



# Insulin Dependent Diabetes Trust

July 2008 Newsletter



## Self-monitoring in Type 2 Diabetes

Offer self-monitoring of plasma glucose to a person newly diagnosed with type 2 diabetes only as an integral part of his or her self-management education. Discuss its purpose and agree how it should be interpreted and acted upon.

NICE Guidelines for Type 2 diabetes, May 2008

## The NICE Guidelines recommend human insulin, not analogues as first line treatment for people with Type 2 diabetes

Preferably begin with human NPH [intermediate-acting] insulin taken at bedtime or twice daily according to need.

**Alternatively, consider a once daily insulin long-acting analogue [glargine/Lantus] if:**

- the person requires assistance to administer insulin injections
- his or her lifestyle is significantly restricted by recurrent symptomatic hypoglycaemic episodes
- twice daily basal insulin injections plus oral glucose lowering medications would otherwise be needed.

**Offer a trial of long-acting insulin analogue [glargine /Lantus] if NPH insulin causes significant nocturnal hypoglycaemia.**

**Consider twice-daily bi-phasic human insulin [pre-mixed] regimens, particularly where HbA1c is greater than 9%. Once daily may be an option when starting this therapy.**

**Consider pre-mixed insulin analogue preparations rather than human insulin preparations when:**

- immediate injection before a meal is preferred
- or hypoglycaemia is a problem
- or there are marked postprandial blood glucose excursions.

**Review use of sulphonylurea if hypoglycaemia occurs with insulin plus sulfonylurea.**

NICE Guidelines for Type 2 diabetes, May 2008

### **What is Patient centred care?**

Treatment should take into account patients' individual needs and preferences. Good communication is essential, supported by evidence-based information, to allow patients to reach informed decisions about their care. Follow Department of Health advice on seeking consent if needed. If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

NICE Guidelines for Type 2 diabetes, May 2008

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## **Latest NICE Guidelines**

The front page of this Newsletter covers three key statements from the recently published NICE Guidance for Type 2 diabetes [National Institute for Health and Clinical Excellence]. We highlight these 3

statements because they recommend what IDDT and many people with diabetes have been saying for a long time, even though what is happening at the 'sharp end' – where people are treated, can be quite different.

Firstly NICE is not saying that people with Type 2 should be refused blood glucose test strips but that they should be offered blood glucose testing alongside education in how and when to carrying it out and how to interpret and act on the results. So in future people who are denied test strips can quote NICE guidelines!

Secondly, first line insulin treatment is not with insulin analogues but with human insulin supporting the view that analogues have not been shown to be superior and of course, they are significantly more expensive, so we assume that NICE is not advocating wasting valuable resources on them, except under certain circumstances. It is worth noting that Levemir is not mentioned in these guidelines – it is still being assessed as a 'new agent' by NICE.

Thirdly, it is good to see that NICE favours addressing individual needs and preferences and that patients should make informed decisions about their care on evidence-based information.

### **NICE Guidance for Type 2 diabetes [May 2008]**

Here is the summary of the key NICE recommendations for the treatment of people with Type 2 diabetes for implementation by health professionals:

#### **Patient education**

- Offer structured education to every person and/or their carer at and around the time of diagnosis – this can be in group sessions run by people who have been specially trained to do this.
- Provide individualised and ongoing nutritional advice from a healthcare professional with specific expertise and competencies in nutrition.

## Setting a target HbA1c

- Involve the person in decisions about their individual HbA1c target level, which may be above that of 6.5% set for people with Type 2 diabetes in general.
- Encourage the person to maintain their individual target unless the resulting side effects [including hypoglycaemia] or their efforts to achieve this impair their quality of life.
- Offer therapy [lifestyle and medication] to help achieve and maintain the HbA1c target level.
- Inform a person with higher HbA1c that any reduction in HbA1c towards the agreed target is advantageous to future health.
- Avoid pursuing highly intensive management to levels of less than 6.5%.

## Self-monitoring

- Offer self-monitoring of plasma glucose to a person newly diagnosed with type 2 diabetes only as an integral part of his or her self-management education. Discuss its purpose and agree how it should be interpreted and acted upon.

## Starting insulin therapy

When starting insulin therapy, use a structured education programme that includes:

- continuing telephone support and support from an appropriately trained and experienced healthcare professional
- frequent self-monitoring
- dose titration to target [how to adjust insulin doses]
- dietary understanding
- management of hypoglycaemia – how to avoid it and treat it
- management of acute changes in glucose control.

