



National Diabetes Audit

Since the last Newsletter, there have been several audits and reports published which tell us that NHS diabetes care and treatment needs to improve. In the UK there are NICE recommendations for high quality services for people with diabetes, but it appears that these are not very well delivered.

It is worrying that GP practice participation in the National Diabetes Audit has dropped from 71% in 2012/13 to only 57% in the latest Audit, so the results could be even worse. The purpose of having an audit is to measure how well the NHS is doing and to encourage all providers of care to improve to the level of the best. If only 57% of those being audited take part, one has to question the value of such audits and ask whether participation should be compulsory.

However, we can only work with what we have got, so this Newsletter contains information from various audits, perhaps the most important one is the first National Diabetes Foot Care Audit, which was released in March 2016.

The National Diabetes Foot Care Audit

This Audit presented findings about treatment and outcomes of more than 5,000 people with diabetes in England and Wales who attended for diabetic foot ulcer assessments between July 2014 and April 2015.

The majority of people (3,699) were referred to specialist services by a GP or other health service and the remainder (1,516) self-referred to the service.

The key findings were that about 50% (2,302) of all patients were ulcer-free 12 weeks after their first expert assessment by a specialist foot care service. However, when 2 weeks or more elapsed between initial presentation and expert assessment, a patient is significantly less likely to be ulcer-free 12 weeks later.

- Of the 2,029 patients seen within 2 weeks or less, 50% were ulcer-free 12 weeks after the assessment.
- Of the 911 patients seen between 2 weeks and 2 months, 43% (394) were ulcer-free 12 weeks after the assessment.
- Of the 359 patients seen after more than 2 months, 34% (123) were ulcer-free 12 weeks after the assessment.
- So the report concludes that when the time to expert assessment is longer than 2 weeks, the condition of the ulcer is more severe. Here is the full report: <http://www.hscic.gov.uk/footcare>

In this issue...

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'IDDT calls for action'

In response to this audit, IDDT issued a press release welcoming the audit and its findings as a good starting point in recognising the importance of foot care in people with diabetes. However, IDDT's key points were:

- People with diabetes need more "proactive rather reactive" foot care.
- Like the recent NICE guidelines, what is concerning is that there is no mention in the report of prevention. People need to be educated and taught about how to prevent damage to their feet because a proactive approach is always going to be better than being reactive.
- Prevention is the key. There needs to be a system in place where feet are examined at least every year and also at any time when new problems and infections occur. By this we don't mean what some people describe as 'having a needle run along the soles of their feet' but a full foot examination by trained people who know what they are looking for.

Around 10% of people with diabetes will have a diabetic foot ulcer at some point in their lives and if this doesn't sound many, it's about 400,000 people with an estimated cost to the NHS is £650 million!

This year as a charity our priority is to push for better foot care and prevention, so watch this space...

Note: IDDT has a free leaflet entitled 'Diabetic neuropathy and foot care'. For your copy call 01604 622837, email enquiries@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS.

DVLA - Good News!

EU changes night-time hypos driving rules for people with diabetes

The European Commission has made changes to the driving rules in relation to severe night hypoglycaemia.

As we are all aware, the EU Directive introduced in 2011 ruled that people using insulin who have one or more severe hypos in any period of 12 months have to inform the DVLA and as a result will have their driving licence revoked. A severe hypo (low blood glucose) is defined as one that has to be treated with the assistance of another person.

One of the major problems with this rule is that there has been no differentiation between day and night hypos, despite night hypos not affecting the ability to drive the next day. This has resulted in people with diabetes losing their driving licence unnecessarily.

Experts review the Directive

Last year experts from across Europe reviewed the Directive and overwhelmingly voted for amendments. The Commission has responded and at the end of March, announced that recurrent night hypos will no longer be included in the 'one or more' hypos in the 12 month period.

Over the last 5 years IDDT and other charities have pointed out how unfair the 2011 Directive has been in terms of night hypos and of course, we have questioned whether it was ever based on evidence. Obviously not! The EU Commission will be asking the DVLA to make the necessary legislative changes by January 1st 2018.

What is the present situation?

Until the law is changed the 2011 Directive still applies and the inclusion of night hypos in the 'one or more' hypos will continue and people have to abide by this.

IDDT has expressed the view to the DVLA that the amendments to the law need to be made as a matter of urgency to prevent people losing their licences unfairly during this interim time. There have also been Parliamentary Questions about this.

Comment: We are sure that more details will become available in the coming months because questions undoubtedly arise from these changes. For example, if people lose their driving licence during the coming months because of a night hypo, will they be eligible to re-apply immediately? What about people who have lost their licence due to night hypos during the past 5 years (and possibly their job), now apparently unnecessarily?

And another apparent change

Dave, an IDDT member reports:

"I received my renewed driving licence from DVLA this morning. I was not expecting this and puzzled as mine gets reviewed every 3 years with visual field checks (Type 1 with laser to both eyes). I called them up and was informed that no visual field test was required. I pushed this further and they checked and confirmed that all the forms have been filled in and received by them. I was then told that they don't require a visual field test if you have not had any more laser treatment since the last licence issue, 3 years ago."

IDDT warning...

We have not been able to confirm that this is a DVLA policy change. We have always argued that if there has been no further laser treatment and no changes to the retinopathy since the last field test, there should be no need to go through the Specsavers field test and licences should not be revoked. So this seems a sensible decision on the part of the DVLA if indeed, it is a policy change.





Ramadan 2016 and fasting

Ramadan is based on the ninth month of the lunar calendar, so this year it is expected that the fast of Ramadan will commence at sunset on June 6th 2016 and will last until July 5th 2016.

During this month it is expected that Muslims who participate will abstain from food, water, beverages, smoking, oral drugs and sexual intercourse from sunrise to sunset.

Ramadan moves forward each year by about 11 days which means the length of fasting is greater at certain times of year than others. The length of fasting has special consequences for people with diabetes, especially those taking insulin and the risk of complications increases with longer periods of fasting.

People with diabetes may be exempted from fasting but the majority of people with diabetes do fast so run increased risks of adverse health effects, such as hypoglycaemia, hyperglycaemia, diabetic ketoacidosis and dehydration. Most of these are as a result of a reduction of food and fluid intake and the timing of meals.

There are no evidence-based guidelines for safe fasting, so people have to rely on expert advice from doctors and their personal experiences. However, a study in people with Type 1 and Type 2 diabetes carried out in Pakistan, has shown that with active glucose monitoring, alteration of drug dosage and timing, dietary counselling and patient education, the majority of patients did not have any serious acute complications during Ramadan.

More recently, researchers have quoted an observational study which showed people with Type 2 who did not have education about fasting were 4 times more likely to have hypos. Therefore, they recommend that those who do not normally carry out self-monitoring of blood glucose should be provided with meters (Diab. Med. February 2016).

The findings of this and other studies suggest that people with Type 1 and Type 2 diabetes should have an assessment with their diabetes team 1 to 2 months before Ramadan about drug/insulin adjustments, exercise and awareness of the risks of hypo- and hyperglycaemia. If they are ill during the fasting, then they should seek advice from their diabetes team.

The winners of IDDT's lottery draws!



We are delighted to announce the winners of the lottery draws for the last 3 months. They are as follows:

Winners of the February 2016 draw are::

- 1st** prize of **£277.44** goes to Jeffrey from St Albans
- 2nd** prize of **£208.08** goes to Anon from Lincoln
- 3rd** prize of **£138.72** goes to Anne from Doncaster
- 4th** prize of **£69.36** goes to Anon from Crewe

Winners of the March 2016 draw are:

- 1st** prize of **£287.04** goes to Anne from Doncaster
- 2nd** prize of **£215.28** goes to Rodney from Wigan
- 3rd** prize of **£143.52** goes to Edward from Norwich
- 4th** prize of **£71.76** goes to Julie from Gosport

Winners of the April 2016 draw are:

- 1st** prize of **£315.84** goes to George from Great Wakering
- 2nd** prize of **£236.88** goes to James from Caister
- 3rd** prize of **£157.92** goes to Arabella from Pwllheli
- 4th** prize of **£78.96** goes to Gethin from Swansea

Note: the winners of the draws for May, June and July 2016 will be announced in our September Newsletter and will be available on our website.

