic predisposition more than 85 per cent of Type 1 diabetes occurs in those with no previous first degree family history, the risk among first degree relatives is about 15 times higher than in the general population.
- The risk of a child developing diabetes if their mother has it is about 2–4 per cent higher than the average, if the father has it is 6–9 per cent higher and if both parents have the condition is up to 30 per cent higher than average.
- Type-2 diabetes can also be affected by genetics have a genetic pre-disposition. Those with diabetes in the family are 2-6 times more likely to develop the condition than those without history in the family.
- Diabetes is a condition which is expected to affect 1 in 10 people globally by 2040, equalling 642 million. This will put diabetes on a par with the number of people being diagnosed with cancer by 2040.
- Diabetes is a globally recognised condition. There is expected to be 1 in 2 adults across the world undiagnosed with Type-2 Diabetes. The International Diabetes Federation (IDF) has estimated that in 2015 seven countries have more than 10 million people with diabetes; China, India, USA, Russia, Indonesia, Mexico and Brazil.

Reports published by the APPG for Diabetes

- Prioritisation of diabetes for government and the NHS (2019)
- International Diabetes Summit (2019)
- Assessing the Diabetes Transformation Fund (2018)
- Flash Glucose Monitoring: what's next in Diabetes Technology (2018)
- Diabetes and Mental Health (2018)
- Reversing Type 2 Diabetes (2018)
- Diabetes and Podiatry (2018)
- Emotional and Psychological Support for people with Diabetes (2018)
- Next Steps for Childhood Obesity Plan (2018)
- The Future of Inpatient Diabetes Care (2017)
- Safety and Inclusion of Children with Medical Conditions at School (2017)
- Industry Action on Obesity and Type 2 Diabetes (2017)
- Levelling up: Tackling Variation in Diabetes Care (2016)
- Taking Control: Supporting People to Self-Manage their Diabetes (2015)

Research into Type 1 Diabetes

A session of the All-Party Parliamentary Group for Diabetes took place on the 28th March 2019 on Research into Type 1 Diabetes to discuss hopes research can bring for people with or at risk of Type 1 diabetes and how innovation and technology can improve the way Type 1 diabetes is managed and prevent devastating and costly complications.

Key witnesses were;

- **Professor John Todd,** *Professor of Precision Medicine at the University of Oxford*
- **Dr Sufyan Hussain,** *Consultant Diabetes Physician at Guy's and St Thomas Hospital*
- **Anna Morris,** *Assistant Director of Research Strategy and Partnerships, Diabetes UK*
- **Sophie Lane,** *Patient voice*

Professor John Todd, Professor of Precision Medicine at the University of Oxford

> ***"The GPPAD Study provides a path to primary prevention of beta-cell autoimmunity on a population-based level. There is currently no other study in the world providing this. If successful, we will see a reduction in the number of children developing Type 1" – Professor John Todd***

Professor Todd explained how part of his research works by screening new-borns to find out those with a genetic risk of developing type 1 diabetes, and then conducting a randomized trial to treat those babies in the hopes of preventing the disease.

Professor Todd explained that one way to avoid the immune attack that causes type 1 diabetes is to train the immune system not to attack insulin producing cells – to make it blind or tolerant to insulin. "We are feeding children with oral insulin every day, for three years", he says, "then we follow up at age 6, making it a seven-year trial. I have never seen such a complex trial become a reality so rapidly". The study provides a path to primary prevention of beta-cell autoimmunity on a population based level. There is currently no other study in the world providing this.

Professor Todd mentioned how they have to screen over 300 thousand new-borns using the official new-born Guthrie blood spot as a source of DNA for the genetic risk screen, and how the families contacted have reacted overwhelmingly positively to the trial. "People really want to prevent it. I am determined to make an impact on type 1 diabetes". At the moment, the study is only active in four maternity hospitals in the Thames Valley, but he expressed a strong desire to expand geographically in England, to accelerate recruitment to this international trial. The trial is generously funded by the New York-based Helmsley Charitable Trust in the order of over $50 million.

Professor Todd also talked about how his trial works whilst debunking the myth that once a child is diagnosed with type 1 diabetes, they have already lost all their insulin-producing cells. "That is not true", he says. At the time of diagnosis or shortly before it, there are still a percentage of cells left in many cases, which are enough to minimise the gravity of future potential diabetic complications.

