



# Insulin Dependent Diabetes Trust

July 2010 Newsletter



## Department Of Health Statement 2010

As a result of a lobbying campaign by IDDT members, in 2005 IDDT received a very important and significant statement from the then Minister of Health, Rt Hon Jane Kennedy, which acknowledged that some people are better suited to animal insulins and they should continue to be available.

However, 5 years has elapsed since this acknowledgement was made and the need for animal insulins to remain as a treatment option still exists today, as many IDDT members can testify. In addition, IDDT continues to receive e-mails and calls from people who know that they have been ill since starting insulin treatment or since changing to insulin analogues.

With only one supplier in the UK, IDDT Trustees are only too aware of the vulnerability of people who need animal insulin and how the continued availability of the animal insulin they need is never far from their minds. So we wrote to the then Minister of Health, Rt Hon Mike O'Brien QC MP, to seek discussions on the present situation and to remind the Department of Health that this issue has not gone away! As reported in our April Newsletter, he arranged for us to meet Dr Rowan Hillson, National Clinical Director for Diabetes. The meeting took place on January 20th 2010 and the promised statement for IDDT members arrived on April 8th 2010 – here it is:

### **Statement from Department of Health regarding the choice and supply of animal insulin**

At a meeting between the Department of Health (DH) and the Insulin Dependent Diabetes Trust (IDDT), it was agreed that the DH would

provide a statement covering patient choice and the supply of medicines.

### **Patient Choice**

The National Clinical Director for Diabetes, Dr Rowan Hillson confirmed that it was her view that people with diabetes should have the choice to use the type of insulin that works best for the management of their condition. She fully supports the importance of informed choice provided that safety is not compromised and that it is practical to supply the medication.

### **DH systems for the management of supply of pharmaceuticals**

Within the DH, the Medicines Pharmacy and Industry Group has a team responsible for the supply of medicines. They work closely with pharmaceutical companies, NHS colleagues and other organisations and individuals, to help ensure that patients continue to get the medicines they need.

As part of this process, the DH and the pharmaceutical industry have published joint best practice guidelines in relation to medicine shortages and discontinuations.

Shortages of medicines can occur for a number of reasons, such as manufacturing problems, regulatory problems or problems in obtaining raw materials. The guidelines “Notification and Management of Medicines Shortages” aim to help minimise the impact of supply problems on patients. They recommend that companies should inform the DH of potential problems as soon as possible, so that all parties can work together to explore the options available to manage the shortage.

To ensure that the discontinuation of a medicine does not cause unnecessary problems for patients and prescribers, the DH and the pharmaceutical industry introduced the guidelines “Ensuring Best Practice in the Notification of Product Discontinuations”. These recommend that companies give the DH advance warning of any medicine discontinuation. They also give advice to companies on

communication about discontinuations – who to tell, when, and what information will be needed.

These guidelines can be found at [www.dh.gov.uk/medicinesupply](http://www.dh.gov.uk/medicinesupply)

### **Supply of animal insulin**

Wockhardt has confirmed that it has no plans to discontinue its animal insulins. If at some time in the future this changes, the company has agreed to notify the DH under the guidelines mentioned above, ‘Ensuring Best Practice in the Notifications or Product Discontinuations’. The guidelines recommend that at least 12 months’ notice of a discontinuation is given if there is no therapeutic alternative.

### **IDDT conclusions**

- ▶ Wockhardt has no plans to discontinue animal insulins
- ▶ Dr Hillson agrees that patients should have the choice of insulin that works best for them, which therefore must include those using animal insulins.
- ▶ She supports the importance of informed choice, providing safety is not compromised, and we know that it is not because animal insulins have been used safely for many years.
- ▶ We should have 12 months notice if Wockhardt decide to discontinue production.

I hope that this is reassuring for our members who use animal insulins. IDDT has always had a plan of action just in case...

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## **Canada Comes To The Same Conclusions - Animal Insulin Must Remain Available**

### **Report on Insulin by a Canadian Expert Panel of the Biologics and Genetic Therapies Directorate**

After many years of raising the issue that some people in Canada need animal insulin, eventually an Expert Panel of the Biologics and

Genetic Therapies Directorate [BGTD] was set up to look into the various issues around the need for and availability of animal insulins. The situation in Canada is that all animal insulins were discontinued by the insulin manufacturers. After much lobbying, Health Canada licensed Wockhardt UK's pork insulin but [i] it is not funded or accepted as essential by all Provinces in Canada and [ii] it is very expensive. Beef insulin is not available at all and people needing beef insulin have to import it from Wockhardt UK, again this is expensive and involved. However, one of the major problems is that the majority of doctors, health professionals and above all, patients are unaware that animal insulins can still be obtained – vital information for those suffering adverse effects when using synthetic insulins.

IDDT's Trustee in Canada, Carol Baker gave evidence to the Panel as someone who has had diabetes for nearly 50 years and also had adverse effects when using synthetic insulins.

#### **Key findings of the panel:**

- ▶ The Panel agreed that based on the currently available data, there appears to be a set of people with insulin-treated diabetes mellitus who seem to have better metabolic and symptomatic control when receiving animal-sourced insulins rather than synthetic human insulin or insulin analogues. Therefore, the panel agreed that animal-sourced insulins should continue to be made available to patients with diabetes mellitus.
- ▶ The Panel agreed that the knowledge of the availability of animal sourced insulins seems to be lacking by some physicians and pharmacists, despite repeated efforts to communicate this. The Panel recommended that Health Canada obtain data, by means of a survey, from pharmacists, diabetes education nurses, and physicians, to determine if there truly is a communication issue or if pharmacists, physicians and diabetes educators are aware but do not consider this to be an important issue. This would help identify where the communication problem is and addressed accordingly. They also recommended that the Panel report should be posted on the Health Canada website.

- ▶ The Panel agreed that Clinical guidelines developed by the Canadian Diabetes Association [CDA] are the best way to communicate the information about animal insulins but recognised that Health Canada has no authority to direct the CDA. However, they felt that suggestions and discussions with CDA about the guidelines could take place.
- ▶ The Panel also recommended that there should be an additional statement about hypoglycaemia unawareness on the labelling and product information for all insulin. They recommend that after describing the warning symptoms, it should be added that hypoglycaemia 'can occur without recognisable symptoms'.

#### **The other key findings of the Panel were:**

- ▶ The lack of post-market studies on insulin constitutes a gap.
- ▶ The Panel also recommended that animal sourced insulins should be made available to those patients with diabetes who require them, and at an affordable cost.
- ▶ The Panel recommended that all insulins should be listed on each province's formulary so that they are available for all patients with diabetes.
- ▶ The Panel expressed concerns with patients using the Special Access Program to access their insulin, on the long term, as the Program was not designed for this purpose. The Panel also suggested that the SAP be expanded to have two levels, one where the product is needed for the short term and the other where the product will be used on a longer term basis.
- ▶ The Panel suggested that Health Canada import the needed insulin into Canada into a facility from where patients could obtain it. This would help alleviate problems with possible shipping delays.
- ▶ The Panel also recommended that Health Canada work with the US Food and Drug Administration to collaboratively bring these insulins into North America so that people are not waiting long periods of time for their insulin.

Our thanks go to Carol Baker for her part in highlighting and obtaining

recognition of the need for animal insulin. The full report and details of the meeting can be found on Health Canada's website <http://www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/sci-consult/insulin/index-eng.php>

## Canada looks at the cost-effectiveness of insulin analogues

As readers know, Germany has already carried out reviews that have concluded that insulin analogues are not superior to other insulins for the majority of people and so recommended that they are not funded by health insurers unless they are the same price as human insulins. Now researchers in Canada have conducted a cost-effective evaluation of insulin analogues compared to conventional insulins. Bearing in mind that the rapid-acting analogues [Apidra, Humalog and NovoRapid] are about 25% less expensive than long-acting analogues [Lantus and Levemir] and human insulins are cheaper, the results and researchers' conclusions were interesting:

- ▶ The cost effectiveness of insulin analogues depends on the type of insulin analogue and whether the patients receiving treatment has Type 1 or Type 2 diabetes.
- ▶ With the exception of rapid-acting analogues in Type 1 diabetes, routine use of insulin analogues is unlikely to represent efficient use of finite health care resources, especially for long-acting analogues for Type 2 diabetes.
- ▶ NovoRapid was more effective and less costly than regular human insulin in Type 1 diabetes.
- ▶ Levemir was less effective and more costly than intermediate-acting human insulin.
- ▶ For some patients who are at high risk of hypoglycaemia, the use of insulin analogues may prove to be cost-effective.

