

In this issue...

- Diabetes in Older People
- National inpatient audit shocking findings
- High blood glucose levels after exercise
- Pancreas and islet transplantation
- Gum disease
- More about driving

The NHS Seems To Be About Processes, Not People!

Many years ago when Mrs Thatcher proposed the first major changes to the NHS, I remember the late Professor Harry Keen saying that when changes are proposed, absolutely nothing happens to benefit patients for the following two or three years, by which time there may be another government in power! He went so far as to say that government time spent discussing potential changes meant that the government actually did nothing and didn't have to put more money into patient care in the NHS.

I have thought of this often over the last couple of years and wondered if what we are seeing is a similar situation.

Oh, no doubt the government would tell us that they are investing millions for the future of the NHS which, as we are so frequently told, faces increasing demands due to the aging population, increasing numbers of people with long-term conditions and increasing costs of treatments and increasing expectations. In fact, according to a National Audit Office Report they are spending a lot of money:

- the NHS reforms had cost £1.1billion by the end of March 2013.
- Over 10,000 staff were made redundant at a cost of more than £430million.
- Average redundancy payouts per person were £43,095 and 2,200, almost a quarter of those made redundant, were subsequently reemployed by the NHS but these sums could not be reclaimed unless the staff were re-employed within 4 weeks.

So yes, it is true the government has spent a lot of money, £1.1bn to be precise but in practical terms of improvements in patient care, what have the changes meant for us? From the patient perspective, so far the changes seem to be all about processes and not about people!

We now have a system and NHS structure that we, those who pay for it and those who use it, don't understand. We can't complain because we don't know who to complain to. There is confusion – it was announced that PALS, the first port of call for complaints, was to be shut down in April 2013 and the website was shut down but in some areas PALS still exists and in others it doesn't!

We can't write to the people involved in decision making because we can't find their addresses. Maybe this suggests incompetence on my part, but as the Co-chair of IDDT, I wanted to write to the new Clinical Director for Obesity and Diabetes but could I find an address for him? No, all that I could find was his NHS Hospital Trust where there are four hospitals listed, so which one should I write to?

Maybe we get angry and frustrated that we have to wait 2 weeks for a GP appointment, that waiting in A&E takes a long time or hospital inpatient treatment no longer meets the targets that were around a couple of years ago. Our anger is understandable but it should not be directed at NHS staff, the vast majority of whom are doing their best under difficult circumstances. They are overworked and having to manage cuts in budgets at the same time as having to deal with the biggest ever changes in the NHS, often imposed from on high.

The responsibility rests with politicians who made these decisions and who often ignored the advice of those working in the NHS, not to mention

patients' views.

Included in this Newsletter are the details of the national audit for hospital inpatients with diabetes. It shows some relatively small improvements in some areas on the previous year but shockingly, it shows that in one week, 60 people with diabetes developed diabetic ketoacidosis [DKA] while in hospital – shocking because this is caused by a severe lack of insulin. This is a clear demonstration that changing processes in the NHS has a long way to go to stop poor care. Will the NHS changes ensure that the education of those looking after people with diabetes in hospital is good enough to prevent these unnecessary and potentially dangerous situations?

Introducing Journal Watch On IDDT's Website

IDDT is pleased to announce that we are now working with the well-known healthcare writer, Jim Young. Jim qualified as a nurse before going on to molecular biology research at the medical School, Swansea and now concentrates on healthcare writing.

He is Editor-in-chief of Glycosmedia http://www.glycosmedia.com He also writes the Diabetes Journal Watch feature for Doctors.net.uk http://www.doctors.net.uk/ the largest and most active network of GMC authenticated doctors in the UK. He also writes a similar monthly Healthcare News feature http://www.diabetes.co.uk/healthcare-news/index.html

Jim is writing a monthly Journal Watch for IDDT which will be on the homepage of our website, so make sure you check it each month.

However, in July Jim found himself in an unexpected situation. Here he explains why...

I sat opposite my GP for the results of some blood tests that I had requested to explore the unlikely scenario of a calcium / vitamin D dysfunction being the cause of some longstanding muscular skeletal pain. (OK, I blame Googling for that long-shot). Luckily my GP glanced at my concurrent ringworm infection and my 64 year old countenance and ordered a full gamut of tests. But as a "fit", normal weight (no car), fish eating "vegetarian", who swims

in the sea all year around I was not expecting any embarrassment to the smug edge that I thought I had on our familial longevity. But Io and behold! My fasting blood sugar was 7.7 (7.6 on repeat), my lipids 7.0, and my TSH 7.0 (although T4 was normal). Gulp! So I am not immortal after all! Although the HDL of 1.8 might help.

My lifestyle needed little adjustment other than cutting out the lovely butter and cheese etc. So it was time to take the pills - with Metformin and Simvastatin being prescribed as the entré.

So should I now read the papers in the Journal Watch with an obsession born of anxiety or do I (as a self-defence mechanism) scan read them as of no immediate pertinence to me? But The Relationship between Type 2 Diabetes Mellitus and Related Thyroid Diseases http://www.hindawi.com/journals/jdr/2013/390534/ for example. interestingly confirms a genetically base for a cohort of signs and symptoms - be it one over which I have no control. So perhaps it is advisable to take the pills, review in three months, and to revaluate treatment in light of target achievement. There will be time enough to investigate choices at the bifurcations in the treatment algorithm when glycaemic control and possible / probable sequelae demand it. But is it not interesting to consider the dichotomy between the "self delusion" of relishing the third person singular of the clinical paper and one's irrepressible academic interest in the latest research, with the investigation of one's own signs, symptoms and treatment choices, such as taking advantage of the National Retinal Screening Programme.

In future essays I will explore the realities of the interface between my clinical evaluation of the disease process and the subjective experience of the symptoms and treatment. The Metformin for example did not result in the gastrointestinal disturbance that I thought might have.

I have a whole hour booked with the diabetic nurse this month - I guess for a head to toe assessment. The tricky problem that I now have is how to explain my reasonably good understanding of the pathology of diabetes whilst ensuring that my need for education as a patient is not overlooked. After all it is a new experience for me. I may even get a blood meter to test my ability not to obsess with post prandial readings - after all my HbA1c was 51mmol/mol before starting treatment. But I do miss the bread and honey that I had for breakfast for the past thirty years - although this muesli stuff isn't half as bad as I thought.

National Audit Of People With Diabetes In Hospital Shows Needs Being Neglected

On June 27th this year, the National Diabetes Inpatient Audit [NaDIA] commissioned by the Healthcare Quality Improvement Partnership, revealed that in just 5 days more than 60 hospital inpatients with diabetes developed diabetes ketoacidosis [DKA].

DKA is potentially life-threatening but preventable and the report says that it is 'shocking' that during their hospital stay people should develop DKA as it is a result of a severe shortage of insulin. Indeed, the audit clinical lead, Dr Gerry Rayman said, "...But staffing levels remain low, and it is of grave concern that some patients are developing DKA, which is a potentially life-threatening complication in hospital. This is due to their needs being neglected and should simply never happen."

The report also found that the majority of hospitals made medication errors – during the 5 days of the audit and more than a third of patients with diabetes experienced a medication error.

NaDIA examined information collected by hospital teams in England and Wales about inpatients with diabetes over a five-day period in September 2012, covering issues such as staffing levels, medication errors and patient experience. It involved 13,410 patients with diabetes in 136 trusts in England and six local health boards in Wales. Over this period, 15.3% of inpatient beds were occupied by people with diabetes, although the majority of people included in the audit were admitted for medical reasons other than diabetes. The aim of the NaDIA is to drive improvements in care for inpatients with diabetes.

What did the audit show? Diabetes ketoacidosis [DKA]

59 inpatients (0.5%) in England developed DKA after their admission to hospital, which was similar to 2011 and 2010. Two patients (0.2%) in Wales developed DKA after their admission to hospital, which was similar to 2011. While the percentage of patients affected is low, this life-threatening condition is entirely preventable.