Thank you to everyone who has joined IDDT's lottery.

Special Prizes for June Lottery draw!

In recognition of Diabetes Week in June and for that month only, we are doubling the prize money for all 4 prizes, so the First Prize will be over £500!

If you would like a chance to win for just £2.00 per month, then complete the form with this Newsletter, give us a call on 01604 622837 or email tim@iddtinternational.org

Sugar Tax is a start...



On March 16th 2016, the government announced that highly sweetened drinks will be subject to a 'sugar tax' to come into effect in 2018. According to Jane Ellison, Minister responsible for diabetes, it's the first step towards the childhood obesity strategy which will be launched this summer.

Who consumes drinks with added sugar?

- Over 90% of households get more than the recommended share of calories from added sugar.
- Households with children consume about 21% from carbonated and non-carbonated soft drinks.
- Households without children consume significantly less - 14%.

The facts according to the Institute for Fiscal Studies:

- Pure fruit juices and milk-based drinks are excluded.
- The main levy rates will be (i) 18p/litre for drinks with 5-8g of sugar per 100mls and (ii) 24p/litre for drinks with more than 8g of sugar per 100mls.
- The revenue target is £500 million for the second year after the introduction of the sugar tax (2019-2020).

BMJ report on sugar in fruit juices and smoothies made five recommendations:

1. Fruit juices/juice drinks/smoothies with high free sugar content should not count as one of the government's '5 a day' recommendations, as is currently the case.
2. Fruit should preferably be eaten whole, not as juice.
3. Parents should dilute fruit juice with water or opt for unsweetened juices and only allow these drinks during meals.
4. Portion sizes should be limited to 150ml a day.
5. Manufacturers should stop adding unnecessary amounts of sugars to fruit drink/juice/smoothie products and if they can't do this voluntarily, the government should step in with statutory regulations. (<http://bmjopen.bmj.com/content/6/3/e010330>)

Without doubt the sugar tax is a start in the right direction...

Yes, the sugar tax is a step in the right direction but we must not forget that many other foods contain unnecessary added sugar and these should not be ignored by the government, or by us. In addition, sugar is only part of the problem causing overweight and obesity – we need to think about portion size but above all, we need to remember that so many of us live sedentary lives compared with years ago and this lack of exercise is an important part of today's problems.

Hopefully over the next 2 years some of the uncertainties about its effects will be ironed out.

- Will it make consumers and manufacturers change their behaviour?
- Will people who have a strong taste for sugar switch to fruit juices, milkshakes, chocolate or confectionery so reducing the effects of the sugar tax?
- Prices need to increase for this to be effective but this will not happen if the taxes are absorbed by the manufacturers.

The effects for people with Type 1 diabetes

Following the announcement of the sugar tax some organisations expressed concerns that this will result in hypo treatments being more expensive and even suggested that it will discriminate against people with Type 1 diabetes. (They should remember that people with Type 2 diabetes also have hypos!)

Perhaps we should get this in perspective, the additional cost of say 100ml of Lucozade to treat a hypo will be a few pence and even if you have a lot of hypos in a year, it is still only a couple of pounds a year.

Consumption of excess sugar is closely linked to the development of Type 2 diabetes, tooth decay, heart disease and some cancers. If the sugar tax helps to reduce these conditions and therefore costs to the NHS, then surely it is well worth people with Type 1 paying the extra few pence, especially as people with diabetes taking medication and insulin receive all prescriptions free of charge, even for conditions not connected to their diabetes but other people pay £8.40 for each prescription item.

Trials for the prevention of Type 1 diabetes

For people with Type 1 diabetes, it is good to see that research into its prevention is actually happening as so often the emphasis is on Type 2 diabetes. Below are four trials.

The Accelerator Prevention Trial

A trial to look into possible ways of preventing Type 1 diabetes is ready to start in Scotland. Researchers from Exeter University will work with researchers from Dundee University who will contact all 6,400 families in Scotland affected by Type 1 diabetes.

Children who have a parent or sibling with the condition will have blood tests to see if they are at high risk of developing it. Those that are, will be invited to take part in the study which will involve looking at the impact of giving them metformin, the most commonly used Type 2 diabetes drug. Each child will either receive metformin or a placebo initially for four months and they will then be tested three times to assess how their metabolism and immune system respond, the question being, will metformin protect the beta cells?

Immune system

Type 1 diabetes is as a result of insufficient insulin caused by loss of the insulin-producing beta cells. According to the 'accelerator hypothesis', beta cells are lost throughout our lives but if the rate of loss is increased, then Type 1 diabetes develops and the faster the loss, the younger is the age of onset. Beta cell loss progresses at different rates in different people, hence the reasons for Type 1 diabetes developing at different ages and the 'accelerator hypothesis' uses the terms fast and slow Type 1 diabetes.

The first stage of the Accelerator Prevention Trial will assess (i) safety, (ii) whether the trial design works, (iii) whether the medication can reduce beta cell stress and (iv) how many participants will be needed to progress the study.

If metformin enables the beta cells to live longer, the children in stage 1 will progress to the next stages of the trial. The trial is starting in Scotland because it has the third highest rate of Type 1 diabetes in the world and has systems in place to identify families. The intention is that the study will roll out to the other 10 Health Boards in Scotland and then to England.

Blood pressure drug could be a possible cure for Type 1 diabetes

Researchers have discovered that the blood pressure drug verapamil reversed Type 1 diabetes in mice by protecting the beta cells, so they will now be testing it in humans. If this is shown to be correct, it would be the first treatment that could increase beta cell numbers and improve function.

The researchers intend enrolling into the study 52 people between the ages of 19 and 45, ideally within 3 months of being diagnosed with Type 1 diabetes. They will be randomized to either verapamil or placebo, and will be treated for one year while continuing with insulin-pump therapy and continuous glucose monitoring.

This study is now just beginning and will last for a year. The lead researcher said that they are not expecting miracles from this study as they will only be treating people for one year and any intervention to create an environment for beta-cell survival or regeneration after such a large number of beta cells have died will take a long time. (Mol Endocrinol. 2014;28:1211-1220, press release April 23 2016)

Has the final piece of Type 1 diabetes puzzle been solved?

As we know in Type 1 diabetes, the immune system destroys the beta cells that make insulin. Studies looking at the unique antibodies made by people with Type 1 have shown that there are five key targets that the immune system attacks. The targets are proteins and some of them have been known for a long time but the final one has been difficult to find for the last 20 years but now a team at the University of Lincoln have found the missing one. This means that there is now a complete picture of the 5 proteins that the immune system attacks.

Research is already taking place into some of these targets with the aim of delaying the onset of Type 1 diabetes but this latest discovery could help to transform the care of Type 1 diabetes by blocking the immune reaction to these five proteins. (Diabetes, April 2016)

Immunotherapy for Type 1 diabetes

A new treatment for Type 1 diabetes is being trialled at Guy's Hospital in London called MultiPepT1De. It targets the autoimmune attack on the insulin-producing beta cells that leads to Type 1 diabetes and is intended to slow the progression of the disease by 'switching off' the autoimmune attack in the hope that it will prevent further destruction of the beta cells.

MultiPepT1De is based on an area of study called peptide immunotherapy, which is being applied to a number of other diseases, including allergies and multiple sclerosis. The treatment will be trialled on 24 people with Type 1 diabetes by autumn 2016. The study team is hopeful of positive results that build upon their previous findings showing that the first generation of MultiPepT1De is safe and well tolerated, with some evidence of positive effects in people with Type 1 diabetes.

Launch of the NHS Diabetes Prevention Programme

Readers can hardly have avoided the publicity about the launch of the NHS Diabetes Prevention Programme which started in April 2016. Let us clear up one thing – it should be called the 'Type 2 Diabetes Prevention Programme' because as we all know, Type 1 diabetes cannot be prevented. It is claimed to be the world's first large-scale nationwide programme to prevent Type 2 diabetes but England is a small country and States in America have been successfully running such programmes since 2012-2013. Global studies provide evidence that intensive, individual support to change lifestyle significantly reduces the risk of Type 2 diabetes. Will the UK Diabetes Prevention Programme offer ongoing support to stop people falling back into old habits? There's no mention of this in the publicity, so do we assume that the programme designers have this planned?