In an ideal world we would not have to look at cost-effectiveness and people would have the insulin that suited them the best but...

## Long-acting insulin analogues and increased risk of DKA in under 20s

The use of long-acting insulin analogues, Lantus [glargine] and Levemir [determir] does not lower the risk of diabetic ketoacidosis [DKA] in children and adolescents any more than what is often referred to as the 'old fashioned' NPH or intermediate-acting isophane insulin, and in fact, slightly increases the risk. These findings from research [Diabetes Care, 2010;33:1031-1033] are arguably more worrying than the lack of benefit of long-acting insulin analogues because DKA is a serious condition. It is caused through lack of insulin, therefore high blood sugars, which results in the body fat being used to provide energy. This causes dangerous ketones and acids to be produced and ketones in the urine, drowsiness, vomiting, laboured breathing and breath smelling of acetone [pear drops].

This new research supports the report by the German Institute for Quality and Efficiency in Health Care which showed that using long-acting analogues appears to give no greater benefits than NPH [Isophane] in children or adults with Type 1 diabetes.

In this study, the researchers assessed the incidence of DKA requiring hospitalisation is 10,682 people with Type 1 diabetes aged 20 years or below between 2001 and 2008.

### Results

- ▶ The overall rate of serious DKA during these years was 5.1 events per 100 patient years.
- ▶ Patients who used long-acting analogues, Lantus or Levemir had an increased risk of 6.6 events compared to 3.6 events per 100 patient years with those using NPH.
- ▶ The results were statistically significant even after adjusting for age of onset of diabetes, diabetes duration, HbA1cs, gender and migration background.

The researchers concluded that the possibility of increased risk of

diabetic ketoacidosis in young patients injecting Lantus and Levemir warrants further attention.

As the UK has already published figures showing that there is a rise in the numbers of admissions to hospital with DKA, IDDT has to wonder if the increasing use of long-acting analogues could be one of the reasons?



## Heart Attacks And Sexual Activity – Doctors Need To Talk

Research presented at the American Heart Association showed that survivors of heart attacks are very likely to avoid sexual activity because they fear it could kill them. The leader of the study said the chance of dying during sex was 'really small'. Experts say that it is safe for heart attack survivors to start having sex again once they are capable of moderate exercise, such as climbing a few flights of stairs.

The study of 1,184 men and 576 women heart attack survivors were assessed one month after the heart attack and a year later. A significant finding was that patients whose doctors had failed to discuss resuming sexual activity with them were more likely to avoid it. Men were 30% and women 40% more likely to report having less sex a year on, compared with before their heart attacks, if they had not been given information on resuming sexual activity. The British Heart Foundation backed the researchers call for doctors to discuss sexual activity with heart attack survivors before their discharge from hospital to allay their fears.

If you have had a heart attack and your doctor fails to discuss sexual activity with you, it may be embarrassing, but it is better for you to ask the question than live with unnecessary fears.

## Holiday Tips

If you are going abroad to find the sun, it may be the first time you have travelled since your diabetes or your child's diabetes was diagnosed. We hope that this article will give you a few practical tips but whether going on holiday abroad or in this country, there is one thing to remember - anticipation of holidays and the day of travel causes excitement, especially in children. Excitement can affect blood glucose levels, so it is important to test regularly and be prepared for some low blood glucose levels!

### Precautions when travelling by air:

- Insulin should not be packed in your suitcase. This will be placed in the hold where the temperature can be below freezing and this is likely to damage your insulin.
- Carry two lots of insulin, testing equipment and syringes/pens and distribute them between two different lots of hand luggage. Luggage does get lost and it could prove difficult to replace your diabetes equipment.
- You should always carry a card to say that you or your child has diabetes. You will need a letter from your GP to explain that you have to carry insulin and other diabetes equipment on board with you.
- Always take more insulin than you need in case of breakages. The country that you are travelling to may not have the type of insulin you need. It is also a good idea to take an extra prescription with you, just in case.
- When you come home it is sensible to throw away the insulin you took on holiday as heat, bright light and vibration can all damage it and make it less effective.
- It is worth remembering that ordering a 'diabetic' meal on flights often results in them being low in carbohydrates, so it is probably not a good idea. On long journeys it is a good idea to have snacks to hand in case there are long periods without meals.

### Time zones

Generally short-haul flights require little or no adjustment and insulin

injections can be carried out as normal. It is advisable to wait until the meal has arrived before injecting to avoid hypoglycaemia.

Longer journeys that cross time zones are more complicated and it is a good idea to discuss this with your diabetes nurse. Westbound journeys extend the day and extra insulin may be needed. Multi-dose regimes make this easier because rapid-acting insulin can be given every 3 to 4 hours as needed. Eastbound journeys shorten the day and so the time between injections. It may be necessary to reduce the dose of long-acting or pre-mixed insulin. It can be helpful to keep your watch on 'home' time to keep track of your insulin doses.

### **Beating jetlag**

Travelling across several time zones will probably cause some degree of jet lag. Symptoms include daytime sleepiness, fatigue, disorientation, poor concentration, headache and irritability. There are a number of ways to relieve jetlag:

- Avoid caffeine and alcohol on the plane - drink plenty of water or fruit juice.
- Eat modestly at times that correspond to the usual mealtimes as this will help your body to readjust to the new time zone.
- After a westward flight, stay awake while there is daylight and try to sleep when it is dark.
- After an eastward flight, get up in the morning but avoid bright light and go outdoors in the afternoon.
- Take moderate exercise, perhaps by sightseeing.

### **Holiday Insurance**

If you or your child has diabetes, travel agents are not the best people to provide holiday insurance. Shop around but always declare your diabetes and any other medical conditions, otherwise you may not be covered if anything goes wrong and you need to use the insurance. If you are going on holiday in Europe, remember to take your European Health Insurance card (EHIC) and proof of being a UK resident eg driving licence. The EHIC is available at the Post Office.

### **Keep your insulin cool in a FRIO Wallet**

FRIO wallets are designed to keep your insulin cool and safe for 45 hours, even if the temperature is over 100 degrees Fahrenheit. The main advantages are that there are no bulky ice packs, you do not have to worry about finding a freezer to get supplies of ice and the wallet is light to carry.

It is activated by immersing it in cold water for about 5-15 minutes. The panels of the wallet contain crystals and these expand into gel with the immersion in water. The system relies on the evaporation process for cooling. Vials and pens can be put into plastic bags to keep them dry without affecting the cooling properties of the wallets but FRIO also supply a zip stop water proof liner at an extra cost. ONLY the vials should be put in the plastic bag and NOT the whole pouch

For further details or to order a FRIO wallet the manufacturers can be contacted at: FRIO UK, PO Box 10, Haverfordwest SA62 5YG  
Telephone 01437 741700 or e-mail [info@friouk.com](mailto:info@friouk.com) visit: [www.friouk.com](http://www.friouk.com)

### **Kitbags to keep diabetes equipment in one place**

Desang kitbags can keep all the tools for managing diabetes (blood testing kit, sugar supply and insulin as well as space for personal notes) in one place. They vary in price according to whether you chose a PVC one or a luxury leather one.

You can buy on-line by visiting [www.desang.net](http://www.desang.net)

### **Coping with diabetes and the heat of summer**

- Drink plenty of water as dehydration can raise blood glucose levels.
- Sunburn can raise blood glucose levels, so avoid spending long hours in the sun and wear sunscreen of at least 30 SPF and children or people with pale skin should use 50 SPF.
- Shield your meter from the sun and test strips should be kept in a cool, dry place.

- People who use a pump may need to protect the adhesive patch from perspiration by using an antiperspirant at the contact site.
- In very hot weather insulin is absorbed more quickly, so test regularly to avoid hypos.
- Do not walk barefoot as your feet can be damaged by hot pavements or sand.

**Finally, perhaps worth remembering...**

- **Hot weather may affect blood glucose levels and can lead to low blood sugars.**
- **Extra exercise is often taken on holiday which may lead to hypos eg swimming, games on the beach, .**
- **It is holiday, so enjoy it!**

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## Blood Glucose Monitoring News

**This should not be ‘news’, but may be it is!**

Blood glucose testing using finger prick tests, test strips and portable meters has been around for the last 30 years and has made a huge impact on the lives of people with diabetes. From the perspective of people living with diabetes, it has largely taken the guess work out of managing diabetes and it has changed our role to make us partners with health professionals in managing blood glucose control. Glucose meters are increasingly used on hospital wards and other points of care because they are so much quicker than sending blood samples to the lab.