**The type of insulins that NICE recommends is covered on the front page.**

## Other recent NICE guidelines

### **Pregnancy and diabetes [April 2008]**

New NICE guidelines on pregnancy and diabetes have been issued and they recommend that:

- women with diabetes should be able to access specialist services before they become pregnant.
- They should aim for a fasting blood glucose of 3.9 to 5.9mmol/l and one hour post-prandial [after meals] blood glucose below 7.8mmol/l if planning to become pregnant and during pregnancy.
- Women should be directed to take folic acid supplements and given lifestyle advice.
- They should be told of the importance of maintaining vitamin D levels during pregnancy and while breast feeding and if required, they should be offered Vitamin D supplements.
- Health professionals should advise on good glycaemic control to reduce the risk of miscarriage, malformation at birth, still birth and neonatal death.
- GPs must tell women who are pregnant and those planning to conceive to avoid alcohol because it can increase the risk of miscarriage in the first trimester.
- Women with gestational diabetes should be offered advice on diet and exercise and offered a fasting plasma glucose test at the 6-week postnatal check and yearly after that.

### **Transplanting donated pancreatic islet cells for patients with Type 1 diabetes [April 2008]**

NICE has issued an 'interventional procedures guidance' on islet cell transplantation and this advises the NHS on when and how new procedures can be used in clinical practice. It is also to help people who have been offered islet transplantation to decide whether to agree to it [consent], or not. In brief NICE says:

- Pancreatic islet cell transplantation is safe enough and works well enough for use in NHS hospitals with experience of the procedure. So it can be offered routinely as a treatment option for

Type 1 diabetes provided that doctors are sure that [i] the patient understands what is involved and consents and [ii] the results are monitored.

- Before the patient agrees [or doesn't agree] to the procedure, doctors should make sure that extra steps are taken to explain the potential risks of the procedure and the uncertainty about how well it works in the long-term.
- A team of specialist doctors should decide which patients should have islet transplantation. They should take into account that it is particularly suitable for people who have sudden hypos without warnings or people who are already using immunosuppressant drugs because of a kidney transplant.
- NICE has decided that more information is needed about how islet transplantations affect quality of life and how well it works long-term.

NICE looked at 8 studies on the benefits and risks of the procedure. The possible benefits appear to be reduction in severe hypos, improved hypo awareness, better control, less fear of hypos. The possible risks are bleeding into the abdomen, a blood clot in the portal vein, high blood pressure in the liver, problems caused by the patients lowered immune system [through using immunosuppressants for life] and the possibility of donor cells carrying infections or cancerous cells.

### **NICE approves Rimonabant for obesity [March 2008]**

NICE has approved the use of rimonabant [sold as Accomplia] for the treatment of overweight and obesity as an addition to a controlled diet and regular exercise for people who are either intolerant or contraindicated for orlistat and sibutramine [two other weight reducing drugs.] This approval means that GPs can prescribe rimonabant to overweight and obese people with associated risks factors such as Type 2 diabetes.

Licensed in 2006, the European drug regulator issued a warning against using rimonabant in people with major depression. However, the US has not approved its use because of concerns over psychiatric risks. A recent study presented at the American College of Cardiology

meeting in April, added to these concerns - it showed that Accomplia [rimonabant] did not slow heart disease in obese people with fat round the waist and 40% of people who took it developed psychiatric problems.

### **NICE guidance on lifestyle changes for repeat heart attacks**

For the first time NICE has issued guidance that has recommended lifestyle change, alongside drugs, for preventing repeat heart attacks. This is in line with the growing evidence that specific lifestyle changes reduce the risk of second heart attacks.

The new lifestyle section says patients should:

- give up smoking
- be physically active for 20-30 minutes a day
- eat a Mediterranean-style diet
- eat more oily fish or be prescribed certain preparations of omega 3 fatty acids.

Research has found that one specific omega 3 supplement called Omacor, cut the risk of a patient dying suddenly by up to 45%. Omacor is currently the only omega 3 supplement with a licence for post heart attack treatment. NICE estimate that the cost to the NHS of using it might be quite high as around 260,000 people have a first heart attack every year and 20% of them might need supplements because they are intolerant to oily fish. NICE estimates that the cost could be £7million.

All NICE Guidelines can be found by visiting: <http://www.nice.org.uk>



## **Injection Issues**

### **Mixing up your insulins**

In IDDT's April Newsletter we supported Diabetes Health's call on

the insulin manufacturers to make changes so that people would not mix up their insulins – especially important with the use of insulin analogues where both the short- and the long-acting insulins are clear. Diabetes Nurse Specialist, Carole Malloch has kindly sent us the solution she has devised for her patients.

### **Simple yet innovative solution for illiterate or non-English speaking people using insulin**

#### **Carole Malloch, Diabetes Nurse Specialist**

A number of our patients are illiterate or cannot read English. This presents a real problem for these patients. Their treatment is multi-daily injections of insulin which they administer themselves. Two different types of insulin are used and it is very important that the correct insulin is administered. There have been numerous incidents when patients have got their insulins mixed up causing their diabetes to be very unstable eg taking the fast-acting insulin, which should be given with food, instead of the night-time

slow-acting insulin can cause a severe hypoglycaemic attack during the night which can lead to fitting and unconsciousness or, worse case scenario, brain damage.