The Programme:

- GPs are being asked to identify people at high risk of developing Type 2 diabetes who will then be offered 13 sessions focusing on exercise, education and lifestyle changes.
- The programme will start by covering 27 areas across a third of the country and the rest of England will follow. It will cost £7 million this year.
- 20,000 people will be offered places in the first year so by 2020, 100,000 people will have taken part - so just 20,000 places a year.

Interesting numbers as the recent Public Accounts Committee recommended that by April 2016, NHS England and Public Health England should set out a timetable to "ramp up participation in the national diabetes prevention programme to 100,000 people a year" – obviously this recommendation has been ignored. There are varying figures produced but one set suggests that there are 200,000 new diagnoses every year and half a million people with undiagnosed Type 2 diabetes, so 20,000 a year on the prevention programme seems like something of a drop in the ocean!

Who will provide the Prevention Programme?

Four private companies: Reed Momenta, ICS Health and Wellbeing (Pulse Healthcare Ltd), Health Exchange CIC and Ingeus UK Ltd. So it will not be the patient's GP that provides the programme but a private company, yet again fragmentation within the NHS.

Press release from the Royal College of GPs (22.03.2016)



While the Chair of Royal College of GPs, Dr Maureen Baker, welcomed anything that can be done towards prevention of Type 2 diabetes, she did make several important points:

- Simply educating people about the importance of behaviour change is not enough. The sort of long term behaviour change we need to see is hard to inspire and requires our patients to have ongoing support and access to help over time.
- There is no 'one size fits all' answer to behaviour change. The lifestyle decisions that our patients make are complex and can be affected by a wide range of social factors, including socio-economic status and deprivation.
- The education services outlined in this scheme will be delivered by third party providers, so risk fragmenting the care our patients receive and the unique GP-patient relationship, which is built over time and which we know our patients with long-term conditions value greatly.
- It would make more sense for the Government to ensure that general practice has the appropriate resources, including thousands more GPs, so that we can run individual and community-based diabetes prevention initiatives at a practice level. This way our patients can receive the high-quality, streamlined care that they need and deserve, whatever their situation and wherever they live."

What's happening in the other nations of the UK?

Wales (23.03.16)

The Welsh Government's health strategy, 'Together for Health', published in 2011, set a five-year vision for the Welsh NHS and its partners. This included the creation of delivery plans for major health conditions, one of which was diabetes. The 10 plans outline actions to improve services and in June 2015, Ministers announced £1 million would be invested directly in each of the plans. This has resulted in improvements.

The All-Wales Diabetes Annual Report issued in March 2016 shows:

- The number of people with diabetes admitted to hospital in emergency has fallen by 5% in the last 5 years.
- The average length of stay in hospital for people with diabetes has fallen from 9 days to 6.8 days over the same 5 years.
- More than 30,000 additional people were registered with their GP as having diabetes, an increase of nearly 20%.
- 98% of children and young people with diabetes had their HbA1cs measured and a children and young people's network has been set up in Wales.

Scotland (23.03.16)

The Scottish Dietary Goals have been revised following advice from the Scientific Advisory Committee on Nutrition and Food Standards Scotland.

- A person's diet should consist of no more than 5% free sugars, a 50% reduction from the previous recommended level - roughly 30g or 6 teaspoons of sugar per day for a typical adult, and less for children.
- People should eat 30g of fibre a day – a 25% increase on previous levels.
- Carbohydrates should make up around 50 per cent of a person's total energy intake.

Northern Ireland (24.03.16)

The Department of Health, Social Services and Public Safety published a document 'Patient Education / Self-Management Programmes for People with Long Term Conditions 2014/15'. There were 40 different programmes provided by one of the five HSC Trusts in Northern Ireland. The number of participants attending a programme specifically for cardiac, COPD, Type 1 diabetes or Type 2 diabetes in 2014/15 was 7,474. This was a 20% (1,234) increase on the number of participants in 2013/14 (6,240).

The Eatwell Plate becomes the Eatwell Guide

In March this year and the day after the budget announced the sugar tax, Public Health England unexpectedly announced that the Eatwell Plate has been replaced by the Eatwell Guide.



IDDT's most popular booklet is Diabetes - Everyday Eating includes a picture of the Eatwell Plate but this will be replaced with the Eatwell Guide in future reprints. However, while there are many similarities to the Eatwell Plate, there are some distinct differences and here they are:

- The knife and fork on the Eatwell Plate have been removed as it was considered that they could cause confusion by implying that the recommendations on the Eatwell Plate should be for every meal.
- The names of the food group segments have been updated to put emphasis on certain products within a food group that can be considered more environmentally sustainable.
- The segment sizes of the food groups have been adjusted to reflect current government advice on healthy eating.
- The small section (purple) differentiates between unsaturated oils (eg vegetable and olive oil) and spreads from other foods that are high in fat, salt and sugar. This is because some fat is essential in a healthy balanced diet but those that are high in fat, salt and sugar are not and should be eaten less often and in small amounts.
- High fat, salt and sugar have been removed from the purple section on the Eatwell Plate and appear outside the main picture of the plate on the new Guide to reflect the need to reduce consumption of these foods.
- The Eatwell Guide reinforces the need to keep hydrated by reinforcing fluid recommendations and the best drinks to choose – water, low-fat milk and sugar-free drinks including tea and coffee.
- Although fruit juice (150 ml/day) still counts as one of the 5-a-day, fruit juice has been removed from the fruit and vegetable segment.
- Energy requirements for men and women have been included and a front of pack nutrition label to help with shopping.

MORE WARNINGS!

EMA confirms recommendations to minimise ketoacidosis risk with SGLT2 inhibitors for diabetes

Previous IDDT Newsletters have warned of cases of diabetic ketoacidosis (DKA) in people with Type 2 diabetes taking any of the class of drugs known as SGLT2 inhibitors. The DKA has occurred in people who have not had the expected high blood sugars that normally occur with DKA.

In February, the EMA updated the product information to minimise the risk of DKA by listing DKA as a rare adverse reaction of SGLT2 inhibitors (affecting 1 in 1,000 patients).

They advise that:

- Health professionals should consider the possibility of ketoacidosis in patients taking these drugs even if blood glucose levels are not high.
- Patients taking these drugs should be made aware of the symptoms of DKA, including rapid weight loss, nausea or vomiting, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat. If they have any of these symptoms they should contact a doctor or the nearest hospital straight away.
- If DKA is suspected or confirmed, treatment with SGLT2 inhibitors should be stopped immediately and not be re-started unless another cause for the DKA is identified and resolved.
- SGLT2 inhibitors should be stopped in patients undergoing major surgery or who are in hospital due to serious illness.
- EMA also warns that SGLT2 inhibitors are not authorised for Type 1 diabetes but cases of DKA have also occurred during off-label use and trials in Type 1 diabetes.

However, the EMA states that the benefits of these medicines continue to outweigh the risks in people with Type 2 diabetes.

In the March Newsletter, we also reported that the FDA in the US has issued warnings about blood and kidney infections in those using SGLT2 drugs.

Yet another EMA review of SGLT2, canagliflozin (Invokana)

More recently, the EMA has started another review of SGLT2, canagliflozin, after an increase in amputations (mostly toes) was found in an ongoing clinical trial called CANVAS.

Cases of lower limb amputation occurred in both the canagliflozin and placebo groups in the trial and the possibility that canagliflozin increases lower limb amputations is currently not confirmed. However, the EMA's Pharmacovigilance Risk Assessment Committee has requested more information from the company to assess whether canagliflozin causes an increase in lower limb amputations.

The EMA has asked that this information be disseminated to anyone who might be interested and who could be more interested than people with diabetes? If you are concerned, discuss your options with your doctor.

SGLT2 inhibitors are available under the following trade names: Ebymect, Edistride, Forxiga, Invokana, Jardiance, Synjardy, Vokanamet and Xigduo.

Pioglitazone raises risk of bladder cancer by 63%

A study published in the BMJ (31st March 2016) has found that a drug used to treat Type 2 diabetes, pioglitazone (Actos), may increase the risk of bladder cancer. The risk was higher for people taking larger doses and for those taking it for a longer time.

Pioglitazone and rosiglitazone (Avandia) belong to a class of drugs called thiazolidinediones. Avandia was suspended from the European market in 2010 after being linked to cardiovascular problems but this recent research did not show it had any increased risk of bladder cancer.

