Insulin Dependent Diabetes Trust

April 2011 Newsletter

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Strange Times

I would like to thank all our members who lobbied their MPs about the proposed NHS Reform Bill. You made your feelings known at a time when it seemed that it was only doctors and nurses who were raising objections – and absolutely right that they should but the people at the sharp end of the changes are actually us, the patients. Who is better placed to be concerned than people with chronic conditions who have to use the NHS on a regular basis? So a big thank you to everyone.

We have collated all the responses you received and clearly there was a party political response from MPs with some Labour MPs saying they would definitely not support the Bill, Liberals trying to defend their position and a variety of responses from Conservatives, with some making no attempt to answer the questions we asked and not even being prepared to seek the answers from the relevant Minister – this is their job! Of course, they were all then given a let out by the coalition government's 'listening exercise', which leaves us all with the big uncertainty of whether this means hearing and action or simply listening but not hearing.

Healthcare uncertainties

I am writing this Newsletter when our future healthcare is associated with more uncertainties than ever before. Our print deadlines are such that we are still awaiting the results of the government's 'listening exercise' but we have received David Cameron's five pledges to the nation. These do give us some clues about the final outcome.

- **We will not endanger universal coverage – we will make sure that it remains a National Health Service.**
- **We will not break up or hinder efficient and integrated care –**

we will improve it.

- **We will not lose control of waiting times – we will ensure they are kept low.**
- **We will not cut spending on the NHS – we will increase it.**
- **And if you are worried that we are going to sell off the NHS and create some American-style private scheme – we will not.**

He ended his speech by saying, "There can be no compromise on this. It's what patients expect and what doctors and nurses want. And it's what the government will deliver."

We have to prepare ourselves for changes

We await the results of the 'listening exercise' but meanwhile we have to prepare ourselves for changes and changes that are already starting to hit. The Prime Minister may well promise that there will not be spending cuts in the NHS and indeed, that they will increase funding, but actually there is a deficit to be covered before all this happens, so now and in the immediate future there are cuts taking place, cuts which are affecting many of us.

Successive governments have told the public that we are part of the decision-making process in managing our health and that we have to take more responsibility for our own healthcare. During this time of change and uncertainty, this holds true more than ever.

So IDDT is preparing a leaflet which will cover issues that will help you to know your rights. It will provide information to help you present a good case to receive the care and treatment to which you are entitled. As patients, each one of us is going to have to be much more vigilant, and probably more vocal, to ensure that our health needs are met. In this Newsletter we will cover the NICE guidance for the treatment of diabetes in adults and the NHS Constitution.

To track the progress of the Health and Social Care Bill visit: **http://www.dh.gov.en/Publicationsandstatistics/Legislation/Actsandbills/HealthandSocialCareBill2011/index.htm**

Blood Glucose Test Strips, Again

IDDT receives many reports of people being denied their usual number of blood glucose test strips. It seems that the most common way this is done is through repeat prescriptions - the number of test strips just happens to get reduced.

For people with Type 1 diabetes or Type 2 diabetes taking insulin, this can be harmful and they cannot follow the advice they have been given to monitor their blood glucose levels 4 times daily. Two packs of 50 strips a month does not enable people to test 4 times daily – the math is not difficult – and nor does it take into account the extra tests necessary during illness or following a hypo!

People with Type 2 diabetes not using insulin are often denied test strips altogether. This is understandable if people are unable to interpret the results and it can cause more anxiety than not testing. However, some people benefit from testing regularly and wish to do so.

NICE Guidelines

The National Institute for Health and Clinical Excellence [NICE] on the treatment of Type 2 diabetes set out situations where self-testing can be useful in managing glucose levels and avoiding hypoglycaemia. NICE does make it clear though, that testing is only useful as part of an education package which helps people to understand how to manage their diabetes and interpret the results. Therefore decisions about testing should be made on an individual patient basis and NOT a blanket ban by PCTs or GP practices, as so often happens. [In theory everyone with diabetes is supposed to receive an education package, so everyone should have the choice of testing!]

What to do if you don't get the strips you need whether you have Type 1 or Type 2 diabetes?

1. Contact your GP and discuss the number of strips you need and explain why.
2. If this fails take the matter up with the Primary Care Trust.

3. You can also contact the Patient Advice and Liaison Service [PALS] for their help and advice – they have offices within your hospital.

Sheffield is being proactive and taking sensible steps – cheaper test strips!
A letter in IDDT's April Newsletter queried why no one has developed cheaper glucose test strips. This caused one of our members to tell us what has happened in Sheffield.

It has been agreed across Sheffield that the most cost effective device for testing blood glucose is the CareSens N meter and CareSens N testing strips and lancets. So everyone with diabetes is being changed to this meter. The meter is being supplied free of charge by the NHS and prescriptions for strips are being issued once people have used up there old strips.

Late note: IDDT has since been told of at least one other area that is going down this route of using the CareSens N

Looking online, the cost of the meter is £4.99 and 50 strips are as little as £12.95 and if GPs are in a particular buying group, they can purchase them at a further discounted rate. Strips for most meters are around £25.00 for 50 – expensive for people who either have to purchase the strips they need.

While Sheffield's decision may not please everyone and there are issues about patient choice, this is a sensible, cost effective decision. This competition may also force the other manufacturers to lower the prices of their test strips. So if you are having to purchase your strips, it may be worth considering changing to the CareSens N meter.

CareSens N Meter and test strips, manufactured by Spirit Healthcare
- It requires only a small sample of blood.
- No coding is needed for the test strips.
- The strips use a highly specific glucose oxidase reagent that will only measure glucose.
- It is small, fitting easily into the hand and has an easy to read display screen, results in 5 seconds.
- 250 test results can be stored in the meter memory and it can be downloaded to a personal computer.
- Test range 1.11 to 33.3 mmols/l

France Suspends Actos [Pioglitazone]

June 9th 2011: We have read much about the eventual withdrawal of the Type 2 drug, Avandia [rosiglitazone] due to serious cardiovascular adverse effects it caused but Actos [pioglitazone], from the same family of drugs, has remained on the market. Well, the French drug regulatory body [Afssaps] has now taken unilateral action and suspended the marketing of Actos because of its link with a small increase in the risk of bladder cancer. Competact, a combination of Actos and metformin is also being suspended. The suspensions will take effect from July this year and the 230,000 French people using Actos are being advised not to stop using it until they have seen their doctor.

The pharmacovigilance data [adverse reaction reports] showed 46 cases of bladder cancer linked to Actos at May 31st 2011. This was supported by an independent study which confirmed an increase in the risk of bladder cancer of around 22% in those taking Actos. It was stated that the beneficial cardiovascular effect of Actos shown in long-term studies is removed by the increase in the risk of bladder cancer that appears after a much shorter period of use.

A day later the German authorities recommended suspending the marketing authorisation of Actos until there is "further clarification" and it is recommended that German doctors should not start new treatments with Actos. At the same time, the UK regulator, the MHRA, said there was not strong evidence to support such a move at this time, Spain will wait for the European Medicines Agency [EMA]

decision due in June [after we have gone to print]. Italy's AIFA has not made a statement.

Reminder - Avandia [rosiglitazone] was banned in Europe because it increased the risk of heart problems. A recent study compared Avandia and Actos and Avandia caused a 16% increase in the risk of heart attack, a 23% rise for heart failure, and a 14% rise in the risk of death, when compared with Actos. So Actos caused fewer heart problems than Avandia but it is worth remembering that Actos does still cause heart problems, weight gain and oedema – just less than Avandia.

The US did not ban Avandia but from November 18th it can no longer be sold by retail pharmacies and prescribers will have to be enrolled on a medicines access programme. And by the way, in the US the manufacturers of Avandia, GSK, is resolving more than 1,200 lawsuits filed against Avandia at a cost to the company of $700million. A further 5,300 cases are pending.

European Regulators Are Protecting Drug Company Profits Rather Than The Lives And Welfare Of Patients

Yes, this is a claim made in an article in the British Medical Journal by Professor Peter Gøtzsche and Dr Anders Jørgensen from the Nordic Cochrane Centre in Denmark. They call for full access to full research trial reports, both published and unpublished, to allow the true benefits and harms of treatments to be assessed by scientists. This way doctors can obtain a true picture of the benefits and harms of drugs when they consider prescribing them for patients.

Despite there being hundreds of clinical trials into drugs and treatments, not all trials are published so there is selective reporting. For instance, if trials are funded by drug companies into one of their products but the results show that the drug does not have benefits or causes harm, then companies tend not to publish the trial. This leads to a bias in favour of the drug but only because all the information is not available. They cite the example of Vioxx, the arthritis drug, which probably caused 100,000 heart attacks in the US alone because trials showing this as an adverse effect were not published.