Dr Sufyan Hussain, Consultant Diabetes Physician at Guy's and St Thomas Hospital

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> ***"There are big gaps in implementation and therefore issues in delivering even more basic technologies to those who can benefit. Whilst research may lead to exciting innovations, we can't move forward before we improve on these issues" –*** ***Dr Sufyan Hussain***

Dr Sufyan Hussain was diagnosed with Type 1 diabetes at the age of 10. After 9 years on multiple daily injections, he received help from a charity at Cambridge for a self-fund an insulin pump, which was life changing.

Higher incidence of complications in type 1 diabetes – investment to prevent expensive and life changing complications needed. Compared to type 2 diabetes, type 1 diabetes has different causes, its more intensive requiring multiple daily doses of insulin and blood sugar checks right from the start. It's a condition that can affect any age, however it often starts at a younger age than type 2 diabetes. This means a higher lifetime burden of an intensive form of diabetes and hence more complications. Whilst only 8% of people have Type 1 diabetes, it accounts for a higher degree of life changing cardiovascular, kidney and eye complications, and impact on mental health, than Type 2 diabetes.

National outcomes for Type 1 diabetes versus Type 2 diabetes: urgent need to improve type 1 diabetes care nationally. Outcomes for type 1 diabetes in adults are poorer than type 2 diabetes. 70% of people (7 out of 10) with type 1 diabetes fail to achieve the very conservative target of an HbA1c of 7.5% - HbA1c being a marker of glucose levels over a 3 month period, which is not great. Also younger people and those with type 1 diabetes achieve less of the three key treatment targets for diabetes (blood pressure, cholesterol and glucose control), when this is the group where more focus is required, is a sign that we are investing in the wrong ways of delivering care. There's more data showing the huge variation in type 1 services throughout the country. Stronger investment in preventing complications is required rather than treating expensive complications in Type 1 diabetes.

Can technologies help improve type 1 diabetes care and outcomes? There is no shortage of RCT, real world data and experiences from leading centres such as Guy's and St Thomas Hospital with some of the best national outcomes for type 1 diabetes - technology does improve lives for people with type 1 diabetes.
Dr Hussain talks about pumps, glucose sensors and the artificial pancreas. Pumps are small programmable devices which are worn by the user and deliver insulin under the skin in an accurate and flexible manner. Glucose sensors or real time continuous glucose monitoring are devices that provide continuous information of glucose including trends or direction of change that help immensely in planning life and managing diabetes. This is different from flash where you get continuous real time glucose readings as well as alarms and alerts when sugars are high or low which helps in making diabetes safer.

Over the recent years there has been great progress in the capabilities of pumps and sensors - simplicity of use, and better connectivity between pumps, glucose sensors and even smartphones and watches. Which has resulted in the era of the artificial pancreas. Pumps and sensors connected to and controlled by an algorithm that may reside on a smartphone. It delivers insulin in an automated fashion; knows your sugar and adjusts insulin as needed to spend more time in the green range and less time high or low; with manual input for meals or activity. Such systems have been in use in an academic setting for some time but the 'do it yourself' diabetes community has lead the way in using it in every day normal settings by providing hacks, codes and algorithms to make this work. With commercial, medically approved systems on the horizon, they have given a clear vision what type 1 diabetes care needs to be like in the future – automated systems that deliver better glucose control, less complications, less hypos, less burden for the person with diabetes and even less need for health care professional - patient interaction once you are up and running!

UK Uptake of technology – low compared to Europe, huge variation and socioeconomic disparity. Unfortunately, the variation on uptake of insulin pumps in comparison to other European countries is not great. And even within England and Wales there is a high degree of variation. Whilst one centre might be have a thriving pump service, few miles away the story is completely different, with no clear mechanism for CCG funding. And what's more concerning is the socioeconomic disparity - you are less likely to be on a pump if you come from a socially deprived background – numeracy skills, level of education, language, ethnicity unfortunately all play a part in the ability to access pumps. The story for glucose sensor is even more concerning with a greater level of variation and even less uptake nationally.