I have therefore, devised stickers to apply to the insulin pen devices. As you will see from the examples of the stickers, the pictures indicate when to take the insulin. [ie one for the insulin to be taken with food and another for the insulin to be taken at bedtime.]

Also insulin cartridges have coloured tops and the border colour of the stickers indicates the coloured top therefore the patient only has to put the correct colour top to match the sticker on the pen. At the moment I am using paper stickers covered with cellotape but ideally the labels should be more durable.

#### **Day-time – at meal times**



#### **Night-time**



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#### **Can't remember whether I've injected or not**

Not difficult for this to happen, once you wonder whether you have injected you can't remember whether it was this morning or yesterday morning!

- One of our members on two injections a day, has countered this by putting out 2 needles for the day then all he has to do is look at the number of needles to know whether or not he has injected.
- Lilly has introduced the Lilly HumaPen Memoir, the first pen with a digital memory for use with Humalog and Humulin insulin cartridges. It enables people to check the time, date and amount of the last 16 doses taken. The Memoir also has a dialling system that enables users to set the dose by turning a knob. The correct dose appears in a display window and any dosing error can be corrected without wasting insulin. For more details visit [www.lilly.co.uk](http://www.lilly.co.uk)

# Hypoglycaemia, Loss of Warnings and Driving

## Reduced awareness of hypoglycaemia still high

Research to date into impaired hypo unawareness [loss or reduced warnings of low blood sugars] has not been very good but there has been a general acceptance that about 25% of people with Type 1 diabetes have reduced warnings of hypos.

A study in Edinburgh recruited 518 adults by random selection over 2 years. [Ref 1] The participants completed a questionnaire about themselves, their hypo awareness and the number of severe hypos they had during the previous year. Impaired hypo awareness was present in 19.5% of the participants. Compared to the people with normal awareness those with reduced warnings were:

- significantly older
- had a longer duration of diabetes
- had a 6 fold higher increase in severe hypos in the previous year. In the group with normal awareness the prevalence of severe hypoglycaemia was 20.1% but was 50.5% in those with impaired hypo awareness.
- There were no differences in control as measured by the HbA1c in the two groups.

The researchers concluded that significant proportion of people with Type 1 diabetes (19.5%) continue to have impaired hypo awareness 'despite the introduction of novel therapies'. This is an interesting comment because the land mark DCCT study in the early 1990s showed that there was a 3 times greater risk of severe hypos with intensified insulin treatment so as more and more people are on intensive treatment and/or targeted to have near normal blood glucose levels, we can hardly expect hypo unawareness to improve!

On a daily basis hypoglycaemia and loss of warnings are the greatest concern to people with diabetes. This study demonstrates that despite introduction of new insulins, multiple injection regimes and increased blood glucose testing, over 20 years there has been no improvements

in the issue that has always mattered most to people with Type 1 diabetes.

Ref 1 Diab Med, April 2008

## Road traffic accidents and insulin use

People with diabetes treated with insulin are restricted from driving group 2 and class C1 and D1 vehicles based on an assumption, rather than evidence, that an increased risk of hypos will cause traffic accidents. A newly published study [Diab Med, 25, 578-584, 2008] has investigated whether the rate of traffic accidents in people with diabetes is higher than that of the non-diabetic population.

Results showed:

- the estimated overall annual accident rate for the non-diabetic population was 1469 per 100,000 and for the diabetic population 856 per 100,000. Less accidents in people with diabetes is an unexpected result and could be due to age differences.
- When looking at insulin treated people by age, there was no significant difference in the accident rate compared to the non-diabetic population.

There are factors that may influence these results:

1. within the diet/tablet treated group of people with diabetes over 90% were over 45 years old whereas in the non-diabetic population 40% were in the younger age group who tend to have more accidents.
2. people with diabetes may be less likely to report accidents for fear of losing their licences and
3. some people with diabetes who have problematic hypos may voluntarily give up driving.

The researchers concluded that insulin-treated people as a group do not pose an increased risk to road safety but emphasised the need for individual risk-based assessment when considering driving restrictions.

This supports the present DVLA system of individual assessment of insulin-treated people who wish to drive vehicles between 3.5 and 7.5 tonnes.

### **DVLA update their website on driving and hypoglycaemia**

The information leaflet issued by the DVLA to all drivers once they are treated with insulin is now on the DVLA website. 'At a glance guide to the current medical standards of fitness to drive' can be found at <http://www.dvla.gov.uk/media/pdf/medical/aagv1.pdf>

The DVLA advise:

- not to drive if blood glucose levels fall below 4mmol/l
- not to resume driving for 45 minutes after the levels have returned to normal
- to take a snack before driving if the levels are 5mmol/l or lower.