Hypoglycaemia

Just over 20% of patients in England and Wales experienced a mild hypoglycaemic episode while in hospital [between 3.00 and 3.9mmol/l] and

10.5% of patients experienced a severe hypoglycaemic episode while in hospital [less than 3.0mmol/l]. These hypos are largely avoidable.

Medication errors

The most common medication error in England and Wales was insulin not being increased when blood glucose was persistently high. Other recorded errors included insulin not being reduced when appropriate, staff failing to note that they had given insulin or writing medication notes unclearly and insulin being given at the wrong time.

- Around one third (39.8%) of inpatients in England included in the audit experienced at least one medication error while in hospital, compared to 40.0% in 2011. So this is improving, a little. The figures were similar for Wales and the same as 2011.
- Insulin prescribing errors decreased, particularly the unsafe practice of abbreviating units to 'U' on prescribing charts an error that can result in a fatal overdose as, for example, 10u can be misread as 100 units.

Staffing levels

- Among the inpatients who should have seen a specialist diabetes team, just 58.5% in England and 59.0% in Wales actually saw one.
- 32.2% of sites in England and 47.1% in Wales had no diabetes inpatient specialist nurse provision for inpatient care.
- 7.0% of sites in England had no consultant time for inpatient care for people with diabetes but in Wales all sites had at least some consultant time.
- 78.4% of sites in England and 64.7% in Wales did not have any specialist dietician time for inpatient care for people with diabetes.

Podiatry

- For patients admitted specifically for a diabetes complication, 44.2% in England and 56.7% in Wales were admitted with active foot disease.
- All patients with diabetes should have a foot examination on admission. This occurred at some point during their stay for 35.1% of inpatients with diabetes in England and 21.7% in Wales – both of these figures were an improvement on 2011.
- All patients with active foot disease should be seen within 24 hours by a member of the multidisciplinary foot team but this occurred in just over half (53.9%) of those patients admitted with active diabetic foot disease in England and just under half (46.6%) in Wales. Only two thirds (66.7%) in England and just over half (51.7%) in Wales were seen at any time during their hospital stay.

• The number of sites with no inpatient podiatrist service has increased in England (from 26.8% in 2010 to 31.2% in 2012) and in Wales (from 22.2% in 2011 to 47.1% in 2012).

What about patient satisfaction?

The majority of inpatients in England (85.7%) stated they were very satisfied or satisfied with their diabetes care while in hospital (compared to 84.9% 2011 and 80.8% in 2010) and 21.1% of inpatients reported that they had definitely been involved in the design of their care plan. The figures were similar for Wales.

IDDT comment...

Perhaps what is surprising is that there was a high level of patient satisfaction when actually these figures are awful – a point raised by one of our readers from abroad. My response was that we know that the hospital staff are doing their best under very difficult circumstances and generally they are kind to us, so we tend to rate them highly. But is this the only reason? If we are not all aware of what care we should receive, then we don't actually know that we are not receiving it! I suspect that sometimes this is the case, so we will appear to be more satisfied than we should be!

Why Are My Blood Sugars High After Exercise?

We are all led to believe that exercise will lower blood glucose levels and it does, but there are times when exercise actually raises blood glucose levels. IDDT is often asked by people with Type 1 diabetes why this happens.

Exercise normally lowers blood glucose levels, often rapidly, because glucose is necessary for the extra energy needed quickly for exercise or physical activity. This is why exercise is a good way of reducing blood sugars that are a bit high instead of giving extra insulin which may have a knock on effect later.

However, while mostly exercise lowers blood glucose levels there are occasions when it can cause them to be high and the most common reasons

are:

- blood glucose levels are too high when you start to exercise or
- if the exercise you are taking is strenuous.

Whenever blood glucose levels are too high, it always means that there is not enough insulin present to bring them down.

High blood glucose levels before exercise

The muscles need energy for exercise and the quickest form of energy is glucose so the muscles temporarily increase their sensitivity and the same amount of insulin releases more glucose into the muscle cells so that they can carry out the extra exercise. However, if there is not enough insulin in the muscles, they will not receive enough glucose from the blood, even if there is enough glucose in the blood. So the muscles send a signal that they need more energy and the body responds by releasing more glucose but as there is still not enough insulin in the muscles to convert the glucose into energy, the blood glucose levels rise. The muscles continue to send out the signals and more glucose is released, so the blood sugars continue to rise. So if blood sugars are high before exercising, exercise can cause them to rise even higher and the reason is not enough insulin. This is why you are advised not to exercise if your blood sugars are high.

Strenuous exercise

Strenuous exercise can have the same effect and can raise blood glucose levels. This is for the same reasons – not enough insulin. During very strenuous exercise the muscles send their signal for more energy and the body responds by releasing more glucose which in turn raises the blood glucose levels.

Under normal conditions the body uses about 60% of its energy as fat and 40% as glucose. The harder you work, the less fat is used and the more glucose is used until you reach a state of anaerobic activity [weight lifting, fast sprinting] which uses 100% glucose. Although it is not what we expect, the harder you exercise the more insulin your body needs to deal with the increased amount of glucose being released for energy.

With this anaerobic exercise, up to 17 times more glucose is required but such large amounts of glucose are not available from the bloodstream and via the insulin transport mechanism, so it is taken directly from the glycogen stored in the muscle. Insulin is not needed for this process. Insulin is used for the glucose to get into muscle cells so that it can be stored as glycogen but insulin is not needed when glycogen derived glucose is burned in the muscle.

Glucose made from muscle glycogen cannot get into the bloodstream and is burned by the muscle in which it was stored but when the glucose is derived from muscle, the glycogen in the liver also produces extra glucose that goes directly into the blood stream and this is why strenuous exercise [anaerobic exercise] can cause the blood glucose levels to go up. Duringstrenuous exercise, glucose is the primary source of energy for the first 15 to 20 minutes of aerobic exercise and initially 70% comes from carbohydrates. After about 20 minutes, fat becomes the primary source of energy with 70% coming from fat. If the exercise then becomes anaerobic, glycogen reserves in the muscles are used and the muscles will use as much glucose as they need. While high blood sugars after exercise are not what we expect, this somewhat complex explanation offers the reasons.

Warning About Dangerous Herbal Medicine

The Medicines and Healthcare products Regulatory Agency (MHRA) has warned people with diabetes not to believe false advertising claims that they can give up their prescribed diabetes medication if they take Vedagrin, an unlicensed herbal medicine.

The advertisement for Vedagrin (also known as Vendate) promotes the unlicensed medicine as an alternative to prescribed diabetes medication with the words "say goodbye to your diabetes medication forever". This breaks advertising regulations for medicines and the MHRA has instructed the company to stop selling the product.

Richard Woodfield, MHRA's Head of Herbal Policy said: *"If these claims are followed they could have dangerous consequences for people with diabetes. It's important that people buy herbal medicines that have either a PL (product licence) or THR (Traditional Herbal Registration) number on the bottom of the packaging. This means the medicines have been assessed against quality standards."* [July 3rd 2013]

Getting Involved In Research – OK To Ask Campaign

The National Institute for Health Research are running a campaign to highlight research with the slogan: *"It's OK to Ask"*. The campaign is being run during 2013 and 2014 and aims to encourage patients and carers to ask healthcare professionals about taking part in studies, as well as giving healthcare professionals 'permission' to ask patients and carers about taking part in research.

Clinical research is the way treatments are improved in the NHS. Doctors will often tell their patients about research but this campaign aims to keep research at the top of the NHS agenda. In a recent poll only 21% of patients and the general public said they would feel confident asking their doctor about research opportunities.

The details about the campaign and taking part in research can be found at the following website: http://www.crncc.nihr.ac.uk/oktoask

For Those Who Lobbied...

"Diabetes Remains A Priority For This Government" Statement by Anna Soubry MP, Minister responsible for diabetes



In answer to a Parliamentary Question [July 4th 2013] Anna Soubry stated:

"Diabetes remains a priority for this Government. The Department's NHS Outcomes Framework and Mandate outline the improvements in health and health care that we envisage the national health service achieving.