So we have come to rely on them and perhaps we all forget the degree of inaccuracy they are allowed to have. There are international guidelines for how accurate meter readings should be and these are as follows:

- ▶ For blood glucose levels of less than 4.0 mmols/l, the meter should read within 0.80mmols/l.
- ▶ For blood glucose levels above or equal to 4.0 mmols/l, the

reading should be within 20%.

- ▶ A meter should be able to achieve this level of accuracy in at least 95% of the samples tested.

It is easy for us to take the reading displayed on the meter as fact, forget the inaccuracies and make insulin dose adjustments on the basis of the displayed results. We should remember that a displayed result of 3.0mmols/l could be as low as 2.2 or as high as 3.3. Both of these mean that blood glucose levels are too low and corrective action of eating something sugary should be taken. However, the situation is different if the reading is 3.8 which may well be seen as good and reassuring but this could be mistakenly so if the actual blood glucose level is 3.0 and on the way down. This is particularly dangerous for people with hypo unawareness.

At the other end of the scale a true blood glucose value of 19 might display a result as low as 15 or as high as 20. Again, one could argue that this doesn't matter too much because the corrective action to lower the blood glucose would be the same but for people using pre-meal multi-dose regimes or when using insulin infusion algorithms in intensive care situations, the differences could affect treatment strategies.

An article in Diabetes Care [April 2010] suggests that the majority of people using meters are unaware of the size of the potential inaccuracy of the results displayed by their meter and that many health professionals also tend to give greater credence to the results than is justified.

Add to this other factors that can lead to inaccurate results – user errors, out of date strips or strips that have been exposed to excess moisture or simply failing to enter the proper code – and the level of accuracy is even worse.

These possible inaccuracies by no means suggests that you should not test but that you should remember that when making insulin dose adjustments either pre-meal or on a more permanent basis, the

results displayed on your meter are not necessarily the absolute level of glucose in your blood. These inaccuracies could account for why sometimes, we all say ‘that shouldn’t have happened to my sugars because my last reading was OK.

### **Roche Accu-Chek® Mobile System**

Accu-Chek have introduced a new blood glucose meter called the Accu-Chek Mobile System which removes the need for test strips by using a continuous tape containing 50 tests and 6 lancets in a single drum. This makes testing easier when you are out and about and has the added advantage of not having to dispose of strips and lancets. It does not need coding and has a 500-test memory and 7, 14 and 30 day averages which can be downloaded to use Excel and Accu-Chek software. IDDT member, David Daintree, has given the meter a ‘test run’. He feels that many younger people may well like it because it has various menus but he found it rather complicated. David is partially sighted and he had difficulty reading the menus and trying to see where to put the blood.

### **Warning - Roche Accu-Chek meters change way test results are calculated**

The new Accu-Chek and all other Accu-Chek meters have changed to new test strips that calibrate the blood glucose concentration in blood plasma as opposed to whole blood which has always been used in the past. There is no change in the measuring process in that you still apply whole blood to the test strip but the results displayed will be a measurement of the blood glucose in the blood plasma rather than whole blood.

Blood glucose concentration is higher in blood plasma than in whole blood and so your readings will display as about 11% higher but this does not mean that your blood glucose control has got any worse but that it is being calculated in a different way. Here are some examples:

<b>Whole Blood [old readings]</b>	<b>Plasma Blood [new readings]</b>
3.1	3.4 - 3.6
4.2	4.6 - 4.8
5.8	6.4 - 6.7
7.8	8.6 - 9.0
10.0	11.0 - 11.5
13.9	15.3 - 16.0
16.7	18.4 -19.2

Roche advise that you discuss with your health professionals how your target blood glucose levels should be adjusted. However, one of our members raised this with us as she was simply supplied with the new strips at the pharmacy without any warnings or advice. Having had diabetes for many years and tested for many years, she found changing to the new results a nuisance and as a result changed her meter to one that still uses whole blood.

### **Identifying the new strips**

The packaging and test strip pot of the new plasma measuring strips are marked with a yellow symbol to warn you – it is a yellow circle with black lines across it.

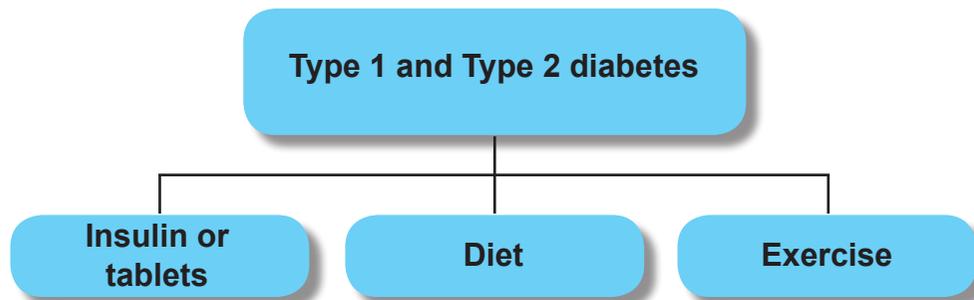
### **New FreeStyle Test Strips**

Abbott have introduced a new generation of FreeStyle® and FreeStyle Lite® blood glucose test strips which they say is designed to provide faster blood application, to reduce the number of error messages and wasted test strips, and an improved level of accuracy. The new test strips are tapered to offer what is described as a ‘better blood glucose testing experience’. They produce finger-stick blood glucose test results such that 95% of results fall within - plus or minus 15% of the true glucose value for glucose values equal to or greater than 5.6mmols/l and plus or minus 0.56 mmol/l of the true glucose value for glucose values less than 5.6 mmol/l.

# Understanding Exercise

Exercise is something we hear so much about these days both for the general population and for people with diabetes. Sometimes the meaning of this may get blurred. For people without diabetes it is to improve their health and try to stem the rising tide of obesity and Type 2 diabetes but for people with diabetes, exercise is part of the treatment and there is a subtle difference. The treatment of both Type 1 and Type 2 diabetes involves three things – insulin / tablets, diet and exercise, as shown in the diagram below. The only exception to this is if Type 2 diabetes is treated by diet and not medication but exercise is still a treatment.

Three important factors in the treatment of Type 1 and Type 2 diabetes:



## Effects of exercise

During any moderate to strenuous exercise the body consumption of oxygen increases to supply energy to the muscles and central nervous system. In people without diabetes the blood glucose levels are maintained at constant near normal levels. This is done mainly through hormonal changes which include a drop in circulating insulin in the blood plasma and a rise in glucagon.

This supply and demand for oxygen is not different in people with diabetes but the risks and benefits of exercise in Type 1 and Type 2 diabetes are different.

## Exercise in Type 1 diabetes

- ▶ The hormonal adjustments in response to exercise, described above, are impaired or absent in people with Type 1 diabetes. In Type 1 diabetes people are reliant on injected insulin.
- ▶ The effect of having too little insulin in the circulation is that there may be an excessive release of counter-regulatory hormone which may increase the already high levels of glucose in the blood, sometimes to the extent that ketones are produced. [This explains why people can have high blood sugar levels after exercise, not what they expect!]
- ▶ But if circulating insulin levels are high, this can lead to increased use of glucose in response to exercise which can result in hypoglycaemia. This effect can last for up to 24 hours after exercise.
- ▶ It is most important that people with Type 1 diabetes understand how exercise affects their blood sugars and how to avoid both hyper- and hypoglycaemia by changing their insulin dose and/or timing and by adjusting their carbohydrate intake before, during and after exercise.
- ▶ Strenuous or prolonged exercise should be avoided if there has been hypoglycaemia in the previous 24 hours because this can lead to further severe hypos with seizures and/or coma as well as other possible damage.

## Exercise in Type 2 diabetes

People with Type 2 treated with insulin can have the above effects but it is seen as less of a problem for people with Type 2 diabetes using insulin. It may not be. For people with Type 2 diabetes not treated with insulin, the effects of exercise are:

- ▶ Regular, moderate exercise is an important part of the treatment of Type 2 diabetes leading to improvements in short and long-term blood sugar control and increased insulin sensitivity.
- ▶ Increased physical activity may lead to a reduction or even discontinuation of medication in significant numbers of people.
- ▶ Exercise has been shown to reduce blood pressure [hypertension] which may be useful for the newly diagnosed with mild hypertension.

- ▶ In conjunction with diet, exercise has been shown to promote weight loss and may help to maintain weight loss over the long-term.