### **And for people in Western Australia...**

There is a new law in Western Australia requiring motorists to report medical conditions that could affect their ability to drive. People with conditions such as diabetes will have to notify the Department for Planning and Infrastructure who will investigate and may change the person's licence conditions. Although difficult to enforce, there will be a fine of \$500 for anyone who does not notify the Department. This brings Western Australia in line with all other States and Territories in Australia.

### **And while taking about the DVLA...**

#### **Visual field loss - grim determination with the DVLA**

In the past the DVLA has removed some people's driving licence simply because they have had laser treatment for retinopathy and in some cases, even after their eyes have remained stable for several years after the original treatment. In previous Newsletters, we reported that the DVLA has now accepted that retinopathy is not always progressive and the DVLA now made it possible for people to have visual field checks with different types of instruments and if

necessary, an on road driving check.

Obviously in cases where people do not meet the required standards of vision or visual fields, then driving licences should not be issued or renewed but some people are being denied their driving licences even when their retinopathy has remained stable ie it has not worsened and they have not had laser treatment for many years. In this situation we advise people to appeal against any decision to remove their licence and where people have already lost their licence, to apply again.

### **Grim determination paid off for Pat Millar after 8 years without a driving licence**

Pat Millar lost his driving licence 8 years ago because he had had laser treatment some years earlier. After reading about the DVLA changes, Pat re-applied for a driving licence as his ophthalmologist had already said he was fit to drive. He had a long battle with the DVLA who were even unwilling to accept the report from his ophthalmologist [eye specialist] as he was not one of 'their registered practitioners'. With the support of his ophthalmologist, he battled on and many letters later, he received a new 3 year driving licence after 8 years of not being able to drive.

Several other people have also received their driving licences back but as far as we know, not after 8 years like Pat. Pat is delighted to be driving again but of course, he is questioning whether or not the DVLA should have removed his licence in the first place.

### **There are some messages here if the DVLA refuses to give you a licence:**

- If you had laser treatment years ago, your retinopathy has remained stable and think you are fit to drive, don't just give in if the DVLA refuse to give you a licence, appeal against the decision. If you are unsure about whether or not you meet the required visual field and vision standards, see your own eye specialist first.
- The DVLA will send you to one of their registered optometrists but you can see your own eye specialist [ophthalmologist] for a

report, even though the DVLA may say otherwise. Obviously an ophthalmologist is better qualified than an optometrist and you can argue that his/her report is sufficient for the DVLA.

- Don't be intimidated by the DVLA or their answers on the telephone.

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## An Aspirin A Day?

Aspirin belongs to a class of medicines known as non-steroidal anti-inflammatory drugs [NSAIDs]. Aspirin has analgesic, anti-inflammatory and anti-oxidant properties. It has already been shown to combat pain, rheumatoid arthritis, heart disease, strokes and some cancers, notably those of the lung, bowel and pancreas.

### **Aspirin may be less effective in people with diabetes**

Many older people are prescribed an aspirin a today to prevent blood clotting in the arteries - thrombosis. Clotting is caused by platlets in the blood joining together to form a clot or thrombosis. Aspirin is an antiplatlet drug which decreases the ability of the platlets to stick to each other. A recent meta-analysis [a review of the findings of studies put together] has suggested that antiplatlet agents such as aspirin, may be less beneficial in people with diabetes with stable vascular disease compared to people without diabetes. So a study was carried out to look at the outcomes in 2,499 unselected patients with acute coronary syndrome. Despite all the patients receiving similar doses of aspirin, the results suggested that aspirin is less effective in reducing mortality rates in people with diabetes than people without diabetes. The researchers suggest that there is a need for more effective antiplatlet strategies to improve outcomes for people with diabetes and unstable coronary disease and they also ask the question of whether people with diabetes have a resistance to aspirin. More research is needed.

[The Evaluation of Methods and Management of Acute Coronary

Events (EMMACE)-2 Study, Diabetes Care, 2008:31:363-5]

### **Aspirin may improve glucose tolerance**

Aspirin has been recognised to improve glucose tolerance and reduce insulin requirements. Now for the first time new research has shown that healthy obese people who take aspirin actually increase their levels of insulin so reducing the chance of developing insulin resistance which can lead to Type 2 diabetes. [Journal of Clinical Endo and Metab, July 2008]

### **Aspirin found to cut breast cancer risk**

A large study carried out by the National Cancer Institute in the US has found that aspirin was linked to a 16% reduction in risk of oestrogen-sensitive breast cancer, the most common form of breast cancer. The study involved 127,000 women aged 51 to 72 who took part in the National Institutes of Health AARP Diet and Health Study, a major US investigation into links between diet, behaviour and cancer. Aspirin and other NSAIDs block cyclo-oxygenase (COX) enzymes, biological catalysts which may affect the growth of cancer.