Through the Mandate, we have asked NHS England to make measurable progress towards making the NHS among the best in Europe at supporting people with on-going health problems such as diabetes to live healthy and independent lives, with better control over the care they receive.

Diabetes is also included in the Cardiovascular Disease Outcome Strategy, published in March 2013, which reiterates our commitment to the NHS Health Check programme. NHS England will be working with Public Health England to make the NHS Health Check programme as effective as possible, helping to reduce people's risk of developing diabetes through advice on lifestyle factors and the earlier diagnosis of diabetes.

The Department, through Public Health England, has provided ring-fenced funding for the first time to local authorities to tackle problems such as obesity which can prevent diabetes. Alongside this, we are working with businesses in the food and drink industry through the Public Health Responsibility Deal to help people make healthier choices."

Interesting Parliamentary Questions!

IDDT monitors the Government actions and Parliamentary Questions [PQs] and we thought some of the answers from Anna Soubry might be of interest.

When did the Minister last meet Dr Jonathan Valabhji, National Clinical Director for Obesity and Diabetes. [156331]

Anna Soubry: *"I have not met with Dr Jonathan Valabhji since his appointment as National Clinical Director for Obesity and Diabetes for NHS England in April. As diabetes and obesity are priority areas, I will look to meet with him in the near future."*

Comment: Dr Valabhji's appointment was announced in March yet the Minister with responsibility for diabetes hadn't met with him by May 20th!

Will the Minister make a statement on the contract between NHS IQ and Diabetes UK. [155897]

Anna Soubry: *"NHS Improving Quality is a joint venture between NHS England and the Department and is hosted by NHS England. NHS Improving Quality works with a number of key stakeholders including charities like Diabetes UK to ensure our work is aligned to patients and carers requirements. NHS England advises that NHS Improving Quality has no contract in place with Diabetes UK."*

Comment: Good to know because the real value of organisations representing the best interests of patients is to remain independent of

What plans has the Minister to issue quality and outcome framework targets to GPs for diabetes screening. [155377]

Anna Soubry: "The national Quality and Outcomes Framework (QOF) is a voluntary incentive scheme that provides additional reward to general practitioner (GP) practices for how well they care for patients based on performance against a number of agreed indicators. Since 2004, GPs have been paid incentives for providing the nine basic checks on people with diabetes. Performance and patient care has improved considerably as a result of this."

Comment:

So actually the 9 checks for people with diabetes recommended by NICE are carried out by GPs on a voluntary basis only, or have we got this wrong?

Finally one to make you smile!

Will the Minister estimate the cost to his Department of rebranding NHS Diabetes to NHS Improving Quality. [155379]

Anna Soubry: "NHS England advises that no NHS Diabetes work or materials have been rebranded and existing materials will be used with the old branding until stock runs out. NHS England also advises that new branding has been developed for NHS Improving Quality and that this work was carried out in-house with an estimated development cost of £235." **Comment:** Dear me, was £235 for ink for the printer???

IDDT News

Just a note ...

For people who purchased a KeepSight Electronic Light Mask, apologies that the company's website and details are not available online at the present time. This will be restored but in the meantime if you need to contact the company, then please contact Nigel Rogers, Managing Director on 07717 61353 or email him: n.rogers@lyncolec.co.uk

Calling people at Pallingswick House

Readers may remember previous articles about Pallingswick House - a

boarding school for children with Type 1 diabetes in the 60s. A BBC film was made about Pallingswick and one of the people who went there is trying to trace the film. So if anyone remembers what programme it was on, please can you get in touch. Just give Jenny a call on 01604 622837.

IDDT Christmas cards

We know that it is early to ask you to buy Christmas cards to help our funds but we don't have another Parents Bulletin until December. So please order our cards from the IDDT website < http://iddt.org/iddt-christmas-cards > – every little helps!

New Safety Information On Lantus

On May 30th 2013 the European Medicines Agency [EMA] completed a review of the new information on the cancer risk with Lantus [insulin glargine]. The conclusion was that the information does not show an increased risk of cancer and the balance of the medicine's benefits and risks remain unchanged.

Why the review took place

As IDDT reported at the time, in 2009, four studies raised concern about possible links between Lantus and cancer, particularly breast cancer. At that time, Committee for Medicinal Products for Human Use [CHMP] concluded that the link between Lantus and cancer could not be confirmed or denied and requested that the company that markets Lantus, Sanofi Aventis, carry out further studies.

Two of the three studies carried out were population based which means that information was collected from large numbers of people who were treated with Lantus, human insulin or combined insulin and they looked at the occurrence of breast, colectoral and prostate cancer with the various insulins. The third study was a case controlled study which compared 775 people with diabetes who had breast cancer with a control group of people with diabetes who did not have breast cancer. The aim was to find out if there was a link between the insulins people were using and the occurrence of breast cancer.

The conclusions of CHMP

CHMP concluded that overall the information from these studies did not indicate an increased risk of cancer with Lantus. It also said that there is 'no known mechanism' by which Lantus would cause cancer and that a cancer risk has not been seen in laboratory studies.

What does this mean?

It is important to look at some of the words used here.

- 'No known mechanism' doesn't mean that there is not a mechanism, just that it is not known. In fact, there always has been a possible known mechanism and that is the similarity to insulin-like growth factor. IDDT funded research has also shown that in vitro [in a lab] analogues can increase cell multiplication [mitogenicity] and affect apoptosis, which also increases the number of cells, so tumours could be formed which could be benign or otherwise.
- 'Information from these studies did not indicate an increased risk' takes us back to the statement that absence of evidence is not the same as evidence of absence. In other words the studies do not indicate an increased risk but they have not provided definitive evidence that there is no risk.

Comment

Without wishing to accuse the EMA of being less than honest, it has to be said that insulin analogues are still at the centre of a heated debate at both scientific and clinical levels. This is reflected in the central stage that this topic is given at important international scientific conferences:

- In a recent Gordon Conference on insulin-like growth factors in health and disease (Ventura, California, March 2013) Pierre de Meyts gave a talk on insulin analogues.
- In addition, October 3-5 there is going to be a Symposium on Obesity, Diabetes and Cancer: the role of insulin and IGFs (organized by Antonino Belfiore in Taormina, Sicily). There is an entire session devoted to this topic.
- Late November there is going to be a 2-day symposium involving this topic in Sao Paulo, Brazil, organized by Daniel Gianella- Netto (Editor of Diabetologia and Metabolic Syndrome).

Tresiba And Ryzodeg - A Perspective From The US

In the June 2013 Newsletter we reported that Novo Nordisk's new longacting analogue insulin, Tresiba, and the pre-mix version, Ryzodeg, have been licensed for use in Europe [now available in the UK], Japan and Mexico but not by the FDA in the United States. The US did not grant approval due to lack of information about cardiovascular effects and we questioned the different standards for approval between Europe and the US. If the US wants more proof of Tresiba's safety, why doesn't Europe?

Writing in Endocrine Today [March 2013], Professor Irl B. Hirsch put an interesting perspective on this issue and I quote:

"The FDA decision is both a disappointment and unexpected, but certainly understandable. It also sets a new bar for insulin as far as safety is concerned. I wonder if insulin glargine [Lantus] would have been approved by today's FDA with concern at the time [2000] of the insulin causing diabetic retinopathy. What is clear is that after the recent history of rosiglitazone [Avandia], all diabetes drugs, including insulin, will have a new set of safety expectations we did not see in the past. Overall, this is beneficial in today's world of diabetes, compared to 20 years ago, since we didn't have the choices of other options like we do now."

Note: the safety and efficacy of Tresiba has not been established in children and adolescents below the age of 18 years. There is also 'no clinical experience' of Tresiba in pregnant women and during breastfeeding. This means that studies have not been carried out in these groups of people.

Obituary

It is with sadness that we have to report the death of Barry Robertson whose book we reviewed in our June 2013 Newsletter. Barry was a great supporter of IDDT and the work we do to help people with both Type 1 and Type 2 diabetes.