Actos, the history

- The problems first surfaced in 2005 when a trial unexpectedly showed higher numbers of people with bladder cancer in those taking Actos compared to people taking a placebo.
- These findings appeared in other but not all studies, so leaving some doubt about whether there actually was a link.
- In 2011 the EMA carried out a safety review of Actos and concluded that it should only continue to be prescribed for carefully selected patients and their response to the treatment should be monitored.



Uncertainty

This uncertainty led Canadian researchers to investigate whether Actos increases the risk of bladder cancer compared to other Type 2 medications. They analysed information from 145,806 people in the UK who started taking diabetes medication for the first time between 2000 and 2013. After removing other factors that could influence the results, they found:

- The use of Actos (pioglitazone) was associated with a 63% higher risk of bladder cancer compared to people who did not take any thiazolidinediones class of medication.
- This risk increased with higher doses and longer use.
- Avandia (rosiglitazone) was not associated with an increased risk of bladder cancer suggesting that the risk is specific to Actos and not to the class of drugs.

Conclusions and recommendations

The researchers stress that in absolute terms the risk of bladder cancer with Actos remains low, in this case 622 people during the follow up period. They recommend that prescribing doctors should be aware of these risks and patients should be made aware so they can choose whether to remain on the drug. As ever, it is important patients are given all the information so that they can make an informed decision about their treatment options.

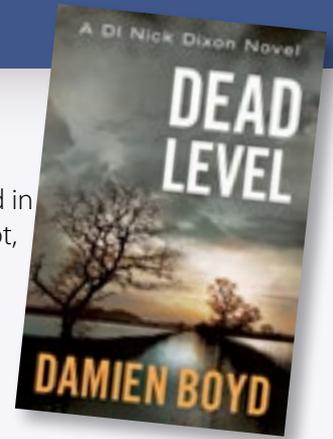
Interesting! Currently in the US, more than 11,000 legal cases have been filed, many of which claim emotional distress due to the fear of bladder cancer. To limit their legal costs, the manufacturer has established a \$2.4 billion settlement pool.

A Good Read!

'Dead Level' is the title of a new novel by Damien Boyd in the DI Nick Gibson crime series. It has a fascinating plot, especially to people with diabetes! In the novel, the murdered victim, Elizabeth Perry, had Type 1 diabetes and all the adverse reactions to 'human' insulin from which she recovered following a change to animal insulin after her husband contacted IDDT!

The author's note at the end of the book says that the plot was born out of bitter experience when someone very close to him was diagnosed with Type 1 diabetes and given 'human' insulin with no advice about the choice of insulin. Even without the diabetes connection, 'Dead Level' is an excellent read!

Dead Level is published by Thomas and Mercer, ISBN 978-1503933095



Study links tendinopathy and diabetes

A recently published study found that patients who suffer from tendon pain are 1.3 times more likely to have diabetes than those without tendinopathy. The study also found that people with Type 2 diabetes are more likely to have thickened tendons and face over 3.67 times the risk of developing tendinopathy compared with people without diabetes. Researchers, who analysed 31 previous studies, said the findings are problematic because exercise is an important part of diabetes management. (British Journal of Sports Medicine, Jan 29th 2016)

Tendon pain linked to diabetes

As the above study has confirmed, people who have diabetes are much more prone to develop problems with tendons than those without diabetes. This could be due to the blood supply to the tendons being less than normal and it could be that very early diabetic changes in the blood vessels may show up first in the tendons. It could also be that high blood sugars may cause thickening of the tendons.

The tendons are the soft tissue that connects muscles to bones. 'Tendonitis' refers to injuries or inflammation of tendons usually caused by overuse or repetitive movements. Many of our readers will be only too well aware that common forms of tendon damage experienced by people with diabetes or at risk of it, are carpal tunnel syndrome, tarsal tendon syndrome and frozen shoulder. It seems that many healthcare professionals are often not aware of the link between tendonitis and diabetes.

One of the major issues for people with diabetes is that exercise is part of the treatment for their condition, but for those with tendonitis it is very important to rest as constant movement can aggravate the pain and make it worse. Indeed, aggressive exercise is a primary cause of tendonitis, especially in people with diabetes.

Suggested methods of prevention are icepacks and stretching regularly, along with help from a physiotherapist and again, that people should not launch themselves too aggressively into exercise programmes and risk injury but should do it in a gradual way.

A few reminders

New standards for blood glucose meters

Previously we have reported that revised standards for blood glucose meters come into effect in May 2016 so that meters will be more accurate. The International Organisation for Standardisation (ISO) published these in 2013 giving until this year for implementation, so all meters not meeting this standard must be replaced and the test strips for non-compliant meters will no longer be available. Meters are marked with the new ISO number ISO 15197: 2013 and many of your meters will already be up to the new standards.

The new standards require that 95% of blood glucose results reach the following standard:

- Within ± 0.83 mmol/L of laboratory results at concentrations of under 5.6 mmol/L (old standards 4.2mmol/L)
- Within $\pm 20\%$ of laboratory results at concentrations of 5.6 mmol/L or more (old standards 4.2mmol/L)

In 2015, the NHS Greater Manchester Medicines

Management Group published a review of blood glucose meters including the accuracy of blood glucose test strips. This is intended as a recommendation for the 12 CCGs in the area, so it is not a complete list of ISO compliant meters but it could be useful for you to check if your meter is up to the new standards. For those with internet access it can be found at: <http://www.diabetes.co.uk/blood-glucose-meters/iso-accuracy-standards.html>

If you have any concerns about your meter, discuss these with your diabetes nurse.

Free prescriptions

Prescriptions are free for everyone living in Scotland, Northern Ireland and Wales. People living in England who use medication or insulin to manage their diabetes are entitled to free prescriptions, but if you are under 60 you need a Medical Exemption Certificate.

Applying for your certificate:

- You should obtain an application form, FP92A, from your GP surgery.
- Complete the form and return it to your surgery for your doctor to sign and send off.
- Your certificate is valid for 5 years and you should receive a reminder a month before it runs out (as long as you register any address change).

Even fewer people receiving recommended health checks

The latest National Diabetes Audit (2014-2015) has shown that even fewer people with both types of diabetes in England and Wales are receiving the recommended annual health checks. The Audit compiled information from 1.9million people and was carried out by the Health and Social Care Information Centre (HSCIC).

- Of those under the age of 40 only 27% of those with Type 1 and 40% of those with Type 2 diabetes received all the recommended checks every year.
- The number of people receiving all the recommended health checks is the lowest in six years since records began in 2009-2010 when 38% of people with Type 1 and 58% of people with Type 2 diabetes received all the checks.
- There are still wide variations in care and treatment in different areas – in some 80% of those with diabetes received all the checks but in other areas it is as low as 24.8%.
- There has been a significant improvement in blood pressure as three-quarters of people are now meeting their blood pressure targets. However, only 18.9% with Type 1 and 41% with Type 2 diabetes met all three targets for HBA1c, blood pressure and cholesterol.

We all have to be worried that not only is the care of people with diabetes not improving but on some measures, it is actually getting worse. Clearly, the Health and Social Care Act has done little to help people with diabetes, especially younger people. We need urgent action from CCGs to help people to manage their diabetes and avoid complications.

Is assessing Clinical Commissioning Groups the answer?

NHS England is planning new measures to make it clear how local services are performing. There will be a Clinical Commissioning Group Improvement and Assessment Framework rating 6 clinical areas of health, diabetes being one. However, there are only two measures for diabetes being looked at:

- the percentage of people achieving 3 NICE targets for HBA1c, blood pressure and cholesterol.
- the level of diabetes structured education.

This has been described as a big step forward but it is difficult to see how this will improve all aspects of care, such as poor foot care.

No knowledge of where education programmes are held!

Keith Vaz MP asked the following Parliamentary Question:

How many (a) DESMOND and (b) DAFNE programmes, in which areas, are provided by clinical commissioning groups in England? [32123]

Jane Ellison MP, Minister responsible for diabetes answered on March 24th 2016: *"This information is not held centrally."*

IDDT comment: while the National Diabetes Audit may show the overall numbers of people receiving care and diabetes education, NHS England and government have no idea where education programmes are available, or more importantly, not available. This leaves them in a position where they cannot put pressure on poorly performing CCGs to ensure that improvements are made – yet another example of the fragmentation of the NHS.