We hope that this information may help you in your choices about taking aspirin.

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## Lancet Discontinuations

On June 1st 2008 Owen Mumford discontinued two types of Lancets: Unilet Superlite(23G) and Unilet GP (21G). The company recommends that you change to one of three alternatives which all deliver enough blood for any meter and are all available on NHS Prescriptions:

- Unilet ComforTouch lancet with a specially shaped 28-gauge lancet and a recapping facility for safer disposal. This lancet is suitable for most skin types and compatible with the majority of finger pricker devices.
- Unilet GP Superlite lancet is a 23-gauge lancet suitable for people

with tougher skin or those used to a thicker lancet. It is compatible with most leading finger pricker devices.

- Unistik 3 is an all-in-one lancing device. It is a preloaded lancet penetrates the skin to precisely the right depth and then retracts back into the device ensuring its safe disposal. It has the added feature of Comfort Zone Technology and is a more comfortable way to take a blood sample. There are three variants available:

1. Unistik 3 Comfort – suitable for most skin types
2. Unistik 3 Normal – suitable for slightly tougher skin
3. Unistik 3 Extra – suitable for tough skin and larger blood samples required for home cholesterol testing.

For more information call: Owen Mumford UK Customer Service on 01993 810052

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## Counting The Clicks - Some Answers

In IDDT's April Newsletter we asked for some suggestions to help a partially sighted man using an insulin dose of 60 units as he has difficulty remembering how many clicks he has counted when dialling up his dose with an insulin pen. We had a large response to this from both health professionals and people with diabetes so thanks to everyone for their helpful suggestions. For other people with similar problems, here are the suggestions but these do depend on whether people are visually impaired or blind.

### For those who are visually impaired:

**Innolet** – using the Innolet which is a dial up injection device which looks like a clock and the unit numbers are larger. You just have to twist to the right number of units. It dials up to 50 units so the first 50 could be dialled up and injected without counting, then there is only a need to actually count the remaining 10 units. The Innolet is made

by Novo Nordisk, so is only available with some of their insulins: Insulatard, Mixtard 30 and Levemir.

**NovoPen Magnifier** – this is a little magnifier that fits over the end of the NovoPen 3 to enlarge the numbers.

### For people who are blind or have very little sight:

- **Counting the musicians way** – this is hard to explain in writing! For example, divide the 60 units up into groups of 6 so that you only have to count up to 10 each time counting as follows: 1 followed by 1 to 10, 2 followed by 1 to 10, 3 followed by one to 10 etc up to 6 followed by 1 to 10. I hope you can follow this!
- Perhaps easier still breaking up the 60 into 6 'chunks' of 10 units and putting 6 coins in a pile on a table and with each 'chunk' of 10 units move a coin from left to right or better still have 2 boxes one with 6 counters and swap a counter to the other box for every 10 units.
- If the pen dials up to say 70 units, dial up the 70 without counting and then count 10 backwards until 60 units is reached.
- Finally after thinking about this for a whole weekend, one member suggested that a sighted person cut a piece of card for the exact distance that the top of the pen when it comes out to the correct dose, and this is used to slotted in for each dose – not sure about this one!

Again many thanks to the health professionals and members who helped with this.

### Some answers to other frequently asked questions...

#### **My insulin dose is large, I have to inject with my pen twice**

The amount of insulin a pen can deliver varies with the different brands of pens, but a frequently grumble made to IDDT by people on high doses of insulin, is that their dose is higher than their pen will deliver in one injection and so they have to inject twice. There is a simple answer – use a 100unit syringe and a vial of your insulin and then

you can draw up to 100units and only inject once each time. You may prefer to use a pen when you are out but you could use a vial and syringe at home. While pens are great, they are not so great if you have to inject twice every time.

**As disposable pens are not good for the environment, is there anything I can do?**

Yes, instead of using a pre-filled 'disposable' pen, you could use a non-disposable pen and just replace the cartridges. It is interesting marketing that the insulin manufacturers never refer to pre-filled as 'disposable' but they are and are not environmentally friendly. IDDT made these points in the regulatory authority consultation when disposable pens first appeared but to no avail - perhaps we were ahead of time as saving the environment was not as high on the agenda. Disposable pens have a place, such as for people who have problems with their hands, but if you want to be more environmentally friendly, talk to your GP practice about changing to a non-disposable pen.

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## Discrimination At Work

From time to time people with diabetes contact IDDT because they are having difficulties at work. This maybe being put under pressure to work without being given time to eat or for newly diagnosed people, having to carrying out tasks that they do feel confident in doing because they are still learning to manage their diabetes. This can become very stressful which does not help diabetes control and makes going to work something to dread.