The Cochrane researchers struggled for 3 years to access unpublished trial reports for two anti-obesity drugs submitted by the manufacturers to the European Medicines Agency [EMA] for marketing approval in the EU. This information was important because people have died from the serious side effects they caused [cardiac complications and psychiatric problems] and most of these drugs have now been removed for safety reasons. However, the EMA refused access on the following grounds:

- commercial interests would be undermined,
- there was no overriding public interest in disclosure,
- the administrative burden involved and the worthlessness of the data once they had edited them.

Only after appeal to the European ombudsman who accused the EMA of maladministration, did it agree to widen public access to the documents. The researchers are calling on all regulators to follow suit. [BMJ 2011;342:d2686]

It beggars belief!

We, the public, tend to believe that drug regulatory agencies act in our best interests and historically this is what they were set up to do. Clearly, this is not the case when regulatory agencies refuse to give access to all information submitted by drug companies that would protect public health. Only if we have ALL the evidence can rational treatment decisions /choices be made by doctors and patients. To date it seems our so-called 'informed decisions' are not actually informed!

For many IDDT readers this is not news as we remember only too well the introduction of human insulin in the 1980s, the complaints from

patients about adverse effects and worst of all, the fact that they were ignored. The frequently used excuse was wheeled out – 'it's all in your mind'. If research was carried out into complication and mortality rates and comparisons of quality of life, it was never accessible and if it wasn't carried out, it should have been. History it may seem to be, but similar situations are still going on.

But there is something wrong when regulatory bodies protect drug companies and not patients. Surely they have lost sight of their priorities! Is there not something wrong when the success of the pharmaceutical industry depends on withholding information from the very people who are going to use their drugs? No wonder the pharmaceutical industry is one of the profitable in the world!

An allied comment from the WHO on the rational use of medicines
A fact sheet issued in May 2010 by the World Health Organisation [WHO] states that more than 50% of all medicines are not correctly prescribed, dispensed and sold and more than 50% of patients take their drugs incorrectly. This situation is worse in developing countries where less than 40% of people are treated according to clinical guidelines.

According to a report in The Lancet [June 12, 2010], several factors contribute to the incorrect use of medicines - prescribers might obtain information from pharmaceutical companies rather than using the evidence-based clinical guidelines; incomplete diagnosis of a patient's disease: patients might buy affordable versions of expensive drugs on the internet.

WHO's recommendations to encourage the rational use of medicines include:

- The setting up of special committees to monitor and improve the use of medicines.
- Training medical students in pharmacology and prescription drugs.
- The removal of financial incentives for prescribers.
- The establishment of standards for ethical drug promotion.

Some might say that many developing countries already have some or all of these in place, well then, perhaps they should be more effective.

New rules from the Association of British Pharmaceutical Industry [ABPI] - GPs must declare links with drug companies
From May 1st 2011, the new rules will mean that GPs who carry out work as consultants or advisors to drug companies must declare their links when writing or speaking in public. Companies must ensure that such links are declared when a health professional speaks in public about a subject related to one of their products. From 2012 the new rules will also require companies to make consultant fees publicly available, although name of the health professionals does not have to be declared. The new rules also restrict the promotional gifts that can be given to health professionals.

When making scientific claims about their products, the new rules mean that companies must also refer to absolute risk whenever figures relating to relative risk are stated. Many of us non-scientific people don't know what relative risk means but referring only to relative risk, especially if there is reduced risk, can be misleading and make a medicine look more effective than it actually is. So by stating the absolute risk, we are more likely to get a true picture of how effective a medicine is.

Why Do Some People With Type 1 Diabetes Never Develop Complications?

In the April 2011 Newsletter, we reported on research that looked at just this question. IDDT member, Tony Huzzey has had Type 1 diabetes for over 60 years and he recounts his story of his 61 years of carb counting in a recently published book. We also pay tribute to another of our members, Alfred Grafton, who recently passed away at the age at the age of 92 having been diagnosed in 1944. They both give the same message – how important it is to follow the rules!

My Life with Diabetes – 61 years of Carb Counting

This is a book by Tony Huzzey who was diagnosed with Type 1 diabetes when he was 12 years old – 61 years ago. IDDT can proudly claim that Tony has been a member of IDDT almost since we first formed and he is an inspiration to children and adults with Type 1 diabetes.

He has lead an enjoyable, successful and socially useful life which makes interesting reading in itself but he recounts his life with diabetes in a way that makes readers realise that his diabetes was just another facet of his life. It did not override his ambitions, his triumphs or his enjoyment of life. In the book he frequently suggests that parents of children with Type 1 diabetes should take note.

At 12 years old, Tony was treated by the famous Dr Laurence who himself had Type 1 diabetes. From the outset Tony was encouraged to 'fight back' by accepting personal responsibility for the maintenance of his own health and this he undoubtedly did! In 1950, the treatment of diabetes was very different from now and the overriding thing that struck me about Tony's life was the relative simplicity of managing his diabetes successfully because he followed the rules and carb counting. I wondered if he followed the rules because of this simplicity which helped him to understand what was happening to his blood glucose levels and why. If so, are there some messages here for today's treatment?

He managed his diabetes by the basic golden rules – twice daily insulin, carb counting and exercise. If his blood sugars were high, his first thought was not to inject more insulin which would have a knock on effect later, but to go for a walk or a cycle ride. Yes, the diet was somewhat restricted and not today's philosophy of eat anything you like and match it with insulin - but it worked. He did not have to worry about injections at lunch time at school or at work, he ate similar amounts of carbohydrate at each meal and he used less aggressive animal insulin, so the pattern of his blood sugars was regular and predictable. And 61 years later he's here telling us all about it.

The book is well worth reading and perhaps provides parents of today's generation of children with Type 1 diabetes with a different perspective of basic diabetes management, remembering that he did not have the luxury of blood glucose testing. Above all it shows how, with encouragement and self confidence, he led a fulfilling and happy life. Diabetes today must seem a huge burden to children, so much testing, so many injections and of course, the risks of hypos with tight control. Tony's way may seem old-fashioned, but he does not come over as being under pressure in the same way that diabetes management seems to be to today's children.

'My Life with Diabetes' by Tony Huzzey. ISBN 078-1-907611-83-4
Price £9.99
Available from Amazon

In Memory of Mr Alfred Grafton

Mr Grafton was a member of IDDT for many years and always took a great interest in IDDT's Newsletters, especially as he was not able to tolerate either human or analogues insulins. Sadly he died recently and his daughter asked me to write a piece about him in the Newsletter because her Dad demonstrated how it is possible to live a long life with diabetes and to stick to your guns to remain using the insulin of your choice, however difficult that becomes!

Mr Grafton was diagnosed in 1944 while serving in R.E.M.E. and preparing for D day. There was no NHS in those days, however he was stabilised and his insulin regime set up. He was not able to rejoin his regiment or hold down a manual job again because of frequent hypos and ill health, nevertheless, he was determined to follow advice and to keep himself as healthy as possible, which paid off because he lived to the ripe old age of 92.

Mr Grafton's daughter tells us that they looked forward to reading the Newsletters together, especially about the fight to maintain supplies of animal insulin. Like many others, Mr Grafton resisted well-meaning doctors who wanted to change him to insulin analogues whenever he went to hospital. Here's what his daughter told IDDT, "I am very proud of my Dad, in all the 66 years of living with diabetes he never

smoked, drank alcohol or veered from his determination to eat the right foods to keep him stable. He was awarded the Lawrence medal for living with diabetes for 60 years by Diabetes UK in 2004 and was justifiably proud of that honour."

What Is C- peptide?

This is a question being asked more frequently by people with diabetes and by researchers. C-peptide is a by-product of insulin production in the pancreas – when insulin is produced C-peptide is also produced and released into the blood stream, so it is a measure of how much insulin the body is producing. Abnormally low or absent C-peptide in the blood suggests that Type 1 diabetes is present, whereas in Type 2 diabetes with insulin resistance where the body is producing insulin but not using it properly, the C-peptide levels could be normal or higher than expected. So carrying out blood tests for the levels of C-peptide plays an important role in diagnosis of diabetes.

What are normal levels of C-peptide?
If you can understand this, normal levels of C-peptide are 0.5 to 2.0 ng/mL [nanograms per millilitre] although results may vary slightly between laboratories.