If you don't have a certificate or it is being processed you will need to pay but...

- Ask your pharmacy for a receipt, FP57, and refund claim form.
- You will be able to claim the money back when your certificate has been issued because it is backdated a month before it is issued.

Increased prescription charges

People with Type 2 diabetes, not taking medication have to pay for their prescriptions and from April 1st 2016 in England, prescription charges increased by 20p per item - from £8.20 to £8.40. The costs of prescription prepayment certificates have been frozen for another year at £29.10 for 3 months and £104 for a year.

90% of people do not pay prescription charges but many of those who do, are often prescribed several medicines. According to the Prescription Charges Coalition, 1 in 3 people with long-term conditions have not collected a prescription item because of cost. This can lead to poorer health, expensive hospital admissions and affect productivity at work.

Obese people can use short needles

It was, and maybe still is, widely believed that obese people need longer needles for good diabetes control. While it has been known for some years that this is not the case, a recent study has now confirmed that there are no significant differences in HbA1cs when groups of obese people used 4mm, 8mm and 12.7mm needles. The study also showed that 4mm needles caused less injection pain than longer needles.

The first National Diabetes Insulin Pump Audit Report

This has recently been published and due to lack of space in the issue, will be covered in the September Newsletter.

The connection between diabetes and gall bladder problems

People with diabetes have more gallstone problems than people in the general population but the reasons for this are unclear.

There are several theories:

- People with diabetes (Type 2) are often overweight and obesity is linked to gallstone disease.
- People with diabetes have higher levels of the triglycerides (fats), which increases the risk of gallstones.
- It may be that gallstones form because of autonomic neuropathy, damage to the involuntary nerves that control movement of bowels and gallbladder.
- Recent research in insulin resistant mice has shown that a specific protein involved in diabetes increases the amount of cholesterol that enters the bile which may lead to the formation of gallstones. (Cholesterol is a major component of gallstones)

For people with diabetes, the way to decrease the risk of developing gallstones is to try to have good diabetes control which will reduce the risk of autonomic neuropathy and keep triglyceride levels lower.

Symptoms of gallstones

Some gallstones do not cause any symptoms and do not need treatment but in many people gallbladder 'attacks' may occur, especially after eating a fatty meal, then the symptoms may include:

- Sudden pain in the right upper abdomen which can last for several hours.
- Pain between the shoulder blades or under the right shoulder.
- Abdominal pain centred on the right side that gets worse after eating.
- Unexplained nausea or vomiting.

Treatment

Avoidance of gallbladder problems is better in people with and without diabetes and the best way to do this is by consistently eating a balanced diet, getting enough exercise and generally good management of their overall health.

In most people with or without diabetes, when gallstones are problematic, the treatment is surgery to remove the gallbladder.

National Clinical Directors announced

National Clinical Director for Obesity and Diabetes

Professor Jonathan Valabhji MD FRCP post as National Clinical Director for Obesity and Diabetes has been extended. He is a Consultant Diabetologist, Physician and Endocrinologist at Imperial College Healthcare NHS Trust with his current research focussing on diabetic foot disease.

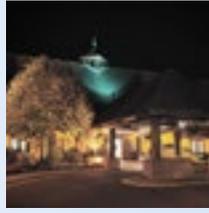
Associate National Clinical Director for Diabetes

Dr Partha Kar has been appointed as Associate National Clinical Director for Diabetes – a new position and interestingly not 'Obesity and Diabetes'. Dr Kar told the Diabetes Times, "There are many areas we need to look at within Type 1 diabetes care, such as how we work closely with Vanguards and free up more innovation. There are exciting times ahead, which hopefully can translate into improving care."

It is good to see that he places an emphasis on Type 1 diabetes! Dr Par is a Consultant in Diabetes & Endocrinology at Portsmouth Hospitals NHS Trust and one of his main areas or passions is in helping to redesign diabetes care in an attempt to integrate chronic disease management across primary and secondary care.

IDDT Conference 2016 – ‘Best Foot Forward’

We are pleased to announce that this year we are holding a conference again at the Kettering Park Hotel. You will see from the conference booking form accompanying this newsletter that it will be an interesting day with speakers and group discussions led by the diabetes nurses from Kings Lynn. The title is ‘Best Foot Forward’ to reflect our concerns about the standards of foot care for people with diabetes and there will be a talk by a podiatrist.



We hope that many of you will be able to join us, so the date for your diary is October 15th 2016!

Holiday Tips

Holidays are approaching and whether staying in this country or going abroad, for families with diabetes, this means more planning and a bit more care when you are away. IDDT has a Holiday Pack which contains information and useful tips for holidays.

If you would like one of our packs of Holiday Tips, just call IDDT on 01604 622837, email enquiries@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS. The Holiday Tips are also on our website: www.iddtinternational.org

IDDT New website

In March 2016 we launched our new website – if you haven't visited it yet, take a look by visiting www.iddtinternational.org

IDDT 14-mile challenge: Fundraising Pack

The third annual IDDT 14-mile challenge takes place on Saturday, July 9, 2016, and will see fundraisers walk, run or cycle their way along the Brampton Valley Way from Market Harborough, in Leicestershire, to Northampton.



They will be meeting outside the Cinnamon Lounge, in Northampton Road, LE16 9HD, from 9.30am and leaving at 10am. Following the challenge, participants will gather at the Windhover pub, in Chapel Brampton, NN6 8AA, which is very close to the finishing line.

A limited number of lifts will be available back to Market Harborough. For more information and to join in, contact the organiser Oliver Jelley by emailing oliver.jelley@ojpr.co.uk or by calling 07803 003811. Registration form and tips on fundraising are available on the homepage of our website: www.iddtinternational.org

Here are some of our valiant supporters at the end of the first IDDT challenge.



Why antibiotics for people with



There has been much written about the overuse of antibiotics because of the spread of drug-resistant bacteria which reduces the ability to control infections. Antibiotic resistance means that current antibiotics may not work and very few new treatments are being developed. An organisation called ‘Antibiotic Action’ asked IDDT to pass on information about the use of antibiotics in people with diabetes because diabetes can increase the risk of infection.

How can diabetes cause infection?

- High blood sugar can damage blood vessels and cause poor circulation. White blood cells and other aspects of the immune system, as well as nutrients that help the healing process are less able to get where they are needed.
- Loss of sensation, particularly in the hands and feet, can make it difficult to notice small wounds that can get infected so it is less likely that people will notice signs of infection.
- Damage to blood vessels in the eyes can cause vision problems, making it more difficult to see signs of infection.

Antibiotics are crucial for controlling these infections and improving health and most people with diabetes will need antibiotics at various times to stay healthy. However, it is vital that antibiotics are preserved so that the spread of bacteria is minimised and people with diabetes are protected against catching antibiotic resistant infections, so:

are important
diabetes

- Don't ask and don't expect antibiotics for colds, sore throats or flu as these are caused by viruses, so antibiotics don't work.
- Only take antibiotics given to you by your doctor and EXACTLY as written on the bottle and always complete the full course.
- Never give your antibiotics to other people.

Another reason to be wary of too many antibiotics!

A study that tracked nearly 164,000 children in Pennsylvania found that healthy young people aged 15 years who had been prescribed antibiotics 7 or more times in their childhood weighed 3 pounds more than those who didn't take these medicines.

The lead researcher said that antibiotics at any age contribute to weight gain. Studies have suggested that antibiotics given to children at age 1 or 2 years contribute to increased weight because the medicines kill off certain bacteria in the gut and leave behind others that break down food differently. This may cause an increase in the calories of the nutrients absorbed.

The researchers examined the medical records of children between the ages of 3 and 18 from 2001 to 2012 and found that children who took an antibiotic put on a little weight then lost it over the next year. However, with each additional antibiotic treatment the weight gain became cumulative and progressive suggesting that this effect is not going to stop at the age of 18 and may continue into adulthood.