### **Exercise recommendations if you have complications of diabetes - the Association of British Clinical Diabetologists [ABCD]**

#### **Retinopathy [eye damage]**

1. If there is no diabetic retinopathy or non-proliferative retinopathy – there are no risks.
2. Moderate to severe non-proliferative retinopathy – activities which are likely to raise systolic blood pressure [the first figure of the BP] should be avoided but activities such as walking swimming and low impact aerobics are allowed.
3. Proliferative retinopathy and people undergoing laser treatment – as above.

#### **Nephropathy [kidney damage]**

1. No nephropathy, micro or macroalbuminuria – generally no restrictions but a medical assessment is advisable.
2. Nephropathy, dialysis etc – exercise is generally reduced and many patients will also have cardiovascular problems. There is no need to avoid low or moderate exercise but high intensity or strenuous physical activity is better avoided.

#### **Neuropathy**

1. No neuropathy – most activities can be carried out safely with no restrictions.
2. Loss of sensation and significant neuropathy – it is better to avoid weight bearing exercise as repeated exercise of this type can cause foot ulcers. It is better to avoid prolonged walking, treadmill and jogging.
3. Activities such as arm exercises, swimming and cycling are allowed.

#### **Peripheral arterial disease**

1. No history of intermittent claudication [hardening of the arteries in the legs] and no signs of blood flow problems – there are no

restrictions on physical activity.

2. Symptoms of intermittent claudication or ischaemic changes – low to moderate intensity exercise with careful supervision of the feet and appropriate footwear.

#### **So what do we know?**

It is important that people with diabetes are advised about the benefits of exercise. In Type 2 diabetes the benefits are in improving metabolic control which is particularly important around the time of diagnosis as this time people are most likely to be motivated to make lifestyle changes.

For people with Type 1 diabetes the emphasis remains on enabling them to make adjustments to their insulin regime and carbohydrate intake to allow safe participation in physical activities, this is especially important in children and young people where diabetes can be seen as a barrier to participation in sporting activities.

#### **Finally – we now have ‘green exercise’!**

Apparently there is growing evidence that combining five minutes of exercise, walking or cycling, in a ‘green’ space such as a park can improve mental well-being. The researchers found improvements in mood and self-esteem and this was particularly so in young people. The biggest effect was seen within five minutes. The positive effects were still seen after longer periods of ‘green exercise’ but to a lesser degree. A bigger effect was seen with exercise in an area that also contained water.



## **Research - Prevention Or Delay Of Type 1 Diabetes**

### **Stopping the decline in insulin production**

A new drug called otelixizumb may halt the rapid decline in the body’s insulin production in Type 1 diabetes according to a recent study

published in Diabetologia. The drug works by turning off the part of the immune system that destroys the insulin producing cells in the pancreas. This stops the damage and allows the pancreas to continue to produce insulin.

In the study patients given the 6 day treatment continued to produce their own insulin or needed to inject only tiny amounts of insulin whereas those given a placebo [dummy pill] needed rapidly increasing amounts of injected insulin. The research suggests that the effects of the drug may reduce after about two years when further treatment with the new drug would be necessary.

Obviously this treatment could only apply to people who are newly diagnosed and would be dependent on how many insulin-producing cells are left at the time of diagnosis.

### **Two cancer drugs in mice**

Researchers at the University of California have reported that two common drugs used to successfully treat cancer have been used to block and reverse Type 1 diabetes in mice. The drugs, known as kinase inhibitors, block tyrosine kinase which the researchers believe may trigger the body's attack on the immune system as well as triggering cell growth.

Non-diabetic mice prone to developing Type 1 diabetes were treated with one of the two drugs and the researchers found that the drugs prevented diabetes past the 7 weeks of treatment. Mice that already had diabetes were also treated and the results showed that after 2 months, 80% of them no longer had diabetes.

The research was conducted as part of the Immune Tolerance Network, partially funded by the JDRF.

### **Reversal of Type 1 diabetes in mice**

Researchers in Canada have reversed Type 1 diabetes in mice using a new type of vaccine, nanovaccine, which only targets the cells which cause the condition. They set out to look for a way to stop

the autoimmune response that causes Type 1 diabetes but without damaging the immune cells that protect against infections.

Type 1 diabetes is caused when certain white blood cells [called T cells] mistakenly attack and destroy the insulin-producing beta cells in the pancreas. The immune system tries to counter this by producing 'good' T cells to fight the 'rogue' T cells, however, these good T-cells are much weaker.

The researchers developed vaccine made up nanoparticles that are thousands of times smaller than the size of a cell. These are coated with fragments of proteins specific to Type 1 diabetes which bind, or stick to molecules that stimulate certain T cells. The nanovaccine worked by boosting the weaker good T cells which were then able to suppress the immune attack that was destroying the insulin-producing beta cells.

A good finding in the study was that only T cells involved in the destruction of the beta cells were affected by the nanovaccine which means that the treatment did not weaken the rest of the immune system. This is a serious consideration for this treatment to be safe and effective in healthy people with diabetes.

[Immunity, April 2010]

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## **First Trial Of The Artificial Pancreas**

The first study to test an artificial pancreas using the two hormones insulin and glucagon in people with Type 1 diabetes was published in April this year. It showed that by delivering both hormones automatically in response to frequent blood glucose tests it is possible to control blood glucose levels without hypoglycaemia, even after high carbohydrate meals. This is because the action of both insulin and glucagon is similar to how the body controls blood sugars.

In healthy people blood glucose levels are controlled by a delicate balance between insulin, which encourages various parts of the body to take up and use blood glucose, and glucagon which raises blood glucose levels. Both insulin and glucagon are produced in the pancreas but in Type 1 diabetes the immune system kills off the insulin producing cells. The glucagon producing cells remain in tact but they do not usually respond to low blood sugar levels, so if there is too much insulin causing the blood sugars to drop, glucagon is not produced so causing a hypo. [This is why injections of glucagon are used if people have a severe hypo and are unconscious.]

So the new artificial pancreas was developed with a computer programme that can use frequent blood glucose readings to dictate when doses of fast-acting insulin [Humalog] and minute doses of glucagon should be delivered. The glucagon counteracts moderate drops in blood sugars throughout the day – just as happens in a healthy body.

The artificial pancreas consists of a blood glucose monitor, insulin pump technology and special software that controls the delivery of insulin and glucagon.

The trial took place at Massachusetts General Hospital in 11 adults with Type 1 diabetes. The researchers are now planning a follow up study using adults and children with Type 1 diabetes. [Sci Transl Med, Vol. 2, Issue 27, p. 27ra27, published online 14 April 2010].

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## Diabetes, Your Driving Licence And Insurance

IDDT also receives quite a lot of queries about driving from people who have recently been diagnosed as well as people who have had diabetes for some time. Whether you have Type 1 or Type 2 diabetes, diabetes does not prevent you driving a car or motorcycle, as long as

your diabetes is well controlled and your doctor says that you are safe to drive. However, there are certain things that you must do:

- ▶ By law, you must tell your insurance company.
- ▶ If your diabetes is treated with insulin or tablets, you must inform the DVLA. People with Type 2 diabetes treated by diet-only do not have to inform the DVLA but if you go on to tablets or insulin, then you must inform the DVLA.
- ▶ If you are applying for a driving licence for the first time and you are being treated with insulin or tablets, you must also inform the DVLA.
- ▶ If you develop any complications that may affect your ability to drive, you must inform the DVLA.

If you do not inform the DVLA and/or your insurance company, your insurance will not be valid and you will not be covered.

The DVLA - what you need to do...

- ▶ If you are applying for a driving licence, on the form answer 'yes' to the question asking if you have diabetes.
- ▶ If you already hold a driving licence, write to the DVLA to tell them you have diabetes and what treatment you are on. If you are treated with insulin, you will be sent a further form [called Diabetic 1] which asks you for more information, including the details of your GP or hospital clinic doctor. You will also be asked for your permission to contact this doctor directly, if necessary, to obtain information on your fitness to drive.
- ▶ If you are treated with insulin, a medically restricted driving licence for vehicles up to 3.5 tonnes will be issued for up to 3 years. When this expires you will be sent a reminder and probably another Diabetic 1 form, for up to date information.
- ▶ **If you are treated with tablets**, you are not always sent a Diabetic 1 form. If you have no other medical conditions that affect driving, usually you will be given a full driving licence.