Has C-peptide a function?
The first use of the C-peptide test was in 1972 when the interest was solely in relation to insulin production and it was thought to have no other function. However, over recent years C-peptide has been found to be active in its own right as it has been shown to affect microvascular blood flow and tissue health. Research in tissue and in animals suggests the C-peptide could improve nerve and kidney function as well as anti-inflammatory effects that help with the repair of smooth muscle cells.

Going back further to proinsulin - the more complicated stuff!
Insulin is produced from proinsulin which is a polypeptide and the action of enzymes on proinsulin produces insulin and C-peptide. C-peptide and insulin are then stored in granules in the beta cells of the pancreas and both are released into the circulation when the insulin is needed eg after food. C-peptide is eventually removed from circulation via the kidney whereas excess insulin is removed by being degraded by the liver.

Is C-peptide present in injected insulin?
The early beef and pork insulins were not highly purified and therefore not all the proinsulin was fully removed. The proinsulin may have caused the body to react and produce antibodies so that a rash or dents and lumps in the skin may have been caused. But since the late 1970s when highly purified pork insulin was introduced, the level of purity was so high that this ceased to be a problem.

It is worth noting that the presence of certain insulin antibodies may have a positive effect in Type 1 diabetes because the insulin binding antibodies effectively increase the insulin clearance rate and distribution helping to prolong the action of the insulin.

Animal insulins today are 99% pure and a statement from Wockhardt about their Hypurin insulins says that they are highly purified but the complex process removes any traces of C-peptide that may be present to extremely low levels.

The synthetic human and analogue insulins do not contain C-peptide because these insulins are manufactured and not actually insulin.

The big question
It is well recognised that one of the reasons hypo warnings are reduced, or absent, with human and analogue insulins is that they do not contain any glucagon, the trigger for hypo warnings. In animal insulins, minute amounts of glucagon are extracted when the insulin is extracted from the pancreases of pigs and cattle, so this helps to provide hypo warnings. So for some people animal insulins give better hypo warnings – important for daily life!

So now that more is known about C-peptide and it has advantages in its own right, perhaps its presence in animal insulin is another advantage which needs further investigation.

Living On The Edge - Boundaries For Eye Screening

According to National Service Framework targets, everyone with diabetes has to be offered eye screening once a year to check for retinopathy because early detection and treatment of any eye damage is an essential preventative measure. The figures for people who have been offered retinal screening are good with most areas being well above 90% but the system has not been without its problems – at least for some patients.

Locally how and what method of screening takes place varies from one area to another and the various options are:

- Fixed and mobile screening with a fixed appointment system.
- Mobile screening with an open appointment system.
- Optometric screening with optometrist practices making the appointments, and optometrists providing first and second disease grading.

Nationally the system for calling patients for screening appears to be dictated by where your GP practice is based. This has meant that some people have their eye screening at a different hospital from where they receive their diabetes treatment and/or at a hospital that is further away. This appears to be a particular problem for people living in rural areas or where their GP is on the edge of the border between Primary Care Trusts [PCTs]

For example, one 23 year old who lives in a rural area drives to work in the town where she has always attended the diabetes clinic and had her eyes screened. Her GP comes under a different PCT, so her appointment to be screened was in a town in the opposite direction to which there is no bus service. So her eye screening meant a day off work for her and a day off for someone to drive her. She was refused all attempts to have her screening at her usual hospital, with almost a 'computer says no' attitude. So this is one area of the NHS where patient choice does not actually apply.

However, her mother took up the issue and wrote to their MP and to the National Screening Programme for Diabetic Retinopathy and her daughter has now been moved to her original screening venue in the town where she works. So if you are in a similar position, the message here is don't just accept it, argue your case and if necessary write to your MP.

Further details of the National Screening Programme can be found by visiting: **http://www.retinalscreening.nhs.uk/pages/**

Information For Health Professionals

The University of Glasgow has organised a Masterclass in Diabetic Nephropathy on 29th July 2011. For health professionals it is an opportunity to hear latest guidelines, best practice and network with colleagues.

Diabetic Nephropathy - A Half Day Masterclass

This in-depth masterclass aimed at primary care and other health professionals will cover the following areas:

- microalbuminuria
- when to refer patients?
- decrease in eGRF
- when to stop metformin
- pregnancy
- end stage or renal disease

To download the leaflet, visit:
http://www.gla.ac.uk/media/media_195397_en.pdf

For further information contact Sarah McNulty on 0141 201 0825 / 9353 or email **sarah.mcnulty@glasgow.ac.uk**

Research

Beta blockers encourage weight gain
Many people with diabetes have high blood pressure and recent research from Australia has confirmed what has been suspected for many years. Beta blockers, blood pressure-lowering drugs, encourage weight gain. The study looked at over 11,000 adults who had high blood pressure or diabetes or both. They found that patients taking beta blockers averaged from 11 to 37 pounds more in weight than those not taking beta blockers. Those using beta blockers typically burned 30 to 50% fewer calories after meals than those not taking beta blockers.

Beta blockers have been around since the 1970s and the ones causing the most weight gain were atenolol and metoprolol but a newer one, carvedilol, is said to carry less risk of weight gain. In addition, many people are now treated with other blood pressure-lowering drugs.

Mice must take their BP meds at bedtime!
According to a study published in May 2011, the time of day that heart drugs are given can make a big difference. Many doctors prefer to give heart patients their drugs in the morning. However, the study carried out in Toronto found that ACE inhibitors, commonly given to people with high blood pressure or after a heart attack, improve the heart structure and function when given at sleep time. In fact, when given during wake time, ACE inhibitors were no better than a placebo [dummy pill]. But before we get too excited, this study was carried out in MICE with high blood pressure!

The researchers' explanation is that the drug affects the natural hormone involved in heart remodelling. Hormone levels increase at night and the heart enlarges causing damage in people with cardiac problems. By targeting these hormones when they are at their highest levels during sleep, the damage they do is reduced.

In the study the researchers also used a short-acting version of ACE inhibitor as it is most active during sleep and not having it active during the entire day, may help to reduce side effects to it. So while more research is necessary, the researchers are recommending that ACE inhibitors are given before bed and a short-acting version may be worth considering. Mice as yet, but seems like good thinking. [Journal of the American College of Cardiology, May 17, 2011]

Thermometer to save loss of limbs
A US based company, Diabetic Solutions, has developed a device which can pick up early warnings of inflammation and damage of the feet before it even breaks through the skin. It is a battery powered thermometer that uses infrared light to detect changes in foot temperature, a sign of inflammation, so that medical attention can be given at an early stage. The idea is that the device can be used at home by people with diabetes who have some existing nerve damage. It must be used daily. If this temperature difference is more than four degrees Fahrenheit, for two days or more, an ulcer may be developing and this is the time to contact the doctor. Studies have shown that ulcer rates can be cut by a third and now a larger clinical trial is under way at Oslo University Hospital, Norway.

An enzyme with meal-time injections?
An enzyme called hyaluronidase given with meal-time analogue insulin injections could help to improve blood glucose control in people with Type 1 diabetes, according to a recent study in California. Hyaluronidase and the rapid-acting insulin analogue, Humalog, given together before meals led to smaller rises in glucose after meals than treatment with Humalog alone without increasing the risk of hypoglycaemia later.

Insulin Analogues and Type 2 diabetes – more studies necessary to understand the effect on long-term complications

Researchers carried out a meta-analysis of 16 randomised controlled trials comparing treatment with insulin analogues in 7759 people with Type 2 diabetes with an average age of 58.2 years. A meta-analysis is when research studies investigating a similar question are put together to see the overall results – in this case, which insulin analogue treatment regime is the best for people with Type 2 diabetes?

Findings

- A larger proportion of people with Type 2 diabetes can achieve a target HbA1c of less that 7% if they are treated with pre-mix analogue insulin eg Humalog Mix 25, NovoMix 30 or with pre-meal analogue insulin [eg Humalog, NovoRapid] rather than with just long-acting insulin eg Lantus, Levemir.
- There was some evidence that a basal bolus regime [long-acting insulin with rapid-acting insulin before meals] could be more effective than pre-mix insulin for achieving the HbA1c targets and both regimes produced similar side effects.
- While long-acting insulin [basal] was associated with a lower proportion of people reaching target HbA1cs compared with pre-meal insulin or pre-mix insulin, there was less hypoglycaemia and weight gain compared with pre-mix biphasic insulin.

The researchers recommend that more studies are necessary to better understand the effect of insulin analogues on long-term complications. [Diabetes Care 2011; 34: 510–517, Feb 2011]

Moves To Improve Things...