While the research had limitations, the researchers feel that the information they have is sufficient to suggest a correlation between antibiotics and weight gain. (International Journal of Obesity, October 2015)

NHS News

NHS Business Plan for 2016/2017

This has been recently issued and is far too long for this Newsletter but there are some key points that directly affect us:

- Diabetes is included specifically but only Type 2 diabetes - the plan is to nationally roll out the diabetes prevention programme. There is no mention of Type 1 diabetes or reducing the complications of those already living with diabetes.
- Improved access to urgent and emergency care, including out of hours GP services by creating a single point of contact through a strengthened NHS 111. The 999 ambulance service is to be reformed to deliver a 'more clinically appropriate service'.
- The improved 111 will allow patients to speak to a clinician, if needed, who will have access to patient's medical records and be able to book them directly to the service they need. (Difficult to see how this will happen as patients have not yet given consent for electronic records to be available.)
- By March 2017 there will be support for hospitals to roll out 7 day emergency care and diagnostic services to 25% of the population across 9 parts of the country and to expand this to cover the whole country by 2020. (At the time of writing, junior doctors are still striking about this!)

Helping healthcare professionals to reduce insulin errors – 'Six steps to Insulin Safety'

In 2010 the National Patient Safety Agency (NPSA) stated that there should be a training programme for all healthcare professionals who prescribe, prepare and administer insulin. Nurses have also expressed their concerns about being able to support people with diabetes in the community who need help in administering their insulin.

A free e-learning programme has been developed by the Primary Care Diabetes Society and TREND UK aimed to reduce insulin errors in clinical practice. The course takes an hour to complete and a downloadable certificate with CPD points will be issued.

The first part of the programme helps community teams to manage their caseloads. The second part is guidance on developing an insulin delegation programme where a registered nurse can allocate responsibility for insulin administration to a non-registered person.

The training has to be good but it is 6 years since the NPSA requirement was stated, so is this more about relieving the workload of registered nurses?

Investment to support diabetes services in Northern Ireland

In March, the Health Minister for Northern Ireland announced an investment of £1.7million to support diabetes services. The investment will focus on several high priority areas including:

- Implementing a diabetes foot care pathway to help to reduce the risk of amputations.
- Improving access to structured diabetes education for people with newly diagnosed Type 2 diabetes.
- Improving access to insulin pumps
- Improving services for women who develop gestational diabetes.

The funding will also support the setting up of a Diabetes Network that will "underpin a more collaborative approach to improving the health and wellbeing of people living with diabetes and, importantly, those at risk of developing Type 2 diabetes".

Helping people in Uganda

IDDT tries to help people with diabetes around the world. We have recently sent out our booklets to Robert in a rural part of Uganda. He is 27 and has had Type 1 diabetes since he was 17 years old. He co-founded the Diabetes Consultation Association which helps people in his area to understand their diabetes, how to manage it and to try to improve the allocation of treatment. Here is Robert receiving the latest parcel IDDT sent to him.



£2.7million research award to develop DAFNEplus

In March 2016, the National Institute for Health Research (NIHR) awarded researchers in Sheffield £2.7million to develop a further education programme called DAFNEplus. The intention is to build on the 5 day DAFNE education programme for people with Type 1 diabetes launched in the UK in 2002.

In the 14 years since it started, 30,000 adults with Type 1 diabetes have taken part and most people have found DAFNE useful. However, one week of high-quality structured education does not offer enough help and support for a lifelong condition that will enable most people to manage their condition effectively and prevent complications.

DAFNEplus aims to give people the support, advice and skills they need to keep managing their glucose levels throughout their lifetime and allow them to tailor it to their lifestyle. The lead researcher, Professor Simon Heller said:

"While DAFNE has been successful in delivering a step change in the way Type 1 diabetes is treated in the UK, it is clear that we need to look at how we can help people sustain the behaviours needed to manage their diabetes successfully on a permanent basis.

DAFNEplus will take this forward with the aim of developing a lifelong package of support and training. At the core of this package will be the use of technology which will assist in breaking down many of the barriers to managing glucose levels including complex calculations of insulin doses and having to count the carbohydrate content of every meal, with the overall goal of helping people live better in managing their condition themselves."

The research is expected to be completed in five and a half years.

Jeremy Hunt Watch



Petition on No Confidence in Jeremy Hunt , Health Secretary

"Mr Hunt recently gave totally inappropriate advice to Google conditions before seeking medical opinion. He referred to Paramedics as Ambulance Drivers and has caused the first Doctors strike in years of the NHS. Mr Hunt is destroying all staff morale in the NHS and will cause recruitment issues."

This petition received 329,487 votes but the House of Commons Petitions Committee decided not to debate it because it does not have the power to schedule debates on motions of no confidence and the petition does not contain a specific request for action on policy.

(Apologies if he has resigned by the time you receive this Newsletter!)

Nurses at tribunals will get credit for honesty

Jeremy Hunt hosted a 'global patient safety summit' on March 9th and announced that as part of a shift towards transparency, if a nurse or midwife makes a mistake but acknowledges it and apologises, they will get credit for it from the Nursing Midwifery Council. He said that any nurses, midwives or doctors who are called to a professional tribunal for a mistake will get credit if they are honest but a "serious sanction" if they are dishonest. He added, "We need to unshackle ourselves from a quick-fix blame culture and acknowledge that sometimes bad mistakes can be made by good people."

NICE Updates

Guidance on the MiniMed Paradigm Veo System

In February, NICE published final guidance recommending the MiniMed Paradigm Veo System (made by Medtronic) for managing blood glucose levels in some people with Type 1 diabetes. The 'some people' are those who have frequent disabling low blood sugars (hypoglycaemia) despite optimal management with an insulin pump. Severe and disabling hypos can affect many aspects of daily life and result in significant anxiety, not only for the person with diabetes but also for their carers.

The MiniMed Paradigm Veo System consists of a glucose sensor placed under the skin which continuously measures glucose levels, an insulin pump which continuously delivers insulin and a transmitter that sends glucose level readings wirelessly from the sensor to the pump. The system alerts the user if glucose levels become too high or low, if levels are rapidly changing, or if the system predicts levels will be too high or too low in the near future. An automated low glucose suspend function operates independently of user action and stops insulin delivery for 2 hours if the user fails to respond to the alert.

But improvements are needed...

Professor Carole Longson MBE, Director of NICE commented, "The committee considered that current evidence suggests that the MiniMed Paradigm Veo system may have benefit in reducing rates of severe hypoglycaemia. But the overall evidence base to support the best use of integrated sensor augmented pump therapy systems needs to be improved. The guidance therefore recommends that the company makes arrangements to collect, analyse and publish data to demonstrate that using the MiniMed Paradigm Veo System results in a sustained clinical impact on preventing or improving control of disabling hypoglycaemia."

Note: the Vibe and G4 PLATINUM CGM system, another integrated automated glucose monitoring system without a low glucose suspend function were also considered by NICE but it concluded that there is currently not enough evidence to support its routine adoption by the NHS.

Petition for continuous blood glucose monitors to be funded by the NHS

A petition with 10,879 signatures was put forward to the government saying that continuous blood glucose monitoring systems should be available to everyone. The answer was as follows:

"NICE has found that, in some cases, continuous glucose monitoring can have benefit but generally it is not more effective than current methods of self-monitoring. NICE keeps all guidance under review..."

"In August 2015, NICE published guidelines which recommend that such devices should not be made routinely available to people with Type 1 diabetes unless they are willing to commit to using them at least 70% of the time and to calibrate them as needed. NICE will next consider updating this guidance in 2 years' time." (Issued in March 2016)

And in Europe...

FreeStyle Libre system approved for use in children, manufacturers negotiating with NHS.

European regulators have approved the FreeStyle Libre system for use in children. Its manufacturer, Abbott, is now negotiating with the NHS to have the system provided free to children with Type 1 diabetes – it normally costs £96 per month.

We have described the Libre system in previous Newsletters because it seems like the answer to our prayers. It is a small device, about the size of a £2 coin, which provides blood glucose readings without the need for finger pricking. The patch is placed on the upper arm and a filament the width of three human hairs pierces the skin. It then reads glucose levels in the fluid in the cells (interstitial fluid). When the patch is scanned this information is sent to a digital reader. Unlike many continuous glucose monitoring systems, the Libre does not have alerts for high and low blood glucose levels.