Barry died on June 2nd, aged 81, after having Type 1 diabetes for 65 years. His wife, Sheila, describes Barry as having led an active life and someone who achieved a great deal. The Trustees of IDDT are extremely grateful for the generous donation to IDDT after a Thanksgiving Service to celebrate Barry's life.

Investigation Of Byetta And Victoza, A Cause For Concern?

An investigation into two drugs for the treatment of Type 2 diabetes was shown on Channel 4's Despatches [June 10th 2013]. The drugs are Byetta [exenatide] and Victoza [liraglutide] and the investigation was carried by the British Medical Journal [BMJ] and Despatches. They uncovered evidence that these drugs may contribute to the causes of pancreatic cancer and pancreatitis.

Byetta and Victoza are injected and increasingly popular for the treatment of Type 2 diabetes. They contain a man-made version of the hormone glucagon-like peptide 1 [GLP-1], which normally is produced by the intestines and prompts the body to release insulin to control blood sugar levels. The drugs also suppress appetite which can help people to lose weight. The investigation found that the manufacturers may be trying to hide potentially harmful side effects. It uncovered documents showing the drugs increase the risk of pancreatitis [infection of the pancreas], which causes 1,000 deaths a year in Britain.

The investigation also found research which showed a number of patients taking the drugs had developed pancreatic cancer, which has the lowest survival rates of all cancers, with only 5% of patients living five years beyond diagnosis. The GLP-1 drugs were first approved for NHS use by NICE in 2009 and around 25,000 prescriptions are issued each year, although it is unclear exactly how many patients are taking them as some get monthly prescriptions

while others receive longer or shorter supplies.

Comments:

- Dr Deborah Cohen, the BMJ's investigations editor, said the individual pieces of evidence 'may seem inconclusive' on their own, but added: 'When considered alongside other emerging and longstanding evidence, a worrying picture emerges, posing serious questions about the safety of this class of drug.'
- Dr Fiona Godlee, BMJ editor-in-chief, said the manufacturers had been 'unwilling to share their data' and that patients and doctors had 'not been kept properly informed about the uncertainties surrounding these drugs'.
- The manufacturers said they were committed to patient safety and insisted they monitor their drugs with rigorous processes.

Other studies

Separate research by the University of California has found that the drugs caused tumours in animals which may lead to cancer. This risk of pancreatitis has been known since the drugs were first evaluated and there have been reported cases. Results from a study by independent academic researchers in the US were recently published which suggest that there is an increased risk of pancreatitis and pre-cancerous cellular changes of the pancreas in patients with Type 2 diabetes treated with these drugs.

The study involved the examination of a small number of pancreatic tissue samples obtained from organ donors, with and without diabetes mellitus, who died due to causes other than diabetes. Some of the patients had received sitagliptin or Byetta [exenatide] in life, both of which belong to the same family of drugs.

The official comment

The European Medicines Agency is currently investigating the information provided by the researchers to determine the need for any change to the way these products are used.

In the US: June 2013, the American Diabetes Association called on manufacturers of this class of drugs [incretin therapies] to disclose all patient-level data on their products for an independent analysis that would help determine if such treatments play a role in pancreatic cancer.

If you have concerns, discuss these with your doctor.

Pharmaceutical News

New insulin pen on the market

Eli Lilly have a new pen on the market – the HumaPen SAVVIO. It is made to look more like a personal accessory than a medical device after consultation with people with diabetes who said they wanted their diabetes to be managed as discreetly as possible. It looks like a fashionable pen and features a compact design - reminiscent of the first pens that came out! It is available in several different colours in the UK for use with Lilly's cartridges of Humalog and Humulin.

The introduction of 4mm pen needles

The recent introduction of 4mm pen needles has been shown to give less discomfort when injecting insulin and to reduce the risk of injecting into muscle instead of the just under the skin [subcutaneous tissue]. Studies suggest that the 4mm pen needles provide reliable subcutaneous injections in adults and recommend them for all children with Type 1 diabetes.

A 4mm pen needle will deposit the insulin under the skin and into the subcutaneous fat tissue with a low risk of injecting into the muscle below the skin. Injecting into muscle is not only painful but will result in quicker absorption of the insulin and may lead to variations in blood glucose levels which are worse with intermediate and long-acting insulins. In addition, if the injection is into a muscle that is then exercised, say the thigh followed by a walk, this increases the risk of hypoglycaemia. Changing the length of your pen needles is something that should be discussed with your healthcare professional.

Novo Nordisk 12mm needle to be withdrawn

In November 2013, Novo Nordisk will be discontinuing the NovoFine 28G 12mm needle. The company says that this is due to newer needles with improved design being developed.

New once-daily injection for people with Type 2 diabetes on insulin

A new drug called Lyxumia has received European approval. It works alongside insulin to regulate blood glucose levels in people with Type 2 diabetes where blood glucose levels cannot be controlled with insulin alone.

It is estimated that over 100,000 people treated with insulin alone have blood glucose levels above the targets despite following dietary recommendations

and a healthy lifestyle because Type 2 diabetes is a progressive disease. It is thought that a third of this group could be helped with Lyxumia, which works by specifically reducing after-meal glucose as well as complementing the reduction in before-meal levels from the insulin. It also helps people to lose weight by preventing the body from storing glucose in fat. It costs £1.90 a day and it is estimated that it could save the NHS at least £7 million over the next 5 years as it is cheaper than many other drugs for Type 2 diabetes.

Diabetes In Older People



It goes without saying that the vast majority of older people with diabetes have Type 2 diabetes. However, as people with Type 1 diabetes are living significantly longer, there are increasing numbers of older people with Type 1 diabetes. As people are living longer, there are also more older people with secondary diabetes, diabetes due to other conditions or the drugs used to treat other conditions, such as steroids.

A few years ago, the 'Golden Years Cohort' study looked

at people who had Type 1 diabetes for 50 years or more and found they had normal body mass index [BMI], low insulin dose, high HDL [good] cholesterol levels and long-living parents.

Unfortunately, it is often assumed that older people with Type 1 diabetes have Type 2 diabetes. This has happened to some IDDT members with Type 1 diabetes who have been denied their usual number of test strips because they are old and so 'must have Type 2 diabetes'! This confusion can be a real problem because if a person with Type 1 has a hypo but they are treated as Type 2, their insulin dose next day could be omitted which would then result in hyperglycaemia and diabetic ketoacidosis.

Understanding Type 1 diabetes in the elderly

Generally Type 1 diabetes in the elderly is not well understood for several reasons. The most obvious is as we mentioned above, people with Type 1 in the past have not lived long enough to know how they and their diabetes change over their lifetime, so much of the knowledge that there is comes

from observations rather than research. The second reason is that in studies older people, such as those over 65, are very often excluded which means for instance, if a new insulin or drug is being tested in trials we don't know if the effects are the same in elderly people as in the younger people. It cannot be assumed they are, especially as many older people will be taking additional drugs for other conditions.

Thanks to an article in Diabetes Update [Spring 2013] we are able to bring you some of the observations from people working in the field.

- The glucose patterns seem to be different in older people with glucose levels lower before breakfast and then rising rapidly afterwards.
- Glucose control can get more 'brittle' with fluctuations between symptomatic hypoglycaemia [lows] and hyperglycaemia [highs] although this is not always the case because retirement and a less hectic lifestyle can lead to improved glucose control.
- The symptoms of hypoglycaemia are less obvious in older people and there may be little warning before they are confused or need assistance, so glucose monitoring is essential, especially for those living alone.
- Diabetes can be harder to manage in older age due to the development of other conditions that may alter the person's abilities or the other treatments may upset diabetes control.
- The frailer person may become very insulin sensitive and therefore needs to avoid hypos. This can be done by raising the HbA1c targets to 8.5% [69mmol/mol]. This can be difficult for someone who for many years has had tight control of near normal blood sugars drummed into them.
- Older people often lose weight so their glucose levels may decrease and less insulin may be necessary.
- Dementia is an increased risk in people with Type 1 diabetes. Avoiding hypos, controlling blood pressure and avoiding Vitamin B12 deficiency may all help to avoid dementia.