### STOP PRESS!

Changes to Driving and Type 2 diabetes treated with tablets, diet or both. The bullet point above states that **if your diabetes is treated with tablets**, then you should inform the DVLA. This **was** the case but the DVLA now states:

“Drivers do not need to tell us if their diabetes is treated by tablets, diet or both and they are free of the complications listed overleaf.”

One of the complications listed is hypoglycaemia [low blood sugar]. Some tablets used to treat Type 2 diabetes can cause hypos. So if you are taking tablets to control your diabetes and you are unsure about whether or not they may cause hypoglycaemia, then it is better to play safe and inform the DVLA. Also remember, however your diabetes is managed you must always inform your insurance company.

### **Safe driving**

If you are unsure about driving, you should discuss this with your diabetes team. You should not drive if you:

- ▶ Have difficulty recognising the warning signs of hypoglycaemia [loss or reduced warnings].
- ▶ Have difficulties with your eyes that cannot be corrected with glasses.
- ▶ Have numbness in your legs.
- ▶ Have been drinking alcohol – apart from this being the same for people without diabetes, alcohol lowers blood sugars.

### **Hypos and driving**

The risk of hypoglycaemia is one of the main reasons there are restrictions on people with diabetes driving.

We know that people with partial or complete loss of hypo warning symptoms should not be driving but recent research highlights one of the conflicts that face people with diabetes who are using insulin.

There is tremendous pressure on people with diabetes to keep their blood glucose levels as near normal as possible to reduce the risk of long-term complications but we also know from research that keeping near normal blood glucose levels increases the risk of severe hypoglycaemia. The conflict arises with driving – managing blood glucose levels that are safe for driving while at the same time trying to follow medical advice to keep blood sugars as near normal as possible.

### **New research has shown that hypoglycaemia can lead to unsafe driving**

In a US study of 452 adult drivers with Type 1 diabetes or Type 2 diabetes requiring insulin, 52% reported at least one driving mishap when their blood sugars were low over the previous 12 months. The average age of the study participants was 42 with an average duration of diabetes of 26 years and who drove about 16,000 miles annually. [Diabetes Care, December 2009] In this study:

- ▶ Driving with low blood sugars did not appear to cause a large number of collisions – overall 22% of the drivers reported some sort of collision but only 2.4% said they were due to low blood sugars.
- ▶ However, about 35% of the time drivers said they had checked their blood sugar 30 minutes before having a driving mishap and in 78% of these times, blood sugar readings were low-to-normal [less than 5mmols/l] and in just less than half, the blood sugars were even lower [3.8mmols/l].
- ▶ More worrying still is that in those who reported at least one low blood sugar related mishap, 32% reported 2 or more and 5% reported 6 or more such mishaps.

### **So the advice for driving is:**

1. Always carry sugary carbohydrate food and/or drink in your car.
2. Do not drive for more than 2 hours before stopping for a snack.
3. Check your blood sugars before and during your journey.
4. Carry identification on you and in the car stating that you have diabetes and how it is treated.

### **If you feel hypo while driving**

1. Stop the car as soon as it is safe to do so.
2. Remove the ignition key and move into the passenger seat so that it is clear that you were not hypo when actually driving.
3. Immediately eat fast-acting carbohydrate – glucose tablets, food or drink. Then eat longer-acting carbohydrate – biscuits, sandwich, even crisps.

4. Check your blood sugar and do not drive again until your blood sugars have been above 4mmols/l for 45 minutes.

### **WARNING – the DVLA are taking their time!**

If you have applied for renewal of your driving licence recently do not be surprised if it takes longer than usual. Many people have contacted IDDT because it has taken up to 6 months for their new licence to be issued. It seems that this has particularly applied to people who have had laser treatment in the past and therefore have to go through visual field tests. One member who contacted the DVLA was told that they are behind in dealing with renewals 'but they would get to his case'. It took IDDT's Bev Freeman nearly 6 months from applying for her licence to actually receiving it.

It is IDDT's understanding that once you have applied for your licence, if the DVLA have not informed you that you should not drive, then you are entitled to continue to drive. However, if your licence has been revoked, then obviously you must not drive. The main difficulty about the DVLA decisions being delayed is particularly frustrating for the group of people who wish to appeal against the decision as they cannot drive and their jobs and livelihoods can be at stake.

DVLA decisions in relation to stable retinopathy are hard to understand. One group of people who often appeal against the DVLA decision to revoke their driving licences is those who have had retinopathy treatment several years ago and since then their retinopathy has remained stable. Here are just a few reports from our members who have had laser treatment for retinopathy years ago and whose retinopathy has been stable since then:

- ▶ My ophthalmologist says my eyes have not changed for several years, yet last year the DVLA reduced my licence to one year only. This year my eyes still haven't changed and now they have given me a licence for 3 years.
- ▶ My eyes have remained stable after laser treatment many years ago and my eye specialist says I am fit to drive, yet every time I apply for a renewal of my driving licence they take it

away. Every time I appeal and every time they give me it back. That's good news but I can't drive for several months while we go through this process!

- ▶ Despite my ophthalmologist saying that I was fit to drive and my eyes hadn't changed for many years since I had laser treatment, the DVLA refuse to issue me with a driving licence and I lost my appeal. I continued to fight the decision and eventually took legal advice and took the DVLA to court. After 3 years of not driving, I won and have just bought myself a new car.

### **Is there anything we can learn from this?**

IDDT has said many times that no one should be driving a car if they are not fit to do so and this applies to people with diabetes whether the cause relates to retinopathy or hypoglycaemia with reduced or lost warning symptoms. However, when it comes to visual fields and stable retinopathy, the DVLA attitude does appear to vary considerably. Does it simply depend on who in their office deals with your particular application? Who knows, but there are messages we can learn. If your eye specialist says that you are fit to drive, yet the DVLA remove your licence – ask your specialist for a letter to this effect and appeal against the decision.

### **Contact details for the DVLA**

website: [www.dvla.gov.uk/motoring](http://www.dvla.gov.uk/motoring) Tel 0300 790 6806, e-mail [eftd@dvla.gsi.gov.uk](mailto:eftd@dvla.gsi.gov.uk) or write to Drivers Medical Group, DVLA Swansea SA99 1TU.

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## **Sorry, But There Is Yet More News About Statins!**

### **GPs warned over high dose of simvastatin**

The MHRA, the UK drug regulators, have warned GPs that a high dose of simvastatin increases the chances of myopathy and should

only be considered in people with severely high cholesterol who are at high risk of cardiovascular complications. There are different forms of myopathy which are all neuromuscular disorders where the main symptom is muscle weakness. Other symptoms include muscle cramps, stiffness and spasm.

The MHRA said that research now suggests that treatment with 80mg tablets of simvastatin provides no additional benefit over a 20mg dose and this lower dose greatly reduces the risk of myopathy. They advise that if you are currently taking 80mg simvastatin, you should continue to take it but be advised to report any unexplained muscle pain to your GP. IDDT's advice is that if you are concerned talk to your doctor.

This decision has resulted in a call for NICE to retract its guidance recommending simvastatin 80mg. Some believe this recommendation should never have been in place after it was shown that the use of simvastatin 40mg was not based on evidence but purely on cost.

### **Statin side effects revealed**

Another study published in May 2010 [British Medical Journal] reveals probably what many patients already know, that some doses and types of statins are linked to a greater risk of adverse effects, including liver problems and kidney failure.

The researchers from Nottingham University stressed that for many people the benefits of statins far outweigh the risks of any side effects but the results of this study would help doctors to weigh up the pros and cons for each patient.

There are plans to prescribe statins to about one in four adults over the age of 40 and the Department of Health has predicted that prescriptions for statins will rise by 30% a year as GPs find more and more people who are eligible for them. However, there has been much debate about side effects and this latest research shows where the problems may lie in the real life population. They looked at information from more than 2 million 30 to 84 year olds from GP practices in England and Wales over six years.

### **Results**

- ▶ Adverse effects include liver problems, acute kidney failure, muscle weakness and cataracts.
- ▶ For kidney failure and liver problems, higher doses of the drugs appeared to be associated with greater risk.
- ▶ The risks of side effects were greater in the first year of use.
- ▶ On the positive side, the analysis also showed no significant association between the use of statins and the risk of Parkinson's disease, rheumatoid arthritis, blood clot, dementia, osteoporotic fracture, or many cancers including gastric, colon, lung, renal, breast or prostate.

The researchers have developed a computer programme to help GPs to work out which patients are most at risk of side effects and whether their risk of heart disease is high enough to warrant them taking statins. Patients should also be able to make an informed choice.