RESEARCH

New research – long-term use of Victoza could lead to increased blood glucose

Victoza (liraglutide) is a GLP-1 receptor agonist used to treat people with Type 2 diabetes because it stimulates the production of insulin. Researchers in Miami and Sweden have carried out a study in mice where they implanted the mice with human insulin-producing cells. The mice were then given daily doses of Victoza for 250 days and the researchers monitored how the pancreatic beta cells were affected.

Initially there was an improvement in the beta cells but they eventually became exhausted and produced less insulin in response to glucose which resulted in higher blood glucose levels. So Victoza became less effective over time but as the study was conducted in mice, clinical studies involving people need to be carried out to validate these findings in people.

The researchers state that this is a very important discovery because there is a lack of long-term studies of Victoza in people with diabetes and question whether these results need to be taken into account before prescribing this class of drugs for long-term treatment.

This also highlights that with new drugs or insulin, there is a lack of evidence about the long-term effects they may have. (Cell Metabolism, March 2016)

'Mini-dose' of glucagon possible option for hypoglycaemia in Type 1 diabetes

Research has investigated whether treatment with a mini-dose of glucagon is an effective treatment of hypoglycaemia in adults with Type 1 diabetes. The study involved 12 adults using insulin pump therapy and showed that a mini-dose of ready to use subcutaneous glucagon is an effective, alternative treatment for mild hypoglycaemia. Further trials are taking place comparing mini-dose glucagon and oral glucose treatment of mild hypoglycaemia to assess efficacy and patient acceptability. This treatment could have advantages of treating hypos without the consumption of additional calories, avoidance of the problems of overshooting with oral carbohydrate and avoidance of nausea and other adverse effects from large doses of glucagon. (Diabetes Care, February 2016)

Comparison of Eylea, Avastin and Lucentis for the treatment of diabetic macular oedema

A 2 year trial compared all three drugs that are used to treat diabetic macular oedema – Eylea (afibercept), Avastin (Bevacizunab), and Lucentis (ranizumab). Diabetic macular oedema is swelling or thickening of the macula due to leakage of blood vessels on the

retina. The macula carries out the pinpoint vision for such things as reading, so these three drugs have been a great step forward. They are injected into the eye and work by inhibiting vascular endothelial growth factor (VEGF) which promotes the growth of abnormal blood vessels and leakage. The drugs all have a similar way of acting but they differ in cost, with Avastin being considerably cheaper.

Most participants received monthly injections during the first six months. Thereafter, they received additional injections of the assigned drug until oedema resolved or stabilised with no further vision improvement. Laser treatment was given if the oedema persisted without continual improvement after 6 months of injections. The results showed:

- There were greater gains in vision with Eylea than Avastin but only in the people starting treatment with 20/50 or worse vision.
- After 2 year, gains were about the same for Eylea and Lucentis, contrary to the one year results which showed Eylea had a clear advantage.
- All three drugs showed similar gains for people with 20/30 or 20/40 vision at the start of treatment.
- After 2 years 41% of people in the Eylea group received laser treatment, compared with 64% in the Avastin group and 52% in the Lucentis group.

The researchers concluded that all three drugs are effective for treating diabetic macular oedema and performed similarly when the vision loss is mild. However, people with vision of 20/50 or worse, may benefit from Eylea, which over the course of the two-year study

outperformed Lucentis and Avastin. (Ophthalmology, February 2016)

NOTE: In March 2016, the Macular Society issued a press release stating that there are inadequate eye health services. The drugs required to treat wet macular degeneration in the general population are the same as those described above. They state that the drugs have to be given promptly because they work best on new, immature blood vessels but once the vessels have matured or the macula becomes scarred they do not work so well.

There have been, and still are, inadequate NHS resources to deal with the demand for the above treatments. The Macular Society hear of many different reasons why follow up treatment is delayed - shortages of qualified staff, lack of appropriate facilities e.g. clean rooms, basically inadequate levels of commissioning and slowness to use new ways of working, such as the training of nurses to deliver injections. However, some areas manage to meet the guidelines so, like many other aspects of care, it is difficult to understand why this cannot be achieved in all areas.

Many people are not aware of how serious delays are or simply accept that delays are inevitable but a delay can cause their vision to deteriorate more than it would have done if the treatment had been given at the right time.

Metformin over time increases the risk of vitamin B12 deficiency

Metformin is the oldest and still the most popular drug for treating Type 2 diabetes and many people take it for many years. It is also used to treat polycystic ovary syndrome. Researchers carried out a study that started with more than 3,000 people over 25 years of age with high blood sugars. They were divided into 3 groups, (i) those who took metformin twice daily, (ii) those who took a placebo (dummy pill) and (iii) those who went on an intensive lifestyle programme that did not include medication.

A new analysis of those taking metformin or a placebo had vitamin B12 levels checked at various points over the years of the study:

At year 5:

- Average B12 levels were lower in the metformin than the placebo group and vitamin B12 deficiency affected 4% of those on metformin compared to 2% not taking it.
- Borderline vitamin B12 deficiency affected nearly 20% of those taking metformin and 10% of those not taking it.
- More people in the metformin group were anaemic than the placebo group.

At year 13:

- Vitamin B12 deficiency was more common in both the metformin group and the placebo group.

Facts about and symptoms of vitamin B12 deficiency

- Vitamin B12 deficiency may cause:
- Fatigue, numbness or tingling.
- Nerve damage which may be irreversible.
- Severe and prolonged B12 deficiency has been linked to impaired cognitions and dementia.
- Anaemia (low red cell count) which is reversible with treatment.

Restoring vitamin B12 levels is easy to achieve with pills or monthly injections. The researchers say that the risk of vitamin B12 deficiency is not a reason to not take metformin but recommend that measuring B12 levels should be considered. (Journal of Clinical Endocrinology and Metabolism, February 2016)

Sources of Vitamin B12

The body does not make vitamin B12 and so we need to obtain it from the animal sources we eat or supplements. Vegetarians may get enough from eating dairy or eggs but vegans should take supplements or fortified grains.





From our own correspondents

Diabetes and lifestyle – so frustrating!

Dear Jenny,

We have been with IDDT for many years and always find your Newsletters interesting.

My husband has had Type 1 diabetes for over 53 years and most times when diabetes is in the press, it refers to obesity and lifestyle as the most likely cause but rarely states the difference between the two types of diabetes.

My husband finds this quite frustrating as he was a very fit, sporty young man when he was diagnosed but mostly we feel for young children and teenagers with Type 1 who might be teased or feel it is their fault. So is it not time for a different title for each group?

Also there are people with Type 2 diabetes who are not obese and do exercise, so this seems a very unfair assumption.

Mrs H. J.

Cornwall

IDDT comment: We have received quite a few calls from people who feel angry at the recent press coverage. Using the term 'diabetes' and associating it with obesity makes people with Type 1 angry because Type 1 diabetes has nothing to do being overweight and cannot be prevented. We also received calls from people with Type 2 diabetes who are not and never have been overweight. Clearly people feel that the adverse publicity is not only inaccurate but is blaming them for having diabetes which understandably, makes them angry.

But can we blame the press? Not really as it is hardly surprising that the media and public now just refer to 'diabetes' when major players use the term 'diabetes' eg the 'Diabetes Prevention Programme'. As I have said earlier in this Newsletter, when the NHS, Public Health England and Diabetes UK, give the programme such a misleading title, we cannot blame the press for following suit. There needs to be a change from the top!

Pycnogenol information

Dear Jenny,

After reading about an IDDT member taking Pycnogenol, I decided to try it as it is also reported to be good for circulation as well as reducing the impact of diabetic retinopathy. I wonder if any of your members who are taking it, have noticed any improvement in their blood glucose levels?

By email

My experience of Specsavers

Dear Jenny,

I thought I'd share my experience of my DVLA field test at Specsavers. I booked in and was told by a sales assistant that I could take the test 3 times, so they would choose the best result at the end. The "room" was a small alcove with a curtain and a crying baby in a pram just outside. I have not taken this test for 6 years so had forgotten how to do it. I was told to fix my eyes on the red dot and shoot the white and green spots. The baby was still screaming and I said the noise was too much so please could the mother of the baby deal with it, or take it somewhere else. The sales assistant wouldn't do that but instead pulled the thin curtain across – hardly sound proofing! The assistant kept walking in and out talking to me and I had several false shots.