Multiple reasons contributing to this wide gap in implementation.
- Firstly technology requires money.
- The policies governing criteria for funding as set by NICE (The National Institute for Health and Care Excellence) are very binary and restrictive.
- Even with this restrictive criteria, there are variations in culture of commissioning especially in regions where there isn't a clear understanding of why an expensive technology may need to be funded for type 1 diabetes, when type 2 diabetes can be managed without this expense.
- They is a very complex reimbursement process that means heavy administrative work for health care professionals making it harder to access funding and more hoops for people with diabetes to jump through.
- There are other big challenges such as availability of diabetes nurses and dieticians who are trained in technology and have time in their jobs to do this. One in four to five pump services are having to hold off pump starts, as waiting lists are over a year.

Need for improvements in access to technology - What is being done?

There has been recent progress from NHSE on some aspects of commissioning flash and sensors in pregnancy; however how its impact on local commissioning and implementation waits to be seen. Separately to the NHS, the formation of a multi-disciplinary professional diabetes technology network to help educate, train and champion diabetes technology has been seen.

Anna Morris, Assistant Director of Research Strategy and Partnerships at Diabetes UK

> ***"For every £1 currently spent on diabetes care in the UK, only half a penny is spent on research. A greater investment would allow us to improve the support for people with Type 1 and lead us to ways to prevent and cure Type 1 in the future." – Anna Morris***

Anna Morris says over 300,000 people are living with Type 1 diabetes in the UK, who take insulin every day to stay alive, and will do so for the rest of their lives. Because the cells in their pancreas responsible for producing insulin have been destroyed by their very own immune system.

Insulin has been the treatment for controlling blood glucose levels in people with Type 1 diabetes for nearly a century. But the ways in which people monitor their blood glucose levels and take insulin has changed dramatically over the past decades, thanks to research giving rise to new technologies like flash monitoring and insulin pumps, and helping people to live longer, healthier lives, as we learn more about how to reduce their risk of complications. But despite these significant advances, fewer than one in five people with Type 1 diabetes is currently able to keep their blood glucose levels below the line that would reduce their risk of complications. And today, almost half of people with Type 1 diabetes have some form of retinopathy. Clearly, more work needs to be done and scientists are looking for other options beyond our century-old treatment, insulin.

Anna articulates, "we understand more than ever about what causes Type 1 diabetes, and we now know that the immune attack underpinning Type 1 diabetes develops many years before someone is diagnosed". Professor John Todd and a global research team are taking advantage of this fact, screening babies to find those at high risk of Type 1 diabetes and test potential ways to intervene early enough to prevent a diagnosis. Scientists are also searching for ways to stop the immune attack in people who already have Type 1 diabetes, rather than those at risk. In 2014, Diabetes UK joined forces with JDRF to fund the Type 1 immunotherapy consortium: a network of scientists and clinical research sites across the UK working together to drive this critical research forward.

Anna mentioned how the technology field continues to move forward rapidly and how we are coming closer to the artificial pancreas. These devices will link a glucose sensor to a pump to automatically administer the right amount of insulin at the right time and bring hope to many. However, there are big gaps in the implementation of technology and therefore issues in delivering even basic technologies to those who can benefit. There is an urgent need to focus on improving this if we are to improve outcomes and benefit from new technologies.

Research holds a great deal of promise for our future and greater investment is the key to getting there. At Diabetes UK, they hope that by working together as scientists, research funders, policy makers & advocates, they can reach a world where diabetes can do no harm.

Sophie Lane, Patient voice

> ***"Type 1 has never held me back – but that doesn't mean it's been easy." – Sophie Lane***

Sophie was diagnosed with Type 1 Diabetes when she was 12. Her family and she had no idea of the symptoms and had brushed them off as nothing too serious. She was fortunately diagnosed before coming anywhere near a state of diabetic ketoacidosis – a complication which commonly occurs with type 1 diagnosis and can be life threatening.

She is extremely positive about life with Type 1 and is a firm believer that diabetes shouldn't stop you from anything. She has achieved & enjoyed a lot over the past 15 years and has travelled the world and experienced so many fun things like learning to snowboard, running a half marathon and a couple of triathlons, etc. She secured the graduate scheme she always wanted, achieved a first-class Master's in Chemistry, a chartership in accountancy, and now works in an industry she absolutely loves.