Improving insulin safety

In June 2010 NHS Diabetes launched online course for health professionals to improve the safety of administration of insulin. All health professionals who care for people with diabetes must now complete training on safer use of insulin.

This follows the publication of a Rapid Response Report by the National Patient Safety Agency [NPSA] showing that for the 95 most serious medication errors, four drug types were identified where two or more fatal incidents had been reported, insulin being one of the four.

Studies have shown that up to a third of people with diabetes who inject insulin have an error on their medical chart and it is hoped that this compulsory training will reduce the numbers of such errors. The NHS Diabetes online course is free and takes about 90 minutes to complete. Let us hope we see a difference!

NPSA Insulin Passport

The NPSA has brought out a credit card sized 'Insulin Passport'. It, or something similar, is supposed to be provided by doctors to all patients taking insulin. This is NOT to be confused with IDDT's Hospital Passport which we introduced in 2010.

IDDT's Hospital Passport is for people with Type 1 and Type 2 diabetes and contains more details but many health professionals are supplying this to patients as it covers the NPSA requirement, and much more!

IDDT's Hospital Passport has proved extremely popular with people with diabetes and health professionals, to such an extent that we are in our second print run already. Individual or multiple copies are available from IDDT just ring 01604 622837, e-mail **martin@iddtinternational.org** or write to IDDT, PO Box 294, Northampton NN1 4XS.

Improving the treatment of hypoglycaemia in hospital

A pilot project to improve safety for people with diabetes is being rolled out throughout the Royal Free Hospital after its success on four wards. It was started in 2008 and has been shown to improve intravenous insulin administration to stabilise blood sugars when patients are acutely unwell or before or after surgery. The medical teams on four wards were provided with a new patient record chart, standardised guidelines for treating dangerously low blood sugars and

an insulin sliding scale pack containing a standardised prescription. The feedback from the medical teams has been entirely positive.

Pharmaceutical Industry News

New device to calculate insulin doses

Abbott has introduced a new glucose monitoring system called the FreeStyle InsuLinx which is designed to prevent insulin calculation errors. It includes a touch screen interface, automated logbook and USB connectivity and the first blood glucose monitor to include a mealtime [bolus] calculator.

It was introduced in selected countries in Europe in May but is not available in the US. It is available in Belgium, France, Germany, Netherlands, and the UK. If you are interested in the FreeStyle InsuLinx System, you should consult your healthcare professional.

Levemir can be used in young children

At present no long-acting insulin analogue [Lantus nor Levemir] is recommended for children between the ages of two and 5 years old. Levemir is a long-acting analogue insulin made by Novo Nordisk and results from a trial recently published show that it is similar to human insulin in 2 to 5 year olds with Type 1 diabetes but it is associated with a lower risk of hypoglycaemia. [Pediatric Diabetes, March 211] Novo Nordisk is applying for a label update for Levemir so that it can be used in children between the ages of 2 and 5 years.

Statements about inhaled insulin powder alleged to be false

The latest news on the development of AFREZZA, insulin powder that can be inhaled, is that the US the drug regulatory agency, the FDA, has turned down the application for a marketing licence and asked for two new trials, one in Type 1 and one in Type 2 diabetes. A lawsuit representing investors in the manufacturers, MannKind, has been filed with the courts on the grounds that certain officers and directors of the company issued false statements about the riskiness of AFREZZA.

Long-acting version of Byetta approved

In April, the European Medicines Agency recommended that Bydureon, a long-acting version of Byetta is suitable for treatment of Type 2 diabetes in adults. Bydureon only needs to be injected once a week whereas Byetta and Victoza, both from the same family of drugs, have to be injected daily. This new class of drugs not only controls blood glucose levels but can also result in weight loss. The European Commission has yet to give approval but this normally takes place within a couple of months. The FDA in the US has not given approval and last October asked for more information on potential heart risks.

New generation ultra-long acting insulin

Novo Nordisk is carrying out trials of a new ultra-long insulin analogue, degludec, and a mix of two different insulin analogues - degludec and the rapid-acting analogue, aspart [NovoRapid].

EU approval for insulin pump with DexCom's glucose monitor

Johnson & Johnson has received approval from European regulators for its Animas Vibe insulin pump that includes DexCom's continuous glucose monitor, G4 Sensor. The company said it will market the device in several European countries, including the UK and Germany.

Diabetes And Coeliac Disease Share Common Genes

Both Type 1 diabetes and coeliac disease are autoimmune diseases. It has been recognised that people with Type 1 diabetes are also susceptible to coeliac disease with some doctors believing that children with Type 1 diabetes should also be tested for coeliac disease. People with coeliac disease cannot tolerate gluten, a protein in wheat,

rye, barley and cereals and which is also in many processed foods.

Research carried out at Cambridge University, suggests that certain gene variants that increase the risk of Type 1 diabetes also raise the risk of coeliac disease. They identified seven chromosome regions which are shared between the two diseases, which surprised the researchers. This suggests that Type 1 diabetes and coeliac disease may be caused by common underlying mechanisms such as autoimmunity-related tissue damage and intolerance to dietary antigens [foreign substances that prompt an immune response]. The development and anatomy of the small intestine and pancreas are closely related and the gut immune system shares connections with pancreatic lymph nodes, which have been linked to an inflammation of the pancreas and destruction of the insulin-producing beta cells.

So Type 1 diabetes and coeliac disease not only share genetic causes but could have similar environmental triggers as well. The next step is to understand how these susceptibility genes affect the immune system and to continue to investigate environmental factors that might alter the risk of developing Type 1 diabetes. [The New England Journal of Medicine, December 10th 2008]

Tip from an IDDT member: the supermarket, Aldi has a wide range of gluten-free products.

By the way - research carried out some time ago showed that chefs have less knowledge about coeliac disease than the general public. Coeliac disease affects 1% of the population but it seems that restaurants are hardly aware of the problem. Of 322 chefs asked, only 17% had heard about the condition compared to 44% of the general public. This makes eating out for people with coeliac disease very difficult!

Coeliac UK's website is very informative and provides a monthly update on available gluten-free foods and it has started to give listings of gluten-free places to eat. Visit **http://www.coeliac.co.uk**

Be Prepared – Know Your Rights
NICE Quality Standards for Diabetes in Adults

What are Quality Standards?

They are a set of specific statements that tell us what high quality, cost effective patient care should be and cover treatment and prevention of different conditions. The aim is that the Quality Standards will help the NHS to deliver the best outcomes from treatments for patients by:

- Helping patients to understand what service they can expect from their health and social care providers, eg GPs, consultants, nurses.
- Helping health and social care providers to make decisions about your care based on the latest evidence and best practice.
- Enabling NHS Trusts to examine the standards of care they provide against the Quality Standards they should provide and to enable commissioners of services to be sure they are providing high quality and cost effective services.

Quality Standards for Diabetes

These are basically the same as the standards laid down in the National Service Framework for Diabetes so here is what you should receive.

1. A structured education programme, annual review and ongoing education.
2. Personalised advice on nutrition and physical activity from a suitably trained healthcare provider.
3. Participation in annual care planning to agree goals and an action plan.
4. Agreement with your health professional of your target HbA1c and an ongoing review to minimise hypoglycaemia.
5. Agreement with your health professional to start, review and stop medications to lower blood glucose, blood pressure and blood lipids [cholesterol].
6. Trained health professionals to start and manage treatment with insulin as part of a structured education programme which includes learning dose adjustment.

7. Women of childbearing age should be regularly informed about the importance of preconception blood glucose levels and any risks, including medication, to the unborn child. If a pregnancy is planned, preconception care should be offered and if not, they should be offered contraceptive advice.
8. An annual assessment for complications and their management.
9. An assessment for psychological problems which, if present, should be appropriately managed.
10. People with, or at risk of, foot ulceration should receive regular reviews by a foot protection team. Those with a foot problem requiring urgent attention should be referred to a foot care team within 24 hours.
11. If admitted to hospital your care should be managed by appropriately trained staff. You should have access to a specialist diabetes team and given the choice of self-monitoring and managing your own insulin.
12. If you are admitted to hospital with ketoacidosis, you should receive educational and psychological support before being discharged and followed up by a specialist diabetes team.
13. If you have experienced hypoglycaemia which required medical attention, then you should be referred to a specialist diabetes team.

The full details can be found at:
http://www.nice.org.uk/aboutnice/qualitystandards/qualitystandards.jsp

Remember this is the care that you should receive and it is part of the government's promise to make sure that the standards of care are high quality.

If you are not receiving this standard of care, then you need to say so. There can be subtle ways of doing this, such as asking when you are going to receive the education programme that you should have or the slightly less subtle ways, such as writing to your GP practice Manager or your local Primary Care Trust.