It is important to remember that all medicines have risks and benefits which have to be weighed up. For people with heart disease or at high risk of it, the benefits of statins outweigh the risks but if you have any adverse effects, you should discuss these with your doctor.

### **Risks of Type 2 diabetes with statins**

A study published in the Lancet [Feb 27, 2010] found that there is a small, increased risk of developing Type 2 diabetes with the use of statins. One way of expressing the risk is that if 255 people are treated with a statin for 4 years, one patient would develop Type 2 diabetes. It seems odd that a drug given to reduce the risk of cardiovascular problems in people with diabetes can also cause diabetes! However, as the risks of developing Type 2 diabetes from the use of statins are small, the consensus view is that these risks are far outweighed by the benefits of taking them.



## “Seal-Tight Changed My Life”

These are the words of one of IDDT’s Trustees, Veronica Readman. For reasons other than diabetes, Veronica has to wear dressings on her feet which must not get wet, so bathing or showering has been a problem – that is until she found a new product called Seal-Tight which is safe and keeps dressings 100% dry. Of course, Veronica immediately thought of people with diabetes who may be in a position of wearing dressings on their feet or legs for foot ulcers or other conditions.

Seal-Tight® is a cast and bandage protector that allows the wearer to take a bath or shower without getting the affected limb wet and without slipping. It can be used on arms or legs and also for skin conditions that must be kept dry. It looks like a strong plastic bag with a non-latex diaphragm which stretches easily over the cast or dressing to form a watertight seal. It is reusable and with normal care will last months even with daily use. It is available on an NHS prescription and comes in different sizes according to need.

This is NOT an advert but Veronica’s enthusiasm is so great that we have to tell you about it. One of the reasons for the enthusiasm is that the inability to shower or bathe has been shown to have a major impact on people’s lives and can be a major factor in causing depression. Until now people have used plastic bags or clingfilm to take a shower but in many cases their dressings become accidentally wet which can result in infection and slower healing.

For more information, contact Autono-med Ltd, Tel 0870 041 -150, e-mail [enquiries@autonomed.com](mailto:enquiries@autonomed.com) or visit their website [www.autonomed.com](http://www.autonomed.com)

## Gastroparesis

Gastroparesis is a stomach condition estimated to affect 25% of people with diabetes to a greater or lesser extent. It is caused by neuropathy affecting the nerves of the stomach so that the stomach muscles do not work properly and the food remains in the digestive system for a long time. The symptoms include:

- nausea
- vomiting
- abdominal bloating, discomfort and/or pain
- feeling full soon after eating
- indigestion or heartburn

In addition to this, gastroparesis affects blood glucose control because the food remains in the stomach for longer than it should and this can lead to erratic blood sugars.

We thought it would be interesting to hear from some who lives with gastroparesis and we would like to thank Ian Ross for sharing his experiences with us.

### **A brief tale of living with gastroparesis**

**By Ian Ross**

I have been insulin dependent for 37 years and have had neuropathy for about 15 years. Five years ago I started having wild swings in my blood sugar test results with hypos shortly after a meal followed by very high blood sugars. I also had extreme stomach disorders, vomiting and ‘the runs’.

My GP prescribed indigestion tablets but eventually I had a serious bout of vomiting and was rushed into hospital. Thanks to a very good, young A&E doctor I was prescribed a liquid diet and diagnosed with gastroparesis.

My GP had not heard of it and asked me if I had any information. I received some information from my Diabetes Centre, they had scoured the internet to give me the little information that seemed to



be available.

At first I was put on a no food / liquid only diet which was fine at first but the liquid food drinks are very high in calories and I put on a vast amount of weight causing further control problems. The dietitian told me to have very small meals and snacks rather than traditional meals. This has worked for me quite well. I also take two medications.

I avoid the foods that people with diabetes are traditionally told to eat such as slow digesting carbohydrates and vegetables containing fibre as these make me very sick. I also do not follow the traditional advice of having my injections before or shortly after meals as the food I have eaten doesn't start to be digested until hours later. So I inject up to two hours after eating. It works for me!

It has taken me 5 years of trial and error to achieve as near normal a life as possible.

If anyone recognises the symptoms or has been diagnosed with gastroparesis and would like to talk to someone in the same position, I would be happy to hear from them - my experiences are purely personal but may be of interest to others. I can be contacted through IDDT, so just ring Jenny on 01604 622837 or e-mail enquiries@iddtinternational.org

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## Racial Differences In Hba1c Results In Children With Type 1 Diabetes

The HbA1c test shows what blood glucose levels have been over the last 6 to 8 weeks and doctors advise treatment to control blood glucose levels largely on the basis of this test. In future, it may be that this test may also be used to diagnose both Type 1 and Type 2 diabetes, as discussed in IDDT's April 2010 Newsletter.

However, researchers have been looking at factors that can influence someone's HbA1c results to make sure that the results can be used accurately and safely to decide on treatment. In a new study researchers looked at whether belonging to different ethnic groups affect the HbA1c results [Diabetes Care. 2010; 33: 1025-1027].

They looked at 276 children with Type 1 diabetes at a New Orleans hospital and after adjusting for other things that could have affected the results, they found that the average HbA1cs for African-American children were 9.1% compared with 8.3% for white children.

Ordinary finger-prick blood glucose tests give the correct results for black children but this new research suggests that the HbA1c test will give misleadingly high results. This could lead to an assumption that the existing doses of insulin are too low and they should be raised. However, as it is the HbA1c test that is inaccurate, this could lead to dangerously low blood sugars, severe hypoglycaemia.

The researchers are recommending that doctors are especially careful to look at blood glucose self-monitoring results as well as HbA1cs when treating black children with Type 1 diabetes. There has not been similar research in the UK, so it is not known whether this US research applies to African or Afro-Caribbean children in the UK.

The magazine, GP [May 21, 2010] carries an article in which Professor Eric Kilpatrick, pathology consultant at Hull Royal Infirmary, says that research has shown that HbA1cs are raised in Afro-Caribbean, Asian and elderly people and it may not be appropriate to use a single HbA1c test for the diagnosis of diabetes. Diabetes UK's response was that they expect the World Health Organisation to use one single cut off value and clinicians will need to use their clinical judgment to use varying screening criteria for different groups.

In the same article, Dr Brian Karet, Royal College of General Practitioner's clinical lead for diabetes expresses the view that using the HbA1c test alone to diagnose diabetes would increase diagnoses by 10-15% and many people of these people will not go on to develop

diabetes. This may prove to be another case of medicalising whole sections of the population.

Mr R.S.  
By e-mail

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## From Our Own Correspondents

### Caution advised with diagnosing using the HbA1c test

Dear Jenny,

I read with interest the article in the April Newsletter, "Diagnosing Diabetes with the HbA1c Test." However, I would counsel caution against using this in isolation.

I am one of perhaps a minority of people in the UK who suffer with Dermatitis Herpetiformis [DH]. This is an autoimmune condition which results from an intolerance to gluten. The exact mechanism isn't fully understood. Details are given at the website [http://en.wikipedia.org/wiki/Dermatitis\\_herpetiformis](http://en.wikipedia.org/wiki/Dermatitis_herpetiformis)

The reason for mentioning this is that the drug of choice for managing DH lesions is Dapsone. It is highly effective at managing DH lesions, but also responsible in some cases for haemolysis which can cause patients with diabetes to return lower than expected HbA1c results. In my own case, HbA1c results of 3 and 4 were being returned with glucose measurements of 13 and above being the norm. The use of a Fructosamine test showed the actual status of my long range control and later I was switched to an alternative drug and away from Dapsone.

This is not to say that the HbA1c is a bad test. Clearly it isn't. It's being used with great results in most cases. However, it's not as perfect in 100% of cases as one might expect. If one relies on it to diagnose all cases of diabetes though, I would probably have been ruled out and been considered normal had the diagnosis been done on the strength of the low HbA1c results.

### Aloe Vera works for me

Dear Jenny,

I have recently started taking an Aloe Vera oral product and I am very impressed with the results. I wondered if other IDDT members have tried it?

If this were not having such a positive contribution for my own diabetic control then I wouldn't even suggest it - but I am 100% convinced that this holistic product has only got positive attributes.

C. B.  
By e-mail

### A letter from Canada

Dear Carol, [IDDT's Trustee in Canada]

I talked to you last Christmas about changing to animal insulin. I made the change and the difference has been dramatic. My hypo warning system is back. My leg pain has disappeared and I now have only minor leg back pain. I am able to work again and I feel like I'm alive again. My family has noted the dramatic change in personality and my daughter who first figured it out says she has her dad back. Also a dramatic change in energy level and I can think again. I postponed writing for my professional status for 5 years as my memory was so bad I knew I could never pass the exam. I'm writing it on Monday.