Although we don't think of diabetes as a 'disability', it does come under the Disability Discrimination Act [DDA] and for those with internet access, information about your rights can be found by visiting [www.disability.gov.uk/](http://www.disability.gov.uk/)

The Disability Rights Commission is now part of the Equality and Human Rights Commission and if you need help or advice relating to discrimination at work or at school, you can call the Equality and Human Rights Commission Helpline.

The details are as follows: for England telephone: 0845 604 6610, for Wales, 0845 604 8810 and for Scotland, 0845 604 5510

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## More On Avandia and Actos

### **Avandia and Actos fracture risks almost double**

While there may still be some debate about the increase risks of heart attacks with Type 2 drug, Avandia, the evidence of increased risks of bone fractures with both Avandia and Actos is now more robust. New Swiss research shows that both Avandia and Actos [rosiglitazone and pioglitazone] can more than double the risk of bone fractures. [Archives of Internal Medicine, April 2008] The records of 1,020 diabetic patients with fractures diagnosed by UK doctors between 1994 and 2005 were compared against a control group of people with diabetes who did not have fractures. The people on Avandia or Actos had double or triple the risks of non-spine fractures - the risks increased among those who took the drugs for 12 to 18 months and was highest for those with 2 or 3 years of therapy. Hip and wrist fractures were the most common. Researchers believe these drugs stimulate the action of a cell that drives the process of reabsorbing bone, making bones more apt to break and advise that people with Type 2 diabetes should carefully weigh up the risks and benefits before taking these drugs.

### **The latest position on Avandia and increased risks of heart attack**

Last November in the US, Avandia received a black box warning alerting doctors and patients that it could increase the risk of heart attacks. The US drug regulator, the FDA, has issued a warning to manufacturers, GlaxoSmithKline [GSK] for not reporting safety problems with Avandia as the FDA was not updated on more than

10 ongoing studies between 2001 and 2007. [FDA website March 25, 08]

In 2007 the European Medicines Agency Committee for Medicinal Products in Humans concluded that the risks of this family of drugs, the glitazones, outweigh their benefits. But the UK Medicines and Healthcare products Regulatory Agency [MHRA] say that Avandia might be associated with a small increased risk of cardiac ischemia and should be used in patients with ischemic heart disease only after “careful evaluation of individual risk.”

### **Position in Scotland on Avandia**

The minutes of the February meeting of the Managed Clinical Network for Diabetes in Glasgow read: “The consensus was that there was no defence for its use unless the goalposts changed in times to come”. In April drugs experts from NHS Greater Glasgow and Clyde, Scotland’s largest health board decided that only consultant diabetologists will be allowed to prescribe Avandia initially with subsequent prescriptions being issued by GPs. This does not ban the drug but it is likely to seriously restrict prescribing of it. Officials advise that patients taking Avandia who have certain heart conditions, such as angina, should have their treatment reviewed by a diabetes clinic at the earliest opportunity. Patients without heart problems should have their treatment reviewed at their next diabetic clinic visit.

### **A low fat vegan diet is safer than Avandia!**

The Physicians Committee for Responsible Medicine in the US has petitioned the FDA requesting that Avandia’s warning label should include a statement that a low-fat vegan diet is a safer, more effective approach to lowering blood glucose levels than Avandia. They say that the benefits of the diet which include lowering of blood pressure and cholesterol levels, weight loss and prevention of heart disease, should be made clear to Avandia users.

With these mixed messages, if you are taking these drugs, we can only recommend that you discuss your options with your doctor.

## **Insulin Pumps Linked To Injuries and Deaths in Teenagers**

As a result of a study carried out by researchers from the US Food and Drug Administration [FDA] advice has been issued that insulin pumps can be risky and have been linked to injuries and even deaths, in teenagers with Type 1 diabetes. They didn’t advise against them but advised parents to be vigilant in watching their children’s use of pumps. They did call for further studies to address safety concerns in teenagers and younger children.

Between 1996 and 2005 this review of the adverse events reported to the FDA found that there were 13 deaths and over 1500 injuries connected with pumps in young people between the ages of 12 to 21. 82% of the cases resulted in hospitalisation. Concerns were also expressed that there is every reason to be concerned that similar results will apply to adult pump users.

At times the pumps malfunctioned but the greatest cause of the problem was down to the user. Some teenagers were careless or took risks but analysis showed that the causes were not all down to this. Many new pumps are very sophisticated and their complexity can overwhelm even experienced users and greatly increase the risk of error in people who are inexperienced with pumps, or distracted, anxious, depressed, or having any temporary confusion problems as often occurs with either severely low or high blood glucose levels.

Insulin pumps are the size of a cell phone and worn on a belt or pocket. They send insulin into the body through a plastic tube with a small tip that inserts under the skin and is taped in place. Users must tell the device how much insulin to give before each meal, based on the estimated carbohydrates in the meal. The devices also deliver a continuous low level of insulin.