Over 200 Diabetes Nurse Specialists Posts Are Unfilled

The response from 385 NHS Trusts to an audit has shown that there are over 200 diabetes specialist nurse positions not filled. This is twice as many as in 2009. Equally worrying is that in many Trusts, if there is a shortfall of nursing staff, specialist nurses are being asked to cover.

This is part of the cost cutting exercise in the NHS but one that shows no joined up thinking and does not look to the future. Cutting specialist nurses when the number of people with diabetes is rising does not make sense but even worse, is that cutting the help and support that people need from specialist nurses in order to be able to manage their diabetes and avoid complications, is harmful to people with diabetes both now and in the future. What is more, it does not save money in the long term because more people will have to be treated for complications.

It may seem a silly question, but what is the point in developing NICE Quality Standards for Diabetes if the standards cannot be reached because the appropriate number of health professionals are not employed? Are the Quality Standards just an aspiration and not possible in reality? Indeed, will Trusts and commissioners take any notice of them?

Banned diabetes drugs

On April 12th 2011, the GP magazine, Pulse, published list of drugs that GPs have been banned from prescribing due to their higher costs. Pulse used the Freedom of Information Act to conduct a survey of Primary Care Organisations and found that more than 50% of the 134 organisations questioned, 73 had placed drugs on black lists or put restrictions on how these could be prescribed. Among those black-

listed were the Type 2 drugs Byetta, Januvia, Victoza and Galvus. These newer drugs tend to be prescribed for people who have not responded well to the cheaper alternatives or who have had side effects to them. Naturally this raises fears that people will have to use cheaper alternatives that do not suit them as well, or they will be moved on to insulin earlier, which has more side effects, namely increased risk of hypoglycaemia.

Rationing of medicines – patients having to fight to gain access to medicines
Unless a treatment has been recommended by a NICE technology appraisal, Primary Care Trusts [PCTs] are allowed to decide not to fund a particular treatment. If a treatment is not routinely covered by a PCT and a GP or consultant wishes to prescribe such a treatment, then they can submit funding requests to the PCT.

Recent figures published in GP [28.04.11] show:
- Funding requests to PCTs rose by 17% from 2008/9 to 2010/11.
- Around half of requests are approved, but approval rates vary from less than 10 per cent in some PCTs to more than 80 per cent in others.
- During this period, 9,000 more requests were received but 1,000 fewer requests were approved.

[Source: Freedom of Information Act responses from 103 PCTs in England]

Will GP Commissioning make this worse?
PCTs are in place until 2013 when the system is expected to change and GP consortia will be in charge of funding. It remains to be seen whether this will make the situation better or worse but one thing is clear, if patients do not receive the treatment they need, then the complaint or argument will be directly with their GP and no longer the PCT. This is probably not a comfortable position for either the patient or the GP and is likely to make the doctor /patient relationship difficult.

How do we deal with this situation?
Perhaps now more than ever, we need to be aware of the NHS Constitution and our rights as patients...

The NHS Constitution

"*The NHS Constitution was created to protect the NHS and make sure that it will always do the things it was set up to do in 1948 – to provide high quality healthcare that's free and for everyone. No government will be able to change the Constitution, without the full involvement of staff, patients and the public*" [NHS website]

What is the Constitution?
The Constitution brings together in one place the details of what staff, patients and the public can expect from the NHS. It sets out your rights as an NHS patient and also your responsibilities. The rights cover how patients access health services, the quality of care you'll receive, the treatments and programmes available to you, confidentiality, information and your right to complain if things go wrong. The NHS also makes certain pledges to you, which it is committed to achieving. These go above and beyond your legal rights and are a commitment to provide high-quality services.

The whole of the NHS Constitution is available online – the easiest way is to Google NHS Constitution, but of specific interest to us in respect to being denied access to treatments, has to be about our rights to choice.

Choice of treatments
You will discuss with your doctor or other health professional your choices of treatment and the more you know about your condition and treatment options the easier it is to make your views known. It is important to explain to your doctor your needs and the reasons for making your choices.

Scientific evidence
It maybe that the doctor will say there is strong scientific evidence to suggest that one treatment is better than others but there are still decisions and choices to be made. You can always ask the doctor for the scientific evidence and take it away to read before you make your decision.

In other cases, it may be less clear which treatments are best. For instance, in diabetes the newer insulins or drugs for Type 2 diabetes often do not show superiority over the old ones, so in these cases it is particularly important to ensure that you understand the options and make your views known. Another example is the treatment of depression – you may prefer to see a counsellor rather than take antidepressants.

These are your rights:

- You have the right to be involved in discussions and decisions about your healthcare, and to be given information to enable you to do this. Your doctor should listen to you and respond to your concerns and preferences about your healthcare. That way, you can find out what's the best treatment for you. NHS staff will give you the information that you need to support these discussions and decisions.
- You have the right to accept or refuse treatment that is offered to you, and not to be given any physical examination or treatment unless you have given valid consent. If you do not have the capacity to do so, consent must be obtained from a person legally able to act on your behalf, or the treatment must be in your best interests.

It is worth remembering that you should always be treated with dignity and respect.

Weighty Matters

WeightWatchers appears to be the best

Two UK Medical Research Council studies suggest that WeightWatchers works better than the strategy recommended by the NHS. So what is the NHS strategy for weight loss?

NHS Choices states:
"*Check your BMI [Body Mass Index] and if it indicates that you are overweight, the best way to lose weight and keep it off is to eat a healthy, balanced diet and get plenty of regular exercise – 30 minutes exercise a day which can be anything that makes you slightly out of breath and warmer than usual.*"

The NHS also advises that you should talk to your GP before getting started - especially important if you have diabetes. They also advise having the support of family and friends to keep you motivated. However, the WeightWatchers research stated that the support, education and motivation offered by WeightWatchers was seen to promote the behavioural and lifestyle changes needed for consistent and long-term weight loss. Visit **http://www.weightwatchers.co.uk**

Paying people to lose weight works!
Almost half of the 400 people taking part in a study, nearly half of whom worked for the NHS, lost 5% of their body weight. On average they shed 8.8lbs [4kg] over a year. The programme paid people up to £425 if they hit their weight loss target and maintained it for 2 years. The researchers said it shows that the scheme works as well as other weight loss programmes, suggesting that money provides a strong motivation. WeightWatchers charge to lose weight, which may be an added factor in why it works better – are people who pay more committed to losing weight?

Slimming Pills
NHS Choices advise that slimming pills should only be used if you are obese and if prescribed by your GP. They will not benefit long-term health and they can have lots of side effects. Some of the slimming

pills can cause low blood sugars, which is the last thing that people with diabetes need! So slimming pills should not be bought over the counter or via the internet where it seems extremely difficult to find information about possible side effects or interactions with medicines and special warnings for people with diabetes.

Go to bed early!
A study has shown that people who go to bed late eat more food, have worse diets and are more likely to be overweight. [Obesity, May 2011] Compared with normal sleepers, participants in the study who got less sleep and went to sleep later ate more calories at their evening meals and after 8.00pm, ate more fast food, drank more high-calorie soft drinks and had lower fruit and vegetable consumption.

However, it's not clear whether they ate more unhealthy food because they preferred it or because there were limited choices of food at late hours. Late sleepers tended to eat less in the morning, then steeply increased their calorie intake in the afternoon and evening. This reinforces the old belief that when you eat is important, so don't stay up late!

Drinking water and weight loss
Researchers reporting the findings of a clinical trial which confirmed that drinking two 8 ounce glasses of water before low calories meals results in significant weight loss. [American Chemical Society, August 21, 2010] The trial involved 48 people aged 55 to 75 who were divided into two groups – one drank two cups of water before meals and the other didn't. Over 12 weeks the water drinkers lost about 15.5 pounds while the non-water drinkers lost 11 pounds. The researchers' possible explanations are that the water fills up the stomach so people feel full and so eat less or that if people drink water before a meal they are less likely to drink calorie containing drinks during the meal.

Note: drinking too much water can cause a rare condition called water intoxication, which can be serious.

Low carb diet is more effective than low glycaemic diet for people with type 2 diabetes
Research has shown that a low-carbohydrate diet improves blood sugar levels in obese people with Type 2 diabetes. [Nutrition and Metabolism, December 2008] In 84 obese people with Type 2 diabetes, they compared a low carb diet with no restrictions on calorie intake with a diet which uses foods with a low glycaemic index and calorie intake restrictions. Low glycaemic index foods are those that don't cause rapid rises in blood sugars.