Note: IDDT's new 'Passport for Diabetes in Care Settings' is designed to help older people with Type 1 diabetes living in residential care or living at home with carers. For copies please call IDDT on 01604 622837 or email martin@iddtinternational.org.

The management of Type 2 diabetes in older people

This study compared blood glucose control and the treatment received in two groups of people all of whom had Type 2 diabetes for over a year. One group they called the 'young-old' aged between 65 and 79 years and the other group they called the 'old-old' those aged between 80 and 89 years. The study's main measures were HbA1cs and the treatments they were receiving.

Results

- The average HbA1cs were similar in the 'young-old' and the 'old-old' and there was no difference in any of the HBA1cs ranges studied.
- Fewer diabetes medications were prescribed for the 'old-old' group compared to the 'young-old' group.
- Comparing the 'young-old' and the 'old-old', prescribing was as follows: 51% were prescribed metformin compared with 33% of the 'old-old', 6.7% glucagon-like peptide-1 agonists [Exenatide and Victoza] compared with none, insulin [Lantus and Levemir] 24.7% compared with 13% and short-acting insulin 15% compared with 7%

The researchers concluded that blood glucose control was similar in the 'young-old' and the 'old-old'. However, the 'old-old' needed fewer medications in order to achieve the same level of control. [The Consultant Pharmacist, May 6, 2013]

Preventing falls in older people

There was an interesting article about falls in older people published by the Institute for Quality and Efficiency in Health Care [IQWiG] in Germany and the main points in the article may be useful for some of our older readers...

Many older people are afraid of falling, breaking a bone and losing their independence and as a result of this fear, may walk or move less. However, this may have the opposite effect as people who stop being physically active may have a greater risk of falling than someone who walks a lot in everyday life.

How common are falls?

- It is estimated that 30 out of every 100 men and women over the age of 65 have a fall once a year.
- People who have already had one fall are at a higher risk of falling again.
- The rate in people who live in nursing homes or residential care is higher than that in people living in their own homes.

Hazards that increase the risk of falling

It is important to recognise hazards that may cause a fall and try to find ways

to avoid them.

Hazards around the house include:

- loose rugs or carpets,
- electric cables,
- slippery floors and bath mats that slip,
- walking to the bathroom in just socks on wooden floors.

Some of these are avoidable and there are things that can be done to help to avoid falls – remove or ask someone to help to remove the tripping hazards from your home.

Health problems may also put people at greater risk of falls and these include:

- for people with diabetes the most obvious risk of falls is hypoglycaemia, especially at night. Neuropathy and other foot problems related to diabetes also increase the risk of falls,
- problems with vision,
- occasional circulatory problems or dizziness caused by blood pressure being too low or too high,
- conditions that affect balance eg ear infections,
- medications that affect concentration and reflexes, such as certain types of sedatives, and interactions between different drugs can also increase the risk of falls.

Preventing falls when there are health problems involved is not so easily solved and will depend on your health conditions. For example, if hypos occur in the night, make sure that sugary options are available by the bed so that you don't have to wander to the kitchen to find something. Other things that may help include exercise programmes, walking aids, a new pair of glasses and having discussions with your doctor about whether the medications you are using could be a cause and could be changed.

Health consequences of falling

- The vast majority of falls end up being quite minor, even in people over the age of 65, and do not lead to any serious health problems, just a bruise or scrape.
- Fewer than one in ten falls lead to a broken bone. If a bone breaks, it is usually the forearm that is affected. Hip or thigh fractures can also cause serious complications and restrict activities. They can result in longer hospital stays and older people are especially at risk of needing nursing

care as a result of a serious fall.

Nevertheless, it is important to remember that the majority of falls are minor and the best way to avoid them is to stay as physically active as possible.

What The Papers Say

A powerful vaccine to stop diabetes "in its tracks" is within scientists' reach, Daily Express, 11 May 2013



According to this article, a simple jab would transform the lives of people at high risk of developing diabetes and it would be the biggest single breakthrough in treating Type 1 diabetes in almost a century. Dr Alasdair Rankin, Diabetes UK's director of research, said that the ground-

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breaking treatment could be available within 20 years and that a vaccine for Type 1 diabetes is now a very realistic prospect. The article reminded readers that Type 1 diabetes is a chronic, life-threatening condition that is on the increase in the UK, particularly among the under-fives.

Cannabis linked to the prevention of Type 2 diabetes The Independent, 15 May 2013

This article says that research published in the American Journal of Medicine, has shown that regular users of cannabis have been found to have lower levels of insulin after fasting and reduced insulin resistance, which may prevent the development of Type 2 diabetes. If this is proved, it could lead to the development of treatments based on the active ingredient of cannabis, tetrahydocannabinol [THC], without its intoxicating effects.

In the US THC has already been approved to treat the side effects of chemotherapy, nausea in cancer patients, anorexia associated with AIDS and other conditions. In the research involving a survey of nearly 5,000 people, 2,000 had smoked cannabis at sometime in their lives and 579 were current users. Only those who had smoked cannabis within the last month showed evidence of protection against diabetes, which suggests that the effects wear off over time.

Previous research has shown that although cannabis users consume more calories, they have a lower BMI, which is the opposite of what could be

expected.

Cap on number of GP visits being considered by Tories. Independent on Sunday. 26 May 2013

An anonymous Tory consultation on local health provision, buried on the website of the Conservative Policy Forum chaired by Oliver Letwin, asks party activists whether they agree or disagree with the idea of an annual limit on GP appointments. It also asks whether evening and weekend appointments with GPs and consultants are a "luxury the country cannot afford".

The document has been widely condemned for targeting the most vulnerable who need to see their doctor more often than others. Dr Clare Gerada, chair of the Royal College of GPs, said *"I would typically see an elderly patient 10 to 15 times a year, and patients with depression three to four times a month."* She described the idea of an annual limit as *"very short-sighted"* and added: *"People come because they are ill or because we are asking them to come because we are concerned about them. What we should do is fund general practice sufficiently so that we can offer flexible appointment times."*

'Artificial pancreas' promises transform to treatment of diabetes. The Independent, 10 June 2013 This article reported that an "artificial pancreas" has now successfully been used at home - a world first. The device monitors blood glucose levels and then relays information to an insulin pump attached to the patient's body, which adjusts insulin levels accordingly. It has previously only been tested in hospitals, but five people in the UK with Type 1 diabetes have now successfully used it at home, expected to rise to 24 by the end of this year. It will be some years before it becomes commonly available as a treatment for Type 1 diabetes and will initially be used only to stop people's insulin levels from falling too low at night. But researchers said the technology could have developed "within a decade" to a point where users would no longer have to manually monitor blood glucose levels. They also said that one day the artificial pancreas could be used to help people with Type 2 diabetes, but this was still a long way off.

Could artificial sweetener cause diabetes? Daily Mail. 30 May 2013

Splenda 'modifies way the body handles sugar', increasing insulin production by 20% which, according to a new study, could lead to Type 2 diabetes. Splenda is a sugar alternative made of sucralose which causes a person's sugar levels to peak at a higher level which in turn, increases the amount of insulin a person produced.

The researchers said that while they did not fully understand the implications of the findings, they suggest that Splenda could raise the risk of diabetes because regularly raised insulin levels can lead to insulin resistance, which is a known to cause Type 2 diabetes. The researchers said that further investigations are necessary to find out if the long-term effects could be harmful.

Sucralose is made from sugar, but once processed its chemical make up is very different. Gram for gram it is 600 times sweeter than table sugar. [Diabetes Care, May 2013]

IDDT's Annual General Meeting 2013

As members are aware from previous Newsletters, we unable to afford to hold a Conference this year but we do have to hold an Annual General Meeting to comply with charity law. So we are holding an afternoon meeting on Saturday, October 12th 2013 at the Hilton Hotel, Northampton [just off Junction 15 of the M1]. We hope that as many of you as possible will be able to join us – it is your opportunity to meet the Trustees and staff and of course, each other.