Thank you for everything.

By e-mail  
Canada

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## Insulin Research

### Is Levemir a once or twice daily insulin?

According to the manufacturer's information on the approval documents, Levemir [also called detemir] is to be used once or twice daily. Readers may remember that when Levemir first came on the market, IDDT's Newsletter questioned what this actually means. Are people supposed to start it once daily and if that doesn't provide control of blood sugars, go on to twice daily?

Levemir is classed as a long-acting insulin analogue that has no peak of action. All other longer acting insulins that have to be given twice daily are classed as 'intermediate-acting', so is Levemir actually a long-acting insulin if or when it has to be given twice daily? Perhaps this is just words and in reality, it doesn't matter what it is classed as except of course in commercial terms – it is Novo Nordisk's competitor to Sanofi-aventis' 24-hour-acting insulin, Lantus [glargine].

The timing of Levemir injections in people with Type 1 diabetes and 'poor control' Research carried out in Spain compared different times of injecting Levemir in 39 people with Type 1 diabetes classed as having poor control. They were randomly assigned to two groups injecting once a day – one before lunch and one at bedtime with NovoRapid being used before meals. If target blood sugars were not reached, then they were switched to twice daily injections.

After 6 months the results were:

- ▶ 12.2% of patients remained on bedtime injections.
- ▶ 30.3% remained in the lunchtime group.
- ▶ 57.5% joined the twice-daily, every 12 hour injection group.
- ▶ Control, as measured by HbA1cs, was below 7% in 30.3% of the patients and of these 15.2% were in the before lunch group, 3.3.% in the bedtime group and 12.2% in the twice daily injection group.

### Researchers' conclusions

One injection of Levemir before lunch could improve metabolic control but most patients required twice-daily injections. [Endocrinol Nutr

2010 Mar 25]

### Smart insulin

We have read a lot over recent times about analogue insulins promoting cell growth and the possible increased risk of cancer. This is because the analogue insulins tend to bind more with receptors that can drive cell growth, called insulin-like growth factor [IGF] receptors than to insulin receptors when compared to other types of insulin. This has been known since the insulin analogues were first introduced and is one of the reasons there has always been some concerns about whether analogue insulins could promote the development of cancers. Now scientists in the US have developed a new insulin molecule which reduces the binding to the IGF receptors that drive cell growth. This new insulin molecule has been engineered to do insulin's primary job – regulate blood glucose concentration not attach to the cancer-related receptors.

## Changes In The Position Of Conventional Insulin Pumps

The January 2010 issue of the Journal of Diabetes Science and Technology published a study which concluded that changing the height of a conventional insulin pump in relation to its tubing and infusion set can significantly impact expected insulin delivery rates. Such changes can occur during routine daily activities like dressing, sleeping or showering.

There was a pronounced siphon or hydrostatic pressure action effect in conventional subcutaneous insulin pumps which caused significant fluctuations in the accuracy of insulin delivery rates when the pump position was moved higher or lower relative to its tubing and infusion site. The researchers commented that this unintended fluctuation in insulin delivery, which may arise from pump movement during normal daily use, can increase blood glucose variability, a risk factor for the progression of complications of diabetes. The effect of hydrostatic pressure was most significant at low basal rates and therefore these

findings may be particularly important for children using pump therapy because they often use pumps at low basal rates.

The conventional pumps tested were MiniMed 512 & 515, which use 110 cm tubing and the Deltec Cozmo 1700, which uses 80 cm tubing and they were compared with the OmniPod tube free pump. The OmniPod was least affected by pump orientation and direction. [The study was supported by a grant from the manufacturers of the OmniPod.]

**NOTE: Using animal insulin in an insulin pump**

We have been asked by one of our members, Sue, to remind readers that both pork and beef insulins can be used in insulin pumps, despite what you may be told. Sue can only use beef insulin as all the other insulins do not suit her. She had a particularly difficult time convincing the specialists about using a pump and beef insulin and many obstacles were put in her way, including that the pump was not suitable for beef insulin and various funding issues. Perhaps the most concerning of these was the mis-information she was given by all the health professionals, except her GP who she describes as ‘fantastic’ and the key to this was: he listened, he was supportive and if he didn’t know something, he found out.

After a very determined and long battle, Sue managed it and two years later she is using beef insulin in her pump – she has HbA1cs of 6.5% with very few hypos, feels well and is happy.

Sue’s message to anyone wanting to use pork or beef insulins with an insulin pump – don’t give up!

## Research Bits And Pieces

### Metformin may lead to Vitamin B12 deficiency

According to a new study carried out in the Netherlands, the most commonly prescribed drug for Type 2 diabetes, metformin, could cause vitamin B12 deficiency which is not temporary and gets worse over time. According to this study, people with Type 2 diabetes taking metformin can lose 19% of their Vitamin B12 levels compared to those given a placebo [dummy pill].

Vitamin B12 has an important role in forming red blood cells and maintaining healthy neurological function. It is found naturally in red meat, salmon, cod, milk cheese and eggs. Deficiency of Vitamin B12 can cause fatigue and anaemia which can easily be misdiagnosed as being due to diabetes itself, its complications or simply ageing.

The authors of the study say that it is reasonable to assume that these symptoms will occur in some patients due to metformin-induced low vitamin B12 levels.

### Oral health linked to glycaemic control

A Cochrane review has shown that treatment of serious gum disease [periodontal disease] may improve control of blood sugars in people with both Type 1 and Type 2 diabetes.

It has been known for some time that poor glycaemic control increases the risk of gum disease and that gum disease itself can cause poorer glycaemic control. The Cochrane review found that compared with no treatment, scaling or root planning and oral hygiene with or without antibiotics, was associated with a 0.4 percentage point drop in HbA1cs. However, the studies reviewed were too small and the reviewers recommend that larger, carefully conducted studies are needed.

### Is this a revolution in the way to treat insulin-requiring diabetes?

Scientists have discovered a new molecule that could protect people with diabetes from the heart damage that is associated with insulin



treatment.

Researchers at Leeds University found that a naturally occurring substance known as C-peptide protects blood vessels from the damaging effects of insulin. C-peptide is produced naturally with insulin in healthy people.

Insulin is given to control blood glucose but over time insulin can cause damage to the blood vessels that supply the heart. It causes some cells in blood vessels to grow more than they should and this leads to a narrowing of the passageway used to get blood to the heart. This is one of the reasons why people with diabetes are more prone to heart attacks and even if they have a heart bypass operation, the new veins grafted to the heart are more likely to become blocked. The Leeds researchers found that if insulin is given with C-peptide, the blood vessels appear to be protected from damage as the excessive growth of the cells was stopped completely.

According to the researchers, it used to be thought that C-peptide had no function and therefore it was not incorporated in man-made insulin [human and analogue insulins]. But their new research suggests that a combination of insulin and C-peptide may provide a more effective treatment than insulin alone to control cardiovascular complications associated with diabetes. This would revolutionise treatment of people with diabetes. [Diabetologia, May 2010]

### **‘White coat’ syndrome**

Most of us know about the ‘white coat’ syndrome – where blood pressure rises during a check by a doctor due to the anxiety of being in the surgery or the hospital. However, research published in the British Medical Journal [07.05.10] says that this effect is even worse in people whose blood pressure is already high and that giving people a cuff to wear for 24 hours is a much better way of checking blood pressure.

Blood pressure can either be measured in the surgery or hospital or by wearing a cuff for 24 hours as people go about their normal activities

[called ambulatory blood pressure]. High blood pressure affects 40% of adults in the UK and in 2001 90 million prescriptions were issued for blood pressure lowering drugs at a cost to the NHS of £840 million.

The researchers monitored 8500 patients who were being assessed at 11 blood pressure clinics across Australia and found that:

- ▶ Blood pressure measurements taken by doctors and nurses can vary by as much as 29 units if a doctor checked it and 17 units if a nurse did so.
- ▶ The differences also varied according to the age and gender of the patient.
- ▶ The closer the patient’s blood pressure was to normal, the less of a difference between measurements taken by wearing a cuff for 24 hours and being checked by a doctor or nurse.