The results over 6 months showed that the low carb diet had greater improvements in their HbA1cs, greater weight loss and increased 'good' cholesterol [HDL] compared to a low glycaemic calorie reduced diet. It was also possible for 95.2% of those on the low carb diet and 62.1% of those on the low glycaemic calorie-reduced diet to eliminate or reduce their diabetes medications.

This adds to other studies that also show that the low-carb diet is effective in the management of Type 2 diabetes, despite all the criticisms it has received in the past! This is something to discuss with your health professionals.

New 'anti-flab jab', according to the newspapers!
Victoza [liraglutide], a Type 2 drug from Novo Nordisk for treatment to lower blood glucose levels, has also been shown to reduce weight, as does Byetta [exanatide] from the same family of drugs. However, Novo Nordisk has approached the US drug regulatory authority to pursue trials of Victoza for a second use - the treatment of obesity. It is reported that in trials people lost 21 pounds in 6 months and kept the weight off for 2 years but University of Glasgow nutrition expert, Professor Mike Lean, warned that obese patients must also exercise and not rely solely on the drug.

On July 16th 2011, the Daily Mirror described Victoza as 'a new anti-flab' jab that makes people feel full for hours. It stated that the Victoza injection is twice as effective as the current most popular slimming drug Orlistat. Interestingly, it says that Victoza also wards off Type 2 diabetes, reduces blood pressure and promotes good cholesterol –

has it been forgotten that it was developed as a treatment for Type 2 diabetes or is it just going to be a huge money spinner if it is accepted as a weight loss drug?

A more dramatic way of losing weight - Bariatric Surgery!
There are three types of surgery for weight loss:

- **Gastric band** – an adjustable band is put round the upper part of the stomach to restrict the amount of food that can be eaten.
- **Gastric bypass** – the stomach is stapled to produce a 'smaller stomach' which results in a feeling of fullness.
- **Sleeve gastrectomy** – this is more radical surgery which removes part of the stomach.

IDF Position Statement on bariatric surgery, March 2011
The International Diabetes Federation [IDF] issued a Position Statement supporting bariatric surgery as a cost effective treatment option for severely obese people with Type 2 diabetes.

Their recommendations are based on increasing evidence that the health of obese people with Type 2 diabetes, including glucose control and other conditions, can substantially benefit from bariatric surgery under certain circumstances. The comments of some of the experts:

President of the IDF Professor Sir George Alberti: "Bariatric intervention is a health and cost effective therapy for type 2 diabetes and obesity with an acceptable safety profile. Bariatric surgery for severely obese people with type 2 diabetes should be considered much earlier in management rather than held back as a last resort. It should be incorporated into type 2 diabetes treatment protocols."
The IDF Position Statement can be found on their website:
http://www.idf.org/webdata/docs/IDF-Position-Statement-Bariatric-Surgery.pdf
What about the evidence?
Bariatric surgery reduces long-term cardiovascular risk in Type 2 diabetes
In the longest study of its kind, bariatric surgery has been shown to reduce the risk of heart attack and stroke in patients with Type 2 diabetes. Experts say that while Type 2 diabetes is not technically a cardiovascular disease, it might as well be one, given the effects of unregulated blood sugar on the heart. The Swedish Obese Subjects [SOS] Study looked at information gathered over 20 years which compared 2,010 bariatric surgeries with 2037 non-surgically treated people receiving medical treatment or lifestyle modification for obesity. The results showed:

- 70% show remission of diabetes after 2 years follow-up.
- 30% are still in remission 15 years after bariatric surgery.
- After 20 years, bariatric surgery has reduced new cases of Type 2 diabetes by 80% among obese people who did not have diabetes at the start of the study.
- The incidence of new cardiovascular events [heart attack or stroke] has been 30% lower amongst post surgery patients compared to those receiving 'normal' treatment.

A study carried out in Utah showed similar results.

What does the National Institute for Health and Clinical Excellence [NICE] say?
Surgery should be available to people who are 'morbidly obese', those with a BMI of 40+ or those with an existing health condition with a BMI of at least 35 where all other treatments have failed. However, a report in GP [03.09.10] says that many areas are not following NICE guidelines because of the costs and have imposed their own restrictions, such as BMI of 50 or more.

Surgery is not an easy option
Patients have to demonstrate a commitment to weight loss and go through a lengthy procedure before approval for the operation is given. Nevertheless, surgery is a fix but it does not get to the route of the problem – the prevention of the obesity epidemic. Exercise and a balanced diet are still the best solution.

IDDT's Annual Conference

'*It's My Diabetes*'
Saturday, October 15th 2011
Kettering Park Hotel and Spa

Never heard of Kettering?
We have moved to a different part of the country in order to give different people a chance to attend. You may not have heard of Kettering but it is a central location for many people and it has good road access from all directions. From the north using the M1 and A14,

from the north west, M6 and A14, from the south M1, A45 and A43 and from the east using the A14. By rail Kettering is an hour from St Pancras, London.

The Programme
The conference aims to help people make an informed choice of how their diabetes is treated. Treatment choice does not just mean what insulin or tablets are taken but also what to eat, how help from pharmacist can be accessed and even what care is wanted from the Healthcare Professionals. As always we will be looking at working together to making living with diabetes a little easier and giving people the chance to talk over their hopes, fears and their feelings about diabetes.

In addition to the programme that members have already received, I am delighted to say that we will be joined by additional speakers – Dr Mabel Blades, Consultant Dietitian and Mr Michael Holden, CEO of the National Pharmacy Association. As usual there will also be plenty of time for discussion groups.

We do hope you will join us and help to make this another successful Conference.
Further details and a booking form can be obtained:

- **Telephone IDDT on 01604 622837**
- **E-mail enquiries@iddtinternational.org**
- **Write to IDDT, PO Box 294, Northampton NN1 4XS.**

Alternatively the booking form can be downloaded from our website:
http://www.iddt.org/events/iddts-2011-conference

Old Chestnuts Worth Remembering!

A reply to the article about new units for HbA1c
Dear Jenny,

Once again we are seeing decisions that make me wonder if these people have nothing better to do with their time…

Do we remember the days when we had carbohydrate exchanges and it worked very well, one portion = 10 grams of carbohydrate? Then about 12 years later for no reason that was evidenced based, they went over to "eat what you want" which must have been a nightmare for more newly diagnosed people because you need to balance your food intake against insulin or IT DOES NOT WORK.

Then later still, enter DAFNE, the so called miracle new teachings when it's all the same clinical nutritional database from the 1990s and back to carbohydrate exchanges...back full circle.

As patients go to their clinics once every 6 months they have become used to their HbA1c readings and what they mean to them...it's simple.

Now we have more changes with the new HbA1c figures! Older patients will be completely confused which will add a level of anxiety because patients won't know where they are which could lead to a detrimental effect. Do these decision makers not realise what effect this will have on patients? It seems like change for changes sake and the confusion could be dangerous.

I hope the UK diabetologists and clinics stick to their guns and resist this change for changes sake, we have had far too many changes in diabetes over the last 20 years. We should stick to what we know works and more importantly, what the patient is comfortable with.

Mr George Johnson
Scotland

Faulty pens
Dear Jenny

Thank you for an excellent newsletter. I am 68 years old and have had Type 1 diabetes 57 years and I wonder if any other reader has had the same problem as me?

I use a NovoRapid Flexpen, incidentally I much prefer a syringe as I am then in control. On at least 12 occasions, I have set the pen to the required dose, but the when I press the pen no insulin is injected. After a few suspicions, I tried it in the air and no insulin came out. I have returned faulty pens to the chemist and have been told this happens randomly and the makers, Novo Nordisk admit no fault.

I'd like to warn other users to be aware and would dearly love to know if anyone else has experienced this. It could be potentially very serious if someone wasn't aware.

Mrs L.J.
N. Yorks

Comment: *Since receiving this letter, IDDT has received another similar complaint, so if you are having problems with any pen injection device, you can take it up with the manufacturers or report it to the body regulating medical devices, the MHRA:*
You can find the details about the regulation of devices by visiting ***http://www.mhra.gov.uk/Aboutus/Whatweregulate/index.htm*** *and contact them at the following address: MHRA, 151 Buckingham Palace Road, Victoria, London, SW1W 9SZ or by phone (weekdays 9:00 -17:00): 020 3080 6000*

Change in strips
Dear Jenny,

Since discovering that my testing strips that had a yellow circle symbol on the box give me a reading 11% more than my blood sugars, I have started to check the insert on my testing strips. Now the yellow circle has gone from the box that meant the strips were 11% different and now I have a green square symbol. The insert says:

'*These test strips are labelled with a green (shown) symbol to distinguish them from earlier test strips that were subject to clinically relevant maltose interference. The green symbol can be found on the test strip box and on the label of the test strip container*.'