The programme for the afternoon will be as follows:

12 noon – Arrival

12.15 to 1.30 - free sandwich lunch

1.45 - Annual General Meeting

3.00 - Tea and biscuits

3.30 - Dr Gary Adams, 'Low blood glucose levels in Type 1 and Type 2 diabetes, shared experiences'

4.30 - Farewell

The AGM

If you would like to nominate someone for election to the Board of Trustees, then please send nominations to IDDT by October 4th with a letter of agreement from the person you are nominating and seconded by another member of IDDT.

Please let us know!

For catering purposes, places must be pre-booked by September 20th. Please contact IDDT by telephone on 01604 622837, Rita by email **rita@iddtinternational.org** or write to IDDT, PO Box 294, Northampton NN1 4XS. Rita will then send you confirmation and a map to find the Hilton Hotel.

The Hotel address

The Hilton Hotel, 100 Watering Lane, Collingtree, Northampton NN4 0XW

Gum Disease – Another Complication Of Diabetes

It has been known for some time that diabetes can cause gum disease but there is now growing evidence that diabetes is a major risk factor for advanced gum disease, called periodontis.

What are periodontal diseases?

This is a group of inflammatory disorders that affect the gums [gingiva], the ligaments that anchor the teeth to the bone and part of the jaw bone that supports the teeth. We have probably all heard of gingivitis which is inflammation of the gums caused by a build up of plaque – the gums are red, swollen and bleed more easily and this is easily treated with improved oral hygiene. However, periodontal diseases are much more serious because the inflammation extends into the bone supporting the teeth and can result in the loss of teeth.

Who is affected?

The most common form of periodontitis typically affects adults in the 40s and 50s and it is generally accepted that it affects between 5 and 15% of adults.

Diabetes and smoking significantly increase the risk of periodontitis and how severe it is. Research suggests that the increased risk is three times greater in people who have diabetes compared to those that don't and like the other complications of diabetes blood glucose control is a key factor in the level of risk.

Most research has focussed on people with Type 2 diabetes but it is now known that Type 1 diabetes also increases the risk of periodontitis, in both children and adults. One study of 350 children with Type 1 diabetes aged between 6 and 18 years showed that the children with diabetes had significantly increased gingival inflammation compared to the same number of children without diabetes.

Causes

Inflammation links diabetes and periodontitis. However, inflammation is also a feature of diabetes - it contributes to vascular complications and to raised blood glucose levels [hyperglycaemia].

Is treatment effective?

Treatment for periodontitis is usually with antibiotics and this may be for a prolonged time until the infection has cleared up. A range of studies into periodontitis and diabetes confirm that treatment of periodonitis improves blood glucose control. A recent Cochrane Review showed a reduction in HbA1cs of 0.40% within 3 to 4 months of treatment. While this may appear to be small, any reduction in HbA1cs reduces the risk of the other complications of diabetes.

Greater awareness needed



Oral hygiene is important to maintain health in everyone but periodontitis is clearly something that there needs to be greater awareness of amongst adults and children with Type 1 diabetes as well as Type 2 diabetes and amongst healthcare professionals.

From Our Own Correspondents

It's good to hear!

Dear Jenny,

I've read in some of your Newsletters that some people with diabetes getting articles, such as blood glucose test strips, needed to treat their diabetes. I cannot speak highly enough of the treatment I receive for my Type 2 diabetes from my local surgery.

I've had a blood glucose meter and test strips for many years. This old meter was rather large for my handbag and I asked my diabetes nurse about a smaller one and she gave me a new smaller one without any question. I am very happy with the care I receive although very sympathetic to people who are not so well cared for. Mrs G.M.

South West

Little cartons of apple juice

Dear Jenny,

My sister has been carrying around small cartons [200ml] of Apple Juice to have in a hypo emergency. She finds these very convenient as they 'travel' well, act fast [20gms of fruit sugar] and replace potassium which can be lost in a severe hypo. They are also convenient to keep by the bed. She asked me to mention this, as it may be a tip for other readers.

Thanks as ever for all you and the team you do – keep going! S.T. Hants

Postcode lottery reduces quality of life

Dear Jenny,

As a subscriber, I read with interest two items in the June Newsletter that I'm happy to elaborate on.

In terms of foot care, I am recovering from my second Charcot Foot injury, where the reconstruction of my right foot has proved a 10 month wait to getting normalised. While my care at my local hospital was very good and better than the previous episode on my left foot, I still have grave concerns regarding lack of knowledge by GP's who fail to recognise the condition and sadly A&E departments who do not understand just how serious this condition is.

It seems that podiatry services are the poor end of healthcare and many people do not know how to recognise that limbs can be lost through lack of understanding and how this condition emerges.

Finally, the postcode lottery regarding cataract removal has meant my eyesight has reduced to half and getting glasses is frustrating as I have the adverse effects of cataracts and this just adds to an already poor quality of life....just 65 and looking forward to retirement was a false perception.

Mr A.S By email

NOTE: IDDT would like to remind you again that our leaflet 'Know Your Rights' has a chart with all nine checks listed so that you can check at your annual review that they have been carried out and record the date.

If you would like a copy of this leaflet, ring IDDT on 01604 622837, email **enquiries@iddtinternational.org** or write to IDDT, PO Box 294, Northampton NN1 4XS

Revised BMI For People Of South Asian Descent

The point at which the level of body fat becomes a risk to health varies between ethnic groups. People from black, Asian and other minority ethnic groups are at a higher risk of developing Type 2 diabetes than white Europeans and they are at an increased risk of chronic health conditions, including Type 2 diabetes, at a lower Body Mass Index [BMI] than the white population [below BMI 25 kg/m2]. People of South Asian descent are up to 6 times more likely to develop Type 2 diabetes is also more common among Chinese people.

NICE has revised the guidelines '**Preventing type 2 diabetes: risk identification and interventions for individuals at high risk**' to give new thresholds for healthy BMI for British Asians. The new lower thresholds to indicate increased risk of Type 2 diabetes are that a 5ft 11in (1.8m) Asian man should weigh below 11st 11lb (75kg) and an Asian woman who is 5ft 3in (1.6m) should weigh less than 9st 4lb (59kg).

In order to help with the prevention of Type 2 diabetes and other health conditions, NICE want health professionals and people from ethnic groups to be aware that the risks are greater at a lower BMI for these groups.

Research News

Using stem cells could help cure type 1 diabetes

As we know, Type 1 diabetes is an autoimmune condition which is caused by the body attacking its own insulin-producing cells [beta cells] and this is why injections of insulin are necessary. Now researchers at the University of Missouri report that the attacks on the beta cells may be more harmful than originally thought. They have discovered that in Type 1 diabetes not only are the beta cells destroyed but also the blood vessels that support them.

The researchers realised how important the blood vessels are to the production of insulin and they have developed a possible cure. This is the combination of a new drug [Ig-GAD2] and adult stem cells. The drug stops the immune system attack and the stem cells produce new blood vessels to help the insulin-producing cells multiply and thrive.

The researchers have previously worked on developing Ig-GAD2 which helped to stop the immune system from attacking the beta cells but on its own too few beta cells survived. However, after using Ig-GAD2 followed by an injection into the pancreas of adult stem cells from bone marrow, new beta cells were produced although not in the way the researchers thought. They found that the bone marrow cells led to the growth of new blood vessels which enabled new beta cells to form.

The researchers hope to continue their work with a view to a cure for Type 1 diabetes. [Diabetes, May 2013]

Is Type 1 diabetes linked to animal infection?

Researchers at Newcastle University suspect that infectious disease carried by animals may trigger the development of Type 1 diabetes.

They conducted a study over a 6 year cycle and found that the number of cases of Type 1 diabetes not only peaked in certain years but also peaked in certain seasons. There was an increase in new cases in the winter months of some years.

According to the researchers this pattern of both short and long-term cycles could be caused by an infection carried by a wild animal which triggers Type 1 diabetes in those who are already susceptible to it. However, they admit that it is difficult to know what infection could be the cause.