She says, Type 1 Diabetes is hard – it's 24 hours a day, unpredictable, uncomfortable and sometimes exhausting. Its carb counting everything you eat, adjusting insulin-to-carb ratios, trying to predict how your hormones, emotions and activity levels will affect your blood sugars – and then trying to guess why it's completely different to how they affected them yesterday. For her, it's up to 30 blood tests a day, 30 decisions to make, and feels like a constant battle of highs and lows, both physically and emotionally.

Diabetes technology has made managing Type 1 Diabetes a lot easier and life changing. She has worn a Freestyle Libre flash glucose monitor for over 3 years now and combined with some hard work, the Libre has helped her achieve the healthiest HbA1c she has had in over 10 years and given her confidence over her control of this condition.

Another encouraging and exciting area within T1 technology is the development of the artificial pancreas, or 'closed loop' insulin delivery system. Using a compatible insulin pump, a CGM and a few other pieces of kit, this system can predict future blood glucose levels, and automatically determine and dose the correct insulin requirements for a patient – taking the decision making away from them. With DIY platforms such as Tidepool Loop currently working to deliver an FDA-regulated solution, and recent studies publishing some promising results around time spent in target glucose range under closed-loop therapy vs traditional pump therapy, this concept looks like it's really going somewhere.

As great as all this is, there's one problem – and that's access. The Freestyle Libre currently costs her £1,300 a year to fund, and if she were to upgrade to a Dexcom CGM, this would move to nearly £2,000 a year. Despite the Libre technically being available on the NHS since November 2017, due to significant variances in funding criteria across UK Clinical Commissioning Groups, it was estimated back in November 2018 that only 3% of the T1 population were able to access it on the NHS. Thankfully, from April 2019, criteria for funding has become consistent across all CCG's, meaning that access will no longer be a 'postcode lottery'. However, as access will still be criteria dependant, its predicted that the 3% will rise to only around 20-25%. When discussing this with her own consultant back in January, she was told 'not to hold her breathe'.

However, the biggest struggle she faced around access and Type 1 is to do insulin pump therapy. She has been on a waiting list for nearly 2 years now, and with problems such as nocturnal hypos, the inability to exercise in the evenings due to severe hypoglycaemia, and future family planning considerations, and despite being an ideal candidate for pump therapy she was once again refused in March 2019.

In her experience, pushing for pump therapy has been hard work, and very disheartening especially when she was told that she didn't meet the criteria for poor control. She finds it devastating that if she wanted to start planning for a family, no healthcare professional would recommend that as her control is considered suboptimal, HbA1C is too high, as would be the risk of complications in pregnancy – and yet when she recognises this, and proactively start trying to gain access to pump therapy to tackle the problem sooner rather than later, she is met with denial.

Sophie hopes for the future with Type 1, that access to technology becomes available on an equal basis to those who will benefit from it. The research and development going into Type 1 is incredible, and gives real hope for those living with this condition in the future nut is no point if those who need them can't access them? Type 1 care needs to be preventative instead of reactive - where patients are given access to the best support & technological tools available from day one, so that they feel equipped and empowered to manage Type 1 as best they can; so that everyone can thrive with this condition, and ultimately reduce the risk of long term complications – which are not only costly to the healthcare provider – but also to their quality of life.

Audience discussions:

Sandy Martin MP mentioned how one of the first things he got involved in Parliament was trying to champion a young person living with Type 1 diabetes, and the issues he was having at school and with accessing pump. "We need to be stronger on challenging the reframe idea that everything what needs to be done is being done", he said. *He* asked ***Dr Hussain*** if there was anyone who would not benefit from accessing technology; to which his response was negative.

George Howarth MP mentioned how he led three debates in Parliament on technology in the past years. "It is quite clear that technology has a massive role to play and we need to get to the bottom of the commissioning system."

Sarah Gatward, who has Type 1 diabetes, raised the issue of how 'need' is defined and how it does not account for the mental health and emotional wellbeing benefits of technology. In response, ***Sophie Lane*** agreed and highlighted how she would have qualified for an insulin pump when she was younger, and not engaged with her diabetes, but does not qualify now that she is working hard to be healthier. "It is backwards and puts me in the position to consider making myself sicker or lying to my healthcare professionals".

Anna Morris mentioned Diabetes UK, through a clinical group, identified the need to research the impact of technology on mental wellbeing and to capture mental wellbeing in trials, alongside biological measures. "That's something we're thinking about how to move forward".