Dr John Buse, the American Diabetes Association’s president for medicine and science: *“Device problems such as blocked tubing*

*can quickly lead to dangerous high blood sugars. In a matter of a few hours, all the insulin in the body disappears. Metabolically, the child starts to spiral out of control. Kids need to be aware of this risk, monitor their blood sugar and be ready to give themselves an insulin injection.”*

The authors of the study: *“The FDA takes pediatric deaths seriously. Parental oversight and involvement are important. Teenagers don’t always think of the consequences of their actions”.*

The key message here is that insulin pumps must be treated with respect and an understanding that without appropriate blood glucose monitoring and care, pumps increase the risk of getting ill more quickly than injections.

It is also worth remembering that just because a younger child has accepted the extra care and attention that is required when using a pump, as children become teenagers they can change. The reliable child you once had can become a rebellious teenager who does not always take care of their diabetes. Adults with diabetes who have gone through this stage will remember the risks they took, some of which their parents never know about! [Pediatrics, May 2008]

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## What Are The Research Priorities of People With Diabetes?

Have you ever wondered who decides which research will be funded? And in making these decisions, are the important issues for patients known and do they play a part in the decisions of which research to fund?

We may think that researchers themselves know better than both clinicians, patients and carers, but do they? How do they know what is important to those living and working with diabetes everyday?

Sometimes we may wonder if researchers are more interested in ‘research’ itself, forgetting that the only reason for doing research is to assist people who have a disease such as diabetes. It makes sense therefore, that the people with diabetes should be involved in driving the research agenda – setting the priorities for research funding.

There is an additional problem nowadays. A large amount of research is funded by the pharmaceutical industry whose motivation is selling drugs and this can skew the research agenda away from the priorities of patients and clinicians. For instance, there are uncertainties about the effects of different diets but industry is hardly likely to fund this type of research - there’s no gain for them. In fact there are cynics who believe that it is not in industry’s interests to question whether it is better to use a low carb or a high carb diet. If the answer is low carb, then the quantities of insulin used would be significantly reduced, as would the profits!

Looking at research priorities is a complex business perhaps especially so in diabetes. This is highlighted by the title question, ‘what are the research priorities for people with diabetes?’ The question is too simplistic. To start with there are two types of diabetes – Type 1 and Type 2 and the research priorities for people with Type 1 diabetes may well be quite different from those of people with Type 2. Then there is another group – the parents and partners of those with both types of diabetes who may have different priorities for research. We can break this down even further to see that the priorities of people who have lived with both types of diabetes for a long time may be different from those who are relatively newly diagnosed.

There are also the clinicians, the doctors who look after people with diabetes in their clinics and surgeries everyday. They will certainly have their views on priorities for research and again these may be different from those of people with diabetes but they are just as valid. How much influence do they have over which research is funded?

### **Just what do we mean by research priorities?**

Perhaps for many of us who are unfamiliar with the research world,

this expression alone sounds out of our league, but it isn't. Research should be driven by what is important to patients, what matters most to them, what bothers them most about living with a condition such as diabetes. A frequently quoted example is that when people with rheumatoid arthritis were asked what bothered them most about living with it, fatigue was top of their list. But had anyone done any research into fatigue and possible ways of combating it? No, but finding that fatigue caused the most problems for people, changed the research agenda.

People with Type 1 and Type 2 diabetes have never been asked in any organised way what concerns them the most about having diabetes in order for this to influence how research money is spent. Perhaps this is surprising as very often this is money they have raised or it has come from the public purse! If the important issues for patients are identified, the next step is to find out if research has already looked at these issues and if not, then this has identified gaps in research that need to be addressed.

For people using insulin, hypoglycaemia is thought to be their major day to day concern and fear of hypos is known to prevent people from achieving the target blood sugars. Linked with this is that impaired hypo warnings are a major problem for many people with Type 1 diabetes. A recent study has shown that nearly 20% of people with Type 1 diabetes have impaired hypo awareness and this percentage has not improved over the last 20 years despite all the new insulins and injection devices. [Diab Med, April 2008] This suggests that hypoglycaemia and loss of warnings have not been treated as a priority for research although it is the greatest concern for patients.