The researchers said that the next stage of their research is to identify which infections might be involved. [PLOS ONE, May 2013]

Note: Many years ago both the seasonal and the peak in certain years was known, my daughter was diagnosed in 1975 and I was told about this then. Many infections have been considered, including mumps and respiratory infections.

Is there hope for the reversal of Type 1 diabetes?

In April 2013 there was a symposium in the US with well known researchers from the diabetes world - classed as visionaries who are not afraid to break from convention and 'think outside the box'. Their view is that the key to the possible reversal of Type 1 diabetes is a two way process, one to induce immune tolerance [to stop the body attacking its own insulin-producing cells] and the other to promote the regeneration of the islet cells that produce insulin.

Some of those attending the symposium think that as examples of both such agents are already approved by the FDA, the first combination of them could start to be tested by the end of this year. However, others thought that these approved agents are not the right choices.

Research at Havard University has identified a protein, betatrophin, which dramatically increases the production of beta cells in mice. However, it is now known that the islets in rodents are very different from those in humans. As mice eat continuously the beta cells are tightly packed whereas in humans the islets contain 5 cell types that secrete 6 hormones all of which are necessary for glucose regulation in humans. The hormones are:

- insulin and amylin made by the beta cells
- glucagon produced by alpha cells
- somatostatin from the delta cells ٠
- pancreatic polypeptide from gamma cells and
- ghrelin from epilepson cells.

Unlike rhodent islets, once human beta cells are attacked by the immune system the islets becoming completely dysfunctional and Type 1 diabetes has developed.

The symposium concluded that there is the ability to protect the immune system but regenerating the new islets is more difficult because of their complexity. The way forward is to look back to see what has and hasn't worked and bring these together to find a new way for Type 1 diabetes.

The Care Bill

It was announced in the Queen's speech that a Care Bill will be introduced to reform payment for long-term care and to avoid the elderly having to sell their homes to pay for care.

The publicity says that the Care Bill will also:

- Introduce measures in response to Francis inquiry and establish Health Education England [which there used to be many moons ago!] and Health Research Authority.
- Help people better understand what care and support is on offer and help plan for the future.
- Reform care and support funding by creating a cap on care costs, extend • the means test threshold for financial assistance and ensure no one has to sell their home in their lifetime to pay for residential care.
- · Prioritise people's wellbeing and prevent or delay care needs from developing, rather than only intervening at crisis point.
- Enshrine a right for the millions of carers in England to receive support from their local council, introduce a duty to meet carers' eligible needs for support, and introduce a new adult safeguarding framework.
- Ensure people needing care can move between local authority areas.
- Provide a new legal entitlement for everyone to a personal budget. •
- Clarifying how people will be protected from their care being disrupted if their care provider goes out of business.

No doubt there will be much debate and we will have to wait and see what the outcome actually is. We will try to keep you posted ...

Pancreas And Islet Transplantation



The nature of Type 1 diabetes is that the beta cells present in the islets of Langerhans in the pancreas no longer produce insulin and so insulin has to be given by injection or via an insulin pump. The aim of transplantation of either the whole pancreas or the islets is to provide working bets cells that will produce insulin.

Pancreas and islet transplantations

are funded by the Department of Health Specialised Commissioning Service. Suitability for transplantation is assessed in the transplant centre by a multidisciplinary team which includes a diabetologist, nephrologist [specialist in kidneys] transplant surgeon, nurse specialist and psychologist. This assessment is not only to carry out a medical evaluation but also to make sure that the patients have a fully informed choice.

Pancreas transplantation

Pancreas transplants in Type 1 diabetes have been done since the late 1960s but early times the survival rates of the patient or the graft have been poor. In recent years an improvement in surgical techniques and the use of immunosuppressant drugs has made pancreas transplants a more viable option.

Pancreas transplants are carried out in 3 possible situations.

- At the same time as a kidney transplant when people with Type 1 diabetes have end-stage renal failure and the organs transplanted are from the same deceased donor. This is called simultaneous pancreas-kidney transplantation. [SPK]
- When someone has already had a kidney transplant and in this case the kidney and the pancreas are from different donors. [PAK] This is carried out when the person has ongoing diabetes complications after the kidney transplant.
- When someone has recurrent severe hypoglycaemia but normal kidney function and in this case the pancreas alone is transplanted. [PTA] As this means the introduction of immunosuppressants, the risks and benefits must be carefully assessed.

Transplantation is not an option for everyone with Type 1 diabetes as there are risks associated with the procedure itself and also there is a need for life-long immunosuppression drugs which make people more susceptible to infections and the development of cancer.

For people in end stage renal failure, the risks associated with immunosuppressants are less than the risks with dialysis whether for pancreas and kidney transplants or kidney transplant alone. So transplantation is justified in this group of people.

Risks and benefits

A recent study was conducted from 2001 to 2009 with a total of 312 people

on the waiting list, 192 of whom underwent transplants – 148 received simultaneous kidney and pancreas transplants, 33 a pancreas after kidney transplant and 11 received a pancreas only transplant. The researchers reported a 30% mortality rate of those who remained on the waiting list compared to a 9% mortality rate in transplant recipients. They concluded that pancreas transplants provide increased survival benefits that outweigh the risk of surgery and immunosuppressant drugs. [Nephrology Dialysis Transplantation, 2013:28 (5)]

As stated above, there are risks with transplants and there is a risk of further complications, which are thought to be due to the long-term effects of diabetes and the pancreas itself. However, over the years the results of pancreas transplants have improved and according to the International Pancreas Transplant Registry, there is a patient survival of 95% at 1 year and 83% at 5 years in all three types of pancreas transplantation. Pancreas transplants restore normal insulin production, so there is no need for insulin to be injected, no more hypos and so an improved quality of life.

Islet transplantation

In islet transplantation, the islets of Langerhans are transplanted and not the whole pancreas. The islets contain the beta cells that produce insulin and they are extracted from the pancreas of a deceased donor. There are seven centres in the UK where the islet extractions take place – Bristol, Edinburgh, North London, South London, Manchester, Newcastle and Oxford.

There are two types of islet transplantation.

- Islet transplant alone. [ITA]
- Islet transplant after a kidney transplant. [IAK]

Although the original intention was to enable people to be insulin independent, most people who receive an islet transplant continue to need low dose insulin treatment. So islet transplants should not be seen as a cure but the aim now is to improve glycaemic control without the risk of hypoglycaemia and so to improve the quality of life. As we know, this is done by reducing the amount of injected insulin. Usually two transplants are necessary to gain maximum benefit.

Suitability for islet transplants

Potentially anyone with Type 1 diabetes who experiences recurrent severe

hypoglycaemia despite the best insulin treatment, is eligible for islet transplantation. It is also performed on people who have had a kidney transplant who have poor glycaemia control.

It is not suitable for people with end-stage renal failure and normal kidney function is required for either type of transplant. The assessment for suitability includes reviewing the insulin requirements including continuous glucose monitoring and a trial with an insulin pump, if appropriate.

Women who are pregnant or planning a pregnancy are not suitable for islet transplantation due to possible side effects of the immunosuppressants and other drugs needed at the time of the transplant. It is not advisable to become pregnant in the first year of the transplant and any planned pregnancy should be discussed with the medical team because it may require a change in drug treatment.

Risks and benefits

Life long immunosuppressants are required with their associated risks. There are other possible complications but the rates for these are low.

The benefits seen so far in the 34 UK recipients of islet transplants are an improvement in glycaemic control, reduced frequency of hypoglycaemia, a reduction in vascular complications and improved quality of life. Internationally 3 years after islet transplants 27% of the 412 recipients were independent of insulin.

Important to remember...

There are benefits from both pancreas and islet transplantation in a select group of people with Type 1 diabetes. However, there are risks in terms of morbidity and mortality and these must be carefully balanced against the potential benefits.

Note: in 2012 the total number people waiting for pancreas and islet transplantations in the UK was 253 and 245 were carried out.