There is a yellow highlighted message which says : 'IMPORTANT INFORMATION FOR HEALTH CARE PROFESSIONALS. Always check for the (shown) symbol on the test strip box to be certain there is no clinically relevant maltose interference.'
What does it mean? Do these strips still register 11% higher? I have looked on the net but I can't find the answer!

By e-mail

Comment: *Yet more confusion! Here is the answer from Roche Diagnostics:*
The new strips marked with the green symbol does not give different readings to the ones marked with the yellow circle, unless you are in a special situation where maltose is present in your body, if for example you are on certain types of dialyses. This is further described in the notes you got with the strips. Both the green and yellow marked strips will give 11% higher readings than our old whole blood test strips.

These strips have been out of the market for quite some time.

Five don't drive
Dear Jenny,

At my recent visit to my diabetes consultant we discussed my problems of lack of warning for hypos and he told me that the general opinion is that if your blood glucose reading is around 5 then do not drive, (five don't drive) and apparently this is the guide given by the DVLC if you wish to keep your licence. Has anyone else heard of this?

R.L.
Suffolk

Misdiagnosis Of People With Diabetes - Update

In IDDT's April 2011 we covered a report by the Royal College of General Practitioners [RCGP] and NHS Diabetes that 50,000 people have been told they have diabetes when they did not and another 50,000 have been told they have Type 1 diabetes when they actually have Type 2 diabetes, or vice versa. The NHS has pledged to improve the diagnosis of diabetes and that new guidelines and audit tools have been developed which will help GPs to diagnose diabetes correctly.
International groups have tried to develop classification schemes for these new types of diabetes but they have been complex. So a group from the RCGP and NHS Diabetes has decided on a practical classification scheme that non-experts can use. The suggested classification scheme is as follows:

The patients who have been misclassified
The research for the report showed that about 40 patients in each GP practice were found to need their records checking for misdiagnosis. The RCGP and NHS Diabetes have developed an audit tool of how GPs can identify misdiagnosed patients. Apparently most of these patients can be easily assessed and their records amended with only a few needing thorough analysis. ***If you are concerned about your diagnosis, make an appointment to discuss this with your GP***.

Diabetes	Non-diabetic hyperglycaemia
Type 1	Impaired glucose tolerance
Type 2	Gestational diabetes
Genetic	
Other	
Unknown	

Supported by a study showing Type 1 should be considered in older people
A study carried out at Newcastle Diabetes Centre found that 20% of the 79 patients diagnosed with Type 1 diabetes during the 2 year study were aged 50 or over. Of the 13 older patients with Type 1 diabetes, 10 had ketonuria, 6 needed admitting to hospital and 3 had ketoacidosis. The researchers concluded that with the increase in the aging population, the diagnosis of Type 1 diabetes in older people is likely to become more common and that Type 1 diabetes should be considered in all older people with normal body Mass Index [BMI] with new onset diabetes.
[Presented at the Diabetes UK Conference, April 2011]

And We Now Have Type 3 Diabetes...

A news item from Toronto says that a revolutionary new product, CinGX, has been developed to prevent and treat Type 3 diabetes. And what is Type 3 diabetes you may well ask. It appears that normally the brain produces insulin but if there is a lack of this insulin resulting in high blood glucose levels, this has a negative effect on brain function.

This can increase the incidence and severity of Alzheimer's disease and dementia, a condition now known as Type 3 diabetes.

CinGx combines two natural extracts which act together to control glucose metabolism, improve cognitive function and at the same time, minimise the risk of developing diabetes. Health Canada approved label claims and advertising for products containing CinGx and these claims include reducing blood glucose levels and cholesterol while at the same time improving memory, cognitive function, energy and mental wellbeing. Apparently, CinGx can be taken as a nutritional supplement or delivered in a wide variety of food and drinks.

And We Have Double Diabetes...

Double diabetes is when someone with Type 1 diabetes develops insulin resistance. The most common cause of insulin resistance is obesity and therefore is very often present in people with Type 2 diabetes. However, people with Type 1 diabetes can become overweight or obese and so also become insulin resistant. Someone with double diabetes will always have Type 1 diabetes even though it cannot be brought on by obesity. Insulin resistance occurs when the insulin levels are high over a prolonged period which reduces the body's own sensitivity to insulin.

The evidence - there seems to be very little evidence for this but a Danish study investigated the effect of twice daily metformin in people with Type 1 diabetes with what was classed as persistent poor control [HbA1c of 9.48%]. A comparison was made between treating with metformin and treating with a placebo [dummy pill] for 12 months. The results showed that metformin did not improve overall glycaemic control, there was no difference in minor or major hypoglycaemia but there were sustained reductions of insulin dose and body weight. [PloS One 2008;3(10):e3363. Epub 2008 Oct 9.] Note: We know that increased insulin doses tends to increase weight, so did the reduction in insulin dose cause the weight loss?

And There's LADA

This is Latent Autoimmune Diabetes which we have discussed in previous Newsletters. This is where people who are over the usual age for Type 1 diabetes diagnosis [around over 40] and are not overweight at diagnosis, as is the classic case for Type 2 diabetes. They are often treated as having Type 2 diabetes and given tablets but in fact they have slow onset Type 1 diabetes and need insulin treatment.

The Sleep Disorder, Obstructive Sleep Apnoea

There are several forms of sleep apnoea but obstructive sleep apnoea is the most common. In the UK, it is estimated that around four in 100 middle-aged men and two in 100 middle-aged women have obstructive sleep apnoea - a sleep disorder caused by disturbed breathing [a pause in breathing]. It is caused by an upper airway collapse affecting the person's ability to draw down air from their lungs which results in a shortage of oxygen. Each pause in breathing can last from a few seconds to minutes and may occur up to 60 times or more each hour. The pauses in breathing or instances of shallow breathing lead to poor quality sleep in short bursts. During sleep vital functions occur for good health to be maintained and lack of enough sleep can lead to cognitive, cardiovascular and metabolic adverse effects.

Causes of obstructive sleep apnoea

The cause can by physiological from large tonsils, large tongue, low soft palate or small chin. It can also be triggered by alcohol or

sedatives but is most commonly caused by obesity, especially around the neck.

Symptoms

Snoring	Overweight or weight gain
Tired all the time	High blood pressure
Morning headaches	Sexual dysfunction
Irritability	Depression
Limited attention span, poor memory	Nocturia [the need to wake to pass urine

Sleep apnoea and diabetes

- It is very common in people with Type 2 diabetes. Research has shown that people with sleep apnoea are at increased risk of Type 2 diabetes but also that people with diabetes are at an increased risk of sleep apnoea.
- Sleep apnoea increases the risk of insulin resistance and therefore Type 2 diabetes.
- A study in Diabetic Medicine [Oct 2010] of 231 patients with Type 2 diabetes found that 48% of those with obstructive sleep apnoea developed severe retinopathy compared with 20% of those who did not have the condition. A separate study found 60% of patients with diabetes and obstructive sleep apnoea had nerve damage compared with 22% of patients with diabetes but not obstructive sleep apnoea.

Treatment

- Treatment for sleep disorders by losing weight and lifestyle changes is likely to improve blood glucose control and energy levels.
- CPAP – a flow generator with mask worn during sleep to gently provide the person with air by ensuring that the airway remains open to avoid episodes of apnoea.
- Mechanical treatments such as a mandibular repositioning device which repositions the jaw and opens the airways.
- Surgery – removing the tonsils, most commonly used in children.

Diagnosis of sleep apnoea is often missed

Often this is because other avenues are explored first but if you snore, have unrestful sleep, sweating and/or nocturia and are tired all the time, it is worth checking with your doctor. It is also worth remembering that it not only affects you and your sleep but it can be very frightening for the person lying in bed next to you.

We Have Not Forgotten Mixtard 30 And Actraphane

Jenny Hirst, Co-Chair

As readers know, IDDT has been very concerned at the withdrawal last December of Mixtard 30 and particularly for the vulnerable group of people who need the Innolet device to inject. There is no similar device which can be used with the nearest equivalent pre-mix human insulin, so people with visual impairment or manual dexterity problems have been denied their independence. What is particularly frustrating is that the Innolet is available in the EU with Actraphane, a pre-mix human insulin but rules and regulations prevent it being accessed because it is licensed. [See April 2011 Newsletter for full details]

We have followed this up with letters to various key people and MEP, Lady Sarah Ludford who took up the issue on our behalf and did establish from Novo Nordisk that Actraphane is the same insulin with a different name for the EU market. So this makes the lack of accessibility even more frustrating!