The researchers maintained that measuring blood pressure by wearing a cuff for 24 hours should be the tool of choice to correctly diagnose high blood pressure but Professor Richard McManus, a cardiovascular expert, writing in the BMJ said that patients with high blood pressure should be managed using both clinic based and ambulatory measurements taking into account where and by whom the test was done.

A review of the NICE guidelines for the treatment of high blood pressure is due to be released next year.

### **Metformin may reduce cancer risk**

The most common drug used to treat Type 2 diabetes is metformin and a number of studies have shown that metformin users have a lower risk of developing certain cancers.

In the study published in Diabetes Care [April 2010] researchers found that among 1,400 women in the UK using medication for Type 2 diabetes, those who had taken metformin for more than 5 years were 56% less likely to have breast cancer than women who had never used metformin. This association remained even after they took into account other factors such as the use of other medications, duration

of diabetes, smoking and weight. The researchers point out that there were only a few women in the study who had used metformin for over 5 years and that it did not prove cause and effect.

A recent study in mice found that adding metformin to a chemotherapy drug was more effective at treating breast tumours than the cancer drug alone. Researchers at Harvard University are currently developing a large clinical trial to find out whether using metformin after standard treatment for early breast cancer helps to prevent cancer reoccurring.

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## NHS News

### Good news!

The Department of Health have issued statistics to the end of March 2010 which show that 96.2% of people with diabetes were offered screening for diabetic retinopathy during the previous 12 months.

### Breaches of the Data Protection Act

The Deputy Commissioner at the Information Commissioner's Office [ICO] told a recent conference on information security that since 2007 the NHS reported the highest number of serious data breaches of any UK organisation, 287 in all. This accounted for 30% of the total number reported. 113 of the breaches were as a result of stolen data or hardware and 82 were cases of lost data or hardware.

In fairness, he said that these problems exist in the private sector too but the public sector had a culture of reporting all breaches and not all private companies have the same degree of openness.

This comes at a time when the NHS is rolling out the system of digital patient records but the Deputy Commissioner said that he was not aware that any of the breaches had affected patient privacy or care. However, as part of the plans to digitalise patient records, the NHS is asking patients if they want their records stored on a national

databases as it is important that people are given the opportunity to opt out.

In April 2010 the ICO introduced fines of up to £500,000 for serious breaches of the Data Protection Act.

### Planned A & E Closures

The future of many Accident and Emergency departments is coming under scrutiny by health trusts that are looking to put highly specialised care in fewer hospitals. A & E doctors say these plans to downgrade some services are based on flawed evidence. The College of Emergency Medicine maintains that it should not be assumed that most patients visiting A & E can be seen elsewhere and the investment in separate walk-in and urgent care centres is misguided and wasteful.

The plans are based on the assumption that 60% of people visiting A & E have relatively minor problems that could be dealt with elsewhere. However, the college say the 60% figure is fictional and the true figure is between 10% and 30%. The Department of Health stance is the usual, "It is for the NHS locally to decide on ways of meeting patients' urgent and emergency care needs ...."

Perhaps in large cities with several hospitals it is not necessary to have A & E departments in all hospitals but in towns with one hospital, surely they have to provide facilities to cover both serious and minor problems. What happens to people admitted in a night hypo, do they have to be taken to the next town 20, 30 or more miles away?

### TV chef to design hospital food

Hospital food designed to appeal to the elderly has been launched by TV chef Heston Blumenthal. As people get older their taste buds decline and food becomes less appealing. The TV chef acted as an advisor to researchers at Reading University who have been experimenting with introducing strong flavours from Japanese food and introducing them into British foods such as shepherd's pie. The aim is to combat malnutrition as 60% of elderly people come into

hospital malnourished. Malnutrition can result in longer periods of illness and slower recovery from surgery and infection. Let us hope that fundamental problems don't get forgotten – that food is often left out of the reach of patients and some need help with eating. And for people with diabetes – it needs to come at the right time!

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## Pharmaceutical Industry News

### Settlements paid out for Avandia

We have reported in previous Newsletters that lawsuits have been taken out against GlaxoSmithKlein [GSK] by people who have alleged that Avandia [rosiglitazone] has caused heart attacks and strokes in some people. In May, a news agency reported that GSK agreed to pay around \$60 million dollars in the settlement of the first 700 cases in the US.

GSK have refused to say how many other cases are pending but previous press reports suggest that it could be as many as 13,000 and trials against GSK will take place during the rest of the year. Analysts suggest that GSK could face liability claims of as much as \$6 billion but Avandia, first approved in the US in 1999, generated annual revenue of \$3 billion in 2006, so one could say that they can well afford the compensation claims!

Sales dropped after the publication of research in the New England Journal of Medicine [May 2007] linking the drug to a 43% increased risk of myocardial infarction [heart attack]. At that point EU and US regulators ordered GSK to strengthen its label warnings. There is still a risk that US regulators, the FDA, could force the company to take the drug off the market, it is reviewing Avandia's safety profile and is expected to report to an advisory committee in July.

Andrew Witty, GSK's chief executive officer has said that he was confident about Avandia's "risk-benefit profile" and the company's

handling of the drug.

### First once a week treatment for Type 2 diabetes may be happening soon

Byetta [exenatide] has been available as a twice daily injectable treatment for Type 2 diabetes. The manufacturers made an application for a once a week version [Bydureon] to be approved in the US but this was rejected in March 2010. A new date has been set for October 2010 and if approved, this will be the first once-weekly treatment for Type 2 diabetes. Like Byetta, Bydureon works by increasing the body's insulin production.

### Novo Nordisk launch new pen for children

In May 2010 Novo Nordisk launched a new pen designed specifically for children. It is called NovoPen Echo®. It has both a simple memory function which allows checking the time since the last dose was given and half unit dosing can be given, often required by children. Denmark is the first country where the new pen is available but no doubt it will come to the UK and other countries.

## Doctors Call For A Ban On Trans-Fats

In the British Medical Journal [April 16, 2010] doctors are calling for a UK ban on trans-fats [also called trans fatty acids]. They claim that consumption of trans-fats raises levels of bad cholesterol, can lead to weight gain, insulin resistance and irregular heartbeat. They say that cutting the overall consumption of trans-fats by just 1% would lead to 11,000 fewer heart attacks each year and 7,000 fewer deaths.

Trans-fats are vegetable oils which have been chemically altered to increase the shelf life of foods. They have no nutritional benefit and are found in many cakes, pastries, pies, chips and fast foods.

Trans-fats are already banned in Austria, Denmark, Switzerland, New York and California. However, the UK Food Standards Agency [FSA] states that the consumption of trans-fats in the UK is about 1% of the total energy intake and therefore is not a cause for concern. In 2007

they carried out a review of trans-fats and their current position is to encourage the food industry to voluntarily remove trans-fats rather than legislation.

Looking at the overall figures may not be relevant as there maybe people who know little about the dangers of eating too many trans fats [cakes, pastries and pies], while others hardly touch them. If this is the case, then overall figures are irrelevant when looking at protecting people's health – it is about changing individual eating habits.



## Snippets

### Customer service, or not?

According to a public accounts committee report, her Majesty's Revenue and Customs, last year [HMRC] failed to answer 45 million telephone calls from members of the public seeking advice on tax and benefits.

### Glowing pill bottle

A glowing pill bottle lid is being tested in a small trial as a way to remind people to take their medication. When it is time to take a tablet the top of the bottle glows orange and if this is ignored it will flash orange with increasing urgency, if this too is ignored, then a wireless transmitter could inform your doctor!

### Pharmaceutical company fines go to a good cause

Pharmaceutical companies that breached the marketing code of conduct in Australia were fined AUS\$1 million. Medicines Australia is giving all the money, less administration costs, to charities that support the health of indigenous communities.

### Germany plan to force drug companies to charge a fair price

In March 2010 the German Health Minister announced a plan to force drug companies to negotiate a fair price for the drugs they supply to

health insurers. Unlike other European countries, in Germany drug companies can set their own prices which results in 30 billion Euros a year being spent on drugs.

### Texts from GPs

GP practices are increasingly using text messaging for such things as reminding patients about appointments, to take their medication or to send test results. However, the Medical Defence Union has said that that it is unwise to rely on patients' implied consent to allow a practice to communicate with them this way - they must ensure that patients have expressly consented to this method of communication. Patients may be surprised to receive a message this way if unexpected or the message could be picked up by someone else.

### Obesity and married couples

Married couples are more likely than single people to become obese. Greek researchers found that married men are three times more likely and married women twice as likely to be obese compared to single people. Married couples also had less sex, took less exercise and had poorer nutrition.

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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