Members of the audience with Type 1 diabetes mentioned their own challenges with access to technology. ***The Chair*** said he does not qualify to the Flash Glucose Monitoring criteria. "My fingers are getting sore, I am getting older. At some point, I will not be able to do it for long". ***Trudi Evans***, who is also attempting to qualify, spoke of the irony that one of the criteria for access is to 'prick your finger more than eight times a day', but she cannot get eight strips out of her doctor. "People do not appreciate how life changing technology is for diabetics". ***Paul Leadbeater*** highlighted the relentlessness of Type 1 diabetes. "Technology should be for everyone, not for NICE criteria". ***Conrad Jarrett*** mentioned his issue with losing the ability to recognise hypos, and how he has already lost his license but still has not been able to access a CGM. "The system is not geared up to support patients."

In response, ***Dr Hussain*** mentioned what healthcare professionals tell CCG Commissioners is the greatest benefit of diabetes technology: making diabetes safer and easier. Unfortunately, he highlights that this is not reflected in the criteria. "It is really shifting our focus thinking about how we can empower the person with diabetes to do better", he said, "I believe technology can sincerely improve mental wellbeing".

Dr Hussain, Conrad Jarrett and ***Sandy Martin MP*** mentioned the need for a centralised mechanism to fund diabetes technology as a potential solution to this issue. But ***Dr Hussain*** highlights the importance of also considering the criteria for access. "Two out of ten people with Type 1 will be covered by the Flash Glucose Monitoring criteria. That means 80% will not be covered."

Peter Davies and ***Anthony Fisher*** mentioned the importance of engaging the wider Type 1 diabetes community and informing and educating people on technology since young. ***Julia Tyson*** highlighted the need to look at other measures of diabetes than HbA1c.

Members of JDRF inquired about a greater focus and investment on developing cross-condition research on auto-immune diseases. In response, ***Anna Morris*** thanked the colleagues and welcomed the initiative, highlighting the importance of charities coming together.

Dan Evans, from Abbott, clarified some concerns over the availability of Flash Glucose Monitoring. "We had supply issues in January and February, but we should be fine now", he said, "Existing users can order it at our shop. New users cannot get it at the moment. We are investing significantly in manufacturing capacity and we hope this will change shortly."

Recommendations:

1. **An increased investment in diabetes research in the UK is required.**
2. **As the UK negotiates its new relationship with the EU:**
   - **Ensure that the UK remains an environment that enables innovative research collaboration across the globe.**
   - **Ensure that the UK remains an attractive destination for global expertise in research.**
3. **Re-consideration of the NICE guidelines for insulin pump therapy is required, with the definition of 'need' or 'suitable candidate' to be reviewed - the current guidelines are restrictive and do not reflect the correct population who would benefit from insulin pump therapy.**
4. **For users of the Freestyle Libre, Healthcare teams should adopt the use of LibreView to monitor which patients are consistently using their Freestyle Libre (and perhaps base access guidelines around this) & offer guidance and support through the patterns and data that this tool provides.**
5. **Further funding for Type 1 Diabetes especially around education (e.g. around exercise, insulin pump therapy, pregnancy and Type 1, etc.) should be provided, so that Type 1 care in the UK becomes preventative instead of reactive. We want to minimise the risk of long-term complications, instead of delaying funding and having to spend significant amounts on treating complications in the future.**
6. **Help address poor outcomes for type 1 and investment gap in preventing complications in this group especially with technology. Members of Parliament to ask Commissioners from their own constituencies regarding type 1 and type 2 diabetes outcomes, spend on complications and spend on technology to see the imbalances. Type 1 diabetes care is fundamentally different from type 2 diabetes.**
7. **Through parliamentary discussions, influence stakeholders including NHSE for different commissioning approach and service delivery for type 1 diabetes as treatment and management of type 1 and type 2 is not the same.**
8. **Improve access to technologies and reduce the implementation gap to take advantage of what technology can offer. Stronger national standards for type 1 care based on metrics that matter to people and include QoL, include hypoglycaemia frequency, time in range and updating our outdated and very restrictive NICE (The National Institute for Health and Care Excellence) criteria.**
9. **More funding and investment is required to provide resources to widen the criteria for pumps and glucose sensors and more resources for health care professional training.**