The CEO of the Medicines and Healthcare products Regulatory Agency [MHRA] in the UK, Professor Kent Woods, has written to IDDT explaining the regulations once again that prevent its importation for personal use. He says that “the MHRA as the regulator in the UK is cognisant of the issues surrounding the withdrawal of Mixtard 30

Innolet. It will continue to take account of and ensure that consideration of, the needs of patients using insulin products, including specific patient needs identified as met by the Innolet device." This sounds good but I'm not sure what it means!

Calling on patients!
If you have been affected by the withdrawal of Mixtard 30 and the Innolet, please send your thoughts and feelings and an accurate account of how this has affected you.

Calling on health professionals!
If you have experience of your patients being adversely affected by the withdrawal of Mixtard 30 and the Innolet, then please send us as many details as you can.

US Safety Warning About High Dose Simvastatin

June 8th 2011: The US Food and Drug Administration [FDA] is recommending limiting the use of the highest approved dose of the cholesterol lowering medication, simvastatin [80 mg] because of increased risk of muscle damage. Simvastatin 80 mg should be used only in patients who have been taking this dose for 12 months or more who have not shown muscle damage [myopathy] and it should not be started in new patients, including patients already taking lower doses of the drug. In addition, FDA is requiring that the label adds new contraindications [should not be used with certain medications] and dose limitations for use of simvastatin with certain medications.

What does the Cochrane Review say about statins?
This review of trials with over 34,000 participants, the authors of this review could find no evidence of harm and mortality, cardiovascular endpoints, and revascularisations were reduced. Nevertheless they concluded: "caution should be taken in prescribing statins for primary prevention among people with cardiovascular risk." [Cochrane Database System R 2011;1:CD004816]

This statement does not seem to be in line with their findings and this is because the authors found the evidence from various studies was not of sufficient quality to allow them to come to a different conclusion. This conclusion is also opposite to other recent published findings which showed that statins significantly reduced the relative risk of a cardiovascular event by 0.75 per 1mmol fall in LDL [bad] cholesterol. All this is confusing for the public.

An article in the Lancet says that GPs should do what they have always done – clearly explain the risks and benefits of statins so that the patient is able to choose the strategy that is best for them. [Lancet Vol 377, Jan 29, 2011]

And by the way...
Feeling anxious or depressed when taking statins? Some people do and here's a possible explanation
A report suggests that the symptoms of anxiety and depression which occur in some people taking statins and in some people on low cholesterol diets could be the result of long-term, low level cholesterol in the brain. [Biochemistry June 30, 2010]

Statins work by blocking a key enzyme involved in the body's production of cholesterol and scientists have previously shown that maintaining normal cholesterol levels is important for the function of cell receptors for serotonin – the brain hormone that influences mood and behaviour. However, the long-term effects of cholesterol depletion on these receptors, which can occur in people taking anticholesterol drugs, has been unknown.

This new research has shown that long-term use of statins caused significant changes in the structure and function of the serotonin cell receptors and when cholesterol was added, the cells were restored to normal. This suggests that the effect of long-term, low cholesterol

levels in the brain might trigger anxiety and depression.

What's Happening With The New Hba1c Units?

The changeover to the new HbA1c units was all supposed to happen by June, but what actually happened? Unsurprisingly, IDDT received very mixed reports!

- Many areas have not been giving HbA1c results in the new and the old units and many PCTs and doctors are still working in the old units.
- One of our members went to his hospital clinic and his results were given in the new units but his GP is giving his HbA1c results in the old units!
- Some hospitals are still using the old method of testing HbA1cs and then simply converting the results with the table. [So why bother with new units?]
- Academic journals will continue reporting HbA1cs in the old percentage units – Diabetologia has not started using the new units and Diabetic Medicine will continue using both methods.

Confused – aren't we all? So in May it was announced that the date for when the new units only will be used has been delayed to October 1st 2011 with the statement that this is a one off delay. But can this really be forced on doctors, hospitals and researchers if they continue to use the old units? We'll wait and see...

Table showing the current DCCT measurements, the proposed new IFCC measurements, and the average blood glucose measurements you can expect to be associated with each particular level of HbA1c

HbA_{1c} (DCCT) Current measurement (%)	**HbA_{1c} (IFCC) Measurement from June 2011 (mmol/mol)**	**Average blood glucose level for this HbA_{1c}, mmol/L**
6	42	7.0 (range 5.5-8.5)
7	53	8.6 (range 6.8-10.3)
8	64	10.2 (range 8.1-12.1)
9	75	11.8 (range 9.4-13.9)
10	86	13.4 (range 10.7-15.7)
11	97	14.9 (range 12.0-17.5)
12	108	16.5 (range 13.3-19.3)
13	119	18.6 (range 14.6-21.1)

Snippets

Unused medicines
Unused prescription medicines cost the NHS £370 million a year. According to newspaper reports, bags of unused medicines are found at some people's homes but they can't be returned to pharmacies under current regulations.

Paediatric reform
The UK Royal College of Paediatrics and Child Health has issued a report, Facing the Future, in which it says that paediatric care is suffering. There are insufficient numbers of qualified staff with many wards being managed by inexperienced doctors. The report calls for a 50% in paediatric consultants posts.

50% of British women have shortage of Vitamin A
Research at Newcastle University has found that almost half of British women have a genetic variation which stops them benefiting from the goodness of beta-carotene, a source of Vitamin A. Women affected by this are more likely to get flu and unhealthy skin. Beta-carotene is

the orange pigment in carrots. Younger women are at a greater risk of a lack of Vitamin A because they tend to eat low fat diets whereas older generations tend to eat more eggs, milk and liver which are naturally rich in Vitamin A.

Sweden to ban trans fats
Sweden's government is developing legislation to ban the use of trans fats in food products. Up to now the food industry has voluntarily reduced trans fats in food products, as is the present position in the UK. Trans fat is unsaturated fat which is a by-product of partially unsaturated plant fats which generally are vegetable oils. They raise cholesterol levels. The largest amount of unsaturated fat consumed is in processed food products such as ready meals, biscuits, ready made sauces and margarine.

Teaching pregnant women to sing...
An NHS project at Chelsea and Westminster Foundation Trust is teaching pregnant women to sing to their unborn babies with the aim of boosting language skills in infants and improving bonding. And the NHS is short of money?

Coca-Cola Vitaminwater sounds healthy but it's not!
The name alone makes it sound healthy and it does contain vitamin C and 4 Vitamin Bs but a 500 ml drink of Coca-Cola's Vitamin water contains 23g of sugar, the equivalent to 4 or 5 teaspoons of sugar. This is more than a quarter of the recommended daily intake of sugar. So beware, the name can fool you!

Earlier this year the Advertising Standards Authority banned the advert for using the word 'nutritious' on the basis that people would not expect a 'nutritious' drink to have such a high sugar content.

US adults and their sugar consumption
On average US adults consume an average 22.2 teaspoons of sugar daily. This is equivalent to 355 calories and more than double the recommendations for me of 9.4 teaspoons and 6.25 teaspoons for women.

New Limits Set On Gluten-Free Prescribing

Although gluten-free foods for people with coeliac disease are more widely available in supermarkets, they are up to three times as expensive as ordinary foods. It has been possible to have a monthly prescription for gluten-free foods although the amount of foods that people have had on prescription has varied, with big differences in the number of products people receive each month. As a result of cuts, new policies to restrict the prescribing of gluten-free foods are being introduced.

Coeliac UK believes that these place unreasonable limits on the number and type of products available on prescription. The concerns are that the new policy is too restrictive and does not take into account the welfare of people with coeliac disease. Coeliac UK maintain that the policy should be as follows:

- Gluten-free prescribing should remain within the NHS.
- Staple foods such as breads (including fresh bread), pasta, flours, pizza bases and crackers listed by the ACBS should remain available and specialist breakfast cereals should be added.
- Cake mixes should no longer be available and sweet biscuits should only be considered in exceptional circumstances based on clinical advice.
- Amounts recommended in the 2004 national guidelines should be treated as the norm.
- Doctors and dietitians should be able to use their clinical judgment in the prescribing of gluten-free foods based on an assessment of clinical need.

More information is available from Coeliac UK website:
http://www.coeliac.org.uk Helpline 0845 305 2060

If you would like to join IDDT, or know of someone who would, please fill in the form (block letters) and return it to:

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From Your Editor – Jenny Hirst

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