At the end the sales assistant came back and was reluctant to let me take the test again. I reminded her I had been told that I could take the test 3 times and insisted on doing it again as the first go I assumed was practice. I was told they don't allow practising! This time there were 3 members of staff behind the curtain laughing and joking, and the sales assistant again kept coming in and out talking to me. The second time she came in she stopped the test saying the optometrist had my first test and he said it would be sufficient. I queried this as I said I had many false positives, the noise factor and the fact I had not been allowed to practice.

It all fell on deaf ears so maybe you could warn others that it may be beneficial to them to phone in advance to see where the machine is positioned in the shop as, in my view, there should be a quiet room. I'm sure students wouldn't be expected to sit their exams in the middle of a nightclub!

Name provided

If you have any information, just let Jenny know on jenny@iddtinternational.org or call her on 01604 622837

Children diagnosed with Type 1 diabetes at the age of six years or under develop a more aggressive form of the disease

A study led by Exeter Medical School found that children with Type 1 diabetes aged 6 and under are left with very few insulin-producing beta cells in their pancreas at the time of diagnosis but those diagnosed as teenagers still retain large numbers of beta cells. Researchers analysed the largest ever collection of pancreas samples from people with Type 1 diabetes and the findings could lead to new approaches to treatment.

This study provides clear evidence that children diagnosed at a younger age have a more aggressive form of the disease. Insulinitis, an inflammatory process, kills off nearly all the beta cells in the young children. However, the progression of Type 1 diabetes is very different in those diagnosed as teenagers where unexpectedly high numbers of beta cells are retained at diagnosis, although they no longer work as they should. This suggests that the cells are dormant, not dead. It was previously thought that teenagers had lost 90% of their beta cells but this is not the case.

The next steps are to find a way to reactivate these cells so that they can release insulin and to find out why Type 1 diabetes progresses differently in younger and older children. For the future of younger children, it is important to find out whether they might benefit from research into halting the immune attack on the beta cells. (Diabetes, Feb 2016)

Gender Differences in Type 1 diabetes

A recent study has shown that adolescent girls with Type 1 diabetes had worse glycaemic control, higher HbA1cs at diagnosis and were more likely to have complications, such as retinopathy in adulthood, compared with adolescent boys with Type 1 diabetes. The findings, based on 4,239 Swedish adolescents and young adults, also found that girls had a higher HbA1c during adolescence. (Journal of Diabetes and Its Complications, Feb 2016)

Reduced deep sleep tied to poor glycaemic control in children with Type 1 diabetes

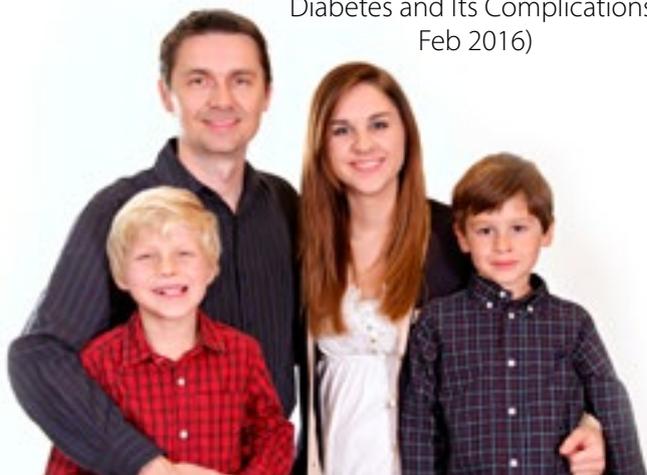
Children and adolescents with Type 1 diabetes have a significantly reduced percentage of efficient and deep sleep time compared to their healthy peers which, in turn can lead to poor glycaemic control. The researchers made every effort to improve control in the children with Type 1 diabetes, then analysed data from 30 children (15 boys) who had diabetes for an average of 9.25 years and 10 healthy children, average ages 15 and 14 years respectively. They found that children with Type 1 diabetes had a reduced percentage of time spent in deep sleep and the efficiency of deep sleep was also reduced in children with diabetes vs. healthy children (41.42% vs. 54.46%). This coincided with non-optimal, long-term glycaemic control.

The researchers say that the quantity and quality of sleep can be important for glycaemic control in children and adolescents with Type 1 diabetes and paediatricians should put more emphasis on sleep in patients with diabetes. (Presented at: ATTD Annual Meeting; Feb. 3-6, 2016; Milan)

HbA1c levels and risk of severe hypoglycaemia in children and young adults with Type 1 diabetes from Germany and Austria

In the past it has been shown that low levels of HbA1c could predict a high risk of severe hypoglycaemia, but it is uncertain whether this association still exists. Because of advances in diabetes technology and pharmacotherapy the researchers hypothesized that the association between severe hypoglycaemia and HbA1c has decreased in recent years. To investigate this they analysed data of 37,539 patients with Type 1 diabetes looking at associations between severe hypoglycaemia, hypoglycaemic coma, and HbA1c levels. They found that the previously strong association of low HbA1c with severe hypoglycaemia and coma in young individuals with Type 1 diabetes has substantially decreased in the last decade, allowing achievement of near-normal glycaemic control in these patients.

<http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1001742>



SNIPPETS

Apps for diabetes

There are around 300 apps available for diabetes. They are mainly for people with Type 1 diabetes and also people with Type 2 diabetes using insulin, for example to help with carb counting. Diabetes UK estimates that apps are only used by 10 to 15% of people with diabetes. Obviously they are largely used by younger people.

People in Liverpool most likely to self-diagnose

Information from 61 million UK internet searches for 160 leading health conditions shows that online self-diagnosis is most common in Liverpool and least common in York. The trend for self-diagnosis rose by 19% in the last year with an average of an extra 848,000 searches per month.

Rising numbers of children start school underweight, anaemic and hungry

We hear a lot about children being obese but a rising number of children are starting their first and final years of primary school underweight and a rising number of infants and pregnant mothers are anaemic. These are the findings in a report by the All-Party Parliamentary Group on Hunger entitled, 'Britain's not-so-hidden hunger'.

- More than 1 in 5 children at some schools arrive hungry each day.
- In some parts of the country a significant number of pupils say they feel hungry and complain of persistent hunger.
- For some children their free school meal may be the only hot food they eat each day.

For one reason or another, a quarter of poorer families are not taking up their entitlement to Healthy Start vouchers so do not benefit from free milk, fruit and vegetables. The Group recommends that the Health Minister takes immediate action to increase the take up of Healthy Start vouchers. The chair of the Group asks, 'How can the world's fifth richest nation not know the extent of physical damage caused to its own children by a lack of food?'

From your editor – Jenny Hirst

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It's eating too much!

Cornell University researchers have found that despite the bad reputation of junk food, fast food and soda, they are not the root cause of America's obesity epidemic. Such foods are sugary, have a high salt content and are not good for health but the researchers found no significant difference between how much of these foods overweight or normal weight people consumed. The main driver making people overweight or obese is that too many Americans eat too much.

The researchers emphasise that these foods are not good for people and there is no case for drinking sugary drinks but just eliminating them is not going to achieve a significant reduction in overweight and obesity. "We need to cut back on total consumption and be better about taking exercise." (Nov 2015, Obesity Science & Practice)

Cholesterol in eggs may not hurt heart health

Research in Finland has found that eggs and other dietary cholesterol may not raise heart disease risk, as was previously thought. Even carriers of a gene, APOE4, which increases sensitivity to dietary cholesterol, were not at increased heart disease risk.

The study tracked the dietary habits of 1,000 middle-aged men, all of whom had healthy hearts at the start and about a third carried the gene APOE4. The average dietary cholesterol consumed was 398 milligrams (mg) and no one reported eating more than one egg per day, on average. One medium-sized egg has approximately 200 mg of cholesterol.

At the end of the 21-year tracking period, 230 of the men had experienced a heart attack but neither egg habits, nor overall cholesterol consumption, had any bearing on heart attack risk or the risk for hardening of the arterial walls.

The American Heart Association dropped its daily cholesterol limit recommendations many years ago and instead, stated that saturated fat and sugars, along with lack of exercise, are more likely culprits in terms of heart disease risk. (American Journal of Clinical Nutrition, Feb 10, 2016)