More About Driving

The DVLA reminds motorists when they should inform them that they have diabetes

In June the DVLA issued a statement to remind motorists of the driving licence requirements if they have diabetes. It can be confusing, so here is what the DVLA said.

Group 1 - cars and motorbikes

- Motorists who control their diabetes by diet or tablets do not normally need to tell DVLA, but they do if they are on insulin.
- Motorists do not need to notify DVLA if they are on any non-insulin medication unless they have suffered from 2 episodes of severe hypoglycaemia within the last 12 months, developed impaired awareness of hypoglycaemia or suffer visual problems.

Group 2 - buses and lorries

- Motorists need to tell DVLA if they have any form of diabetes for which they take medication.
- If Group 2 motorists are on insulin, they need to: [i] provide 3 months of continuous meter readings every time they apply for a licence,

[ii] test their blood glucose no more than 2 hours before the start of their first journey of the day and every 2 hours while driving.

In case you are confused by the term non-insulin medication, IDDT assumes that this phrase is being used to cover tablets and also the newer drugs for Type 2 diabetes, Byetta and Victoza which are injected but are not insulin.

Just to remind you about the frequency of testing

As we have previously reported the DVLA have changed their form DIB1 in relation to testing and it now reads:

'I have insulin treated diabetes and I understand the need to test my blood glucose/sugar at times relevant to driving (not more than 2 hours before the start of the 1st journey and every 2 hours while driving).

If you take multiple short trips you do not have to test before each journey as long as you test every 2 hours while driving.'

This is a sensible change and allows for more flexibility for the driver. It is

also worth remembering that a test only tells you what your blood sugar levels are at that moment and not whether they are going up or down, so the DVLA statement '**Don't drive below 5**' is a very sensible one.

Responsibilities of GPs in relation to the new DVLA standards

IDDT still receives a lot of emails and calls about the new DLVA driving standards for people with diabetes, sometimes about when and what doctors tell the DVLA.

It is worth remembering that GPs have legal and ethical responsibilities relating to their patients with diabetes who are drivers. GPonline, [April 29, 2013] had an article by the Medical Defence Union reminding doctors of these responsibilities which may be of interest to people with diabetes who are drivers.

The article makes the point that confidentiality is central to the trust between doctors and patients but this can be breached in certain situations, including disclosures to the DVLA. Doctors should explain to patients that diabetes is a condition which might affect their driving and that they should inform the DVLA. If patients refuse to accept this, the doctor may wish to obtain a second opinion but will advise patients not to drive while waiting for this appointment. If patients still refuse to inform the DVLA, the doctors should follow the General Medical Council guidance, which is below.

Doctors should:

- Make every attempt to persuade the patient to stop driving.
- If the patient agrees, involve the patient's family in these attempts.
- Tell the patient he/she will need to inform the DVLA if they continue to drive.
- Inform the DVLA medical adviser in confidence and inform the patient that the information has been disclosed to the DVLA.

Test strips – response from the DVLA

There have been quite a lot of people having problems obtaining sufficient numbers of test strips to comply with the DVLA regulations for testing. One man wrote, "I enquired at my GP practice if I could have more test strips on my monthly prescription as I did not have enough to last. I was telephoned by a nurse to ask why I required more strips as my diabetes is well controlled. [Probably because I test on a regular basis!] When I explained about the DVLA regulations, the surgery seemed to think that this was something I had made up!"

So IDDT wrote to the appropriate department at the DVLA to suggest that perhaps they could do more to publicise the need for extra test strips for drivers with diabetes, perhaps in Medical / Nursing Journals.

Here is the response from the DVLA

"As you will be aware, it is the responsibility of the licence holder to ensure that they comply with the necessary DVLA medical standards for road safety. As you will know, testing sticks can be bought 'over the counter' in most chemists. Unfortunately therefore it is not for DVLA to comment on, or attempt to influence, the NHS with regard to the prescription (or otherwise) of blood glucose testing sticks in GP surgeries.

In view of this, all DVLA can do is highlight the ongoing requirement to meet our standards, when communicating with stakeholders on diabetes - we already do this and are happy to continue to do so in the future. I am sorry for what may be a disappointing reply." In other words a resounding 'NO'.

Don't Share Injection Pens

Everyone is aware that needles should not be shared but there maybe people who don't know that insulin pens should not be shared. It may even happen in hospital situations.

The reason pens should not be shared is that when insulin is injected sometimes there is back pressure and body fluid can pass through the needle back into the pen. It may only be a small amount of fluid but it does contaminate the insulin left in the pen. If a second person them injects from the same pen, some of this fluid can be passed to the second person.

Snippets

Doctors have no confidence vote in Health Secretary

At the 2013 British Medical Association annual representative meeting doctors backed a no confidence vote in the Health Secretary, Jeremy Hunt. They also attacked the imposed GP contract arrangement and backed a

possible withdrawal from commissioning. Doctors also demanded a repeal of the Health and Social Care Act and a BMA campaign to achieve this.

Some interesting facts

A Mori poll carried out in February 2013 showed that of 17 categories, doctors were the most trusted profession [89%] with politicians coming last with 18%. It also showed that GPs still deal with 90% of all NHS work but have only 9% of NHS funding.

Walking distances on menus

A study has shown that people who saw menus with information about distances required to burn off the calories in each item, ordered meals that averaged 826 calories, compared with 1,020 calories ordered by those who viewed menus without such information. Participants whose menus featured calorie content only and calorie content plus walking minutes also had orders with fewer calories. Sounds like a plan! [Appetite, March 2013]

Lack of sleep in young men affects portion sizes

According to a small study, lack of sleep may make you eat larger portions of high-calorie foods and therefore increase the risk of weight gain. Researchers in Sweden asked 16 normal-weight men, average age 23, to choose their ideal portions of high-calorie meals and snacks. The men made their choices after a normal night of about eight hours sleep and after a night without sleep. After the sleepless night, participants chose larger portion sizes both before and after having had breakfast suggesting that sleep deprivation increases food intake regardless of whether a person feels full. *[*Psychoneuroendocrinology, February 18, 2013]

Diabetes in Vietnam on the increase

The population of Vietnam has seen an increase in diabetes of 211% in the last 10 years. There has been a conference held by the Ho Chi Minh Nutrition Centre and the Health Department to implement a plan for diabetes prevention and control.

Obesity is a disease

The Lancet [Vol 381, June 29, 2013] reports that the American Medical Association has officially classified obesity as a disease. It is expected that this may improve treatment efforts and reduce the social stigma for people who are obese. About a third of the American population and 17% of

American children have a BMI above the threshold for obesity.

Diet drinks - not what we thought

An analysis of 66,188 women monitored for 14 years has confirmed a link between sweet soft drinks and Type 2 diabetes. Not surprising, you might say but contrary to popular belief, there is a higher risk of Type 2 diabetes from so-called 'diet' or 'light' drinks than from normal sweetened soft drinks. Apparently, women who drink diet drinks, drink more of them than those who drink normal sweet soft drinks but when an equal quantity of each is drunk, the risk of Type 2 diabetes is higher in those who drank the diet drinks. To find out if this association is just associated with diet drinks, the researchers investigated the effect of 100% natural squeezed fruit juices and found no association with a risk of diabetes.

The link between diet drinks and the risk of diabetes can be partly explained by a greater craving for sugar in general by females but aspartame, one of the main sweeteners used today, causes a rise in glycaemia which in turn causes a rise in insulin level by comparison to those produced by sucrose [sugar]. [American Journal of Clinical Nutrition, Feb. 2013]

Electronic cigarettes

Smoking is bad for everyone but people with diabetes really should not. For those trying to quit smoking, electronic cigarettes appear to help with 1.3 million people in the UK using them. However, from 2016, they are to be regulated and will be licensed drugs available over-the-counter. This follows research which shows wide variations in the quality and nicotine content in electronic cigarettes presently available. If you would like to join IDDT, or know of someone who would, please fill in the form (block letters) and return it to:

IDDT PO Box 294 Northampton NN1 4XS		
Name: Address:	 	
Postcode:	 	

From Your Editor – Jenny Hirst

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