**Here's an unanswered question:** *if we avoided some hypos by raising target blood glucose levels to 5 to 8mmol/l instead of 4 to 7, would the risk of complications be any greater and if so, how much greater? The answer to this question could make life a lot easier and enable people treated with insulin to make more informed choices about what blood glucose levels we want to achieve in relation to the risks of hypoglycaemia.*

### **And what about the priorities of people with Type 2 diabetes?**

A recent report showed that between 12 and 50% of them would be willing to give up 8 years of healthy living to avoid complications and 10 to 18% said they would give up 8 to 10 years of healthy life to avoid treatments because this adversely affects their quality of life. [Diabetes Care 2007;30:1-6] So at a time when the number of drugs given to people with Type 2 diabetes is rising, an uncertainty for patients is do I really need all these drugs and are there ways of simplifying or modifying treatments to improve my quality of life? This would not be a priority for the pharmaceutical industry and may not be for clinicians who may believe that avoidance of complications by treating blood sugars, blood pressure and cholesterol levels is the top priority.

### **But there are treatment uncertainties that we may not realise are uncertainties!**

We may think that the treatment we are receiving is based on evidence of benefit and that it is known to be the best for us. But is the case? Do we ask this question? Very often we don't, we simply assume that the treatment we are given is 'the best'. Sometimes we may prefer not to ask questions because the answer could be 'I don't know' and some people find this difficult to live with.

For example, it is hard to believe that once a new insulin appears on the market, suddenly it appears that our clinic decides that this is the best insulin for everyone – and there are group sessions of transferring people to the new insulin, as happened with Lantus. But do we know which groups of people are better suited to certain types of insulin? No we don't, because the research has not been done. So although insulin is the very basis of treatment for Type 1 diabetes and some people with Type 2 diabetes, it is staggering to realise that we don't know which insulins suit which people best. If this isn't a treatment uncertainty, I don't know what is!

### **DUETS and Diabetes**

DUETs stands for 'Database of Uncertainties about the Effects of Treatments' which lists treatment uncertainties which arise from clinicians, patients and from reviews of research which highlight that

more research is needed into a particular topic. Thanks to Dr Roger Gadsby and the team at Warwick University, I am delighted to say that there is now a DUETs for diabetes. So far there are about 39 uncertainties listed, questions that have been raised, searched to find out if they are unanswered by existing research and then listed as treatment uncertainties. There's an interesting list of uncertainties so far, so if you have access to the internet, visit <http://www.duets.nhs.uk/> and just type 'diabetes' in the search box.

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## Diabetes and The Dentist

### Attending the dentist

People with diabetes are more prone to gum disease and tooth decay than the general population, partly because glucose remains in the saliva. An article in General Dentistry [Nov/Dec 2007] highlights the need for people with diabetes to communicate their needs to their dentists due to harmful interactions that could occur because of the materials and medications used in dental treatment. This is especially important for those taking insulin but your dentist needs to know all the medications you are taking including prescription drugs, over-the-counter drugs and any herbal remedies.

The article issues the following advice:

- See the dentist on a regular basis and inform him/her of any changes in your health and medications.
- Tell the dentist about any sores, swellings, redness or painful areas in your mouth.
- Eat a normal meal before the dental appointment, take all your usual medications on time, take your blood glucose monitor with you and tell the dentist if you have hypo symptoms.

### Gum disease and gestational diabetes

Recent dental research [Journal of Dental Research, April 2008] at

New York University has found evidence that pregnant women with gum [periodontal] disease are more likely to develop gestational diabetes than women without gum disease. 256 women were followed for the first 6 months of pregnancy and 22 of them developed gestational diabetes and these women had significantly higher levels of periodontal bacteria and inflammation than the other women. It is believed that the inflammation associated with gum disease plays a role in the onset of gestational diabetes perhaps by interfering with the normal functioning of insulin. While gestational diabetes usually disappears at the end of the pregnancy, women who have had gestational diabetes are more at risk of developing Type 2 diabetes later in life so the authors recommend that pregnant women and those considering pregnancy should see a dentist.

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## Research News

### Probably the most exciting research of our time

Some time ago American researcher, Dr Denise Faustman realised that a drug that killed 'bad' white blood cells could help to reverse Type 1 diabetes. She was looked upon with some skepticism by some other researchers. However, in animal studies she went on to identify the vaccine BCG as one that effectively depleted the abnormal immune cells that attack and destroy the insulin-producing islet cells in the pancreas that cause Type 1 diabetes. The BCG vaccine is commonly used vaccine used to protect against tuberculosis.

Dr Faustman found that mice with a form of diabetes similar to Type 1 diabetes in humans started to improve within days of being injected with the BCG vaccine and eventually were free of diabetes. The vaccine destroyed the abnormal white blood cells which were obstructing the production of insulin in the cells of the pancreas.

Trials on humans are taking place at Massachusetts General Hospital to see whether this will work on the abnormal autoimmune cells

present in Type 1 diabetes in humans.

The first step is to find out if the same strategy can be of BCG vaccination can be used in humans. The research will be a long process but it seems one of the best hopes there has ever been. The trial information is available at [www.faustmanlab.org](http://www.faustmanlab.org).

### **Six new genes linked to Type 2 diabetes**

Scientists have found six new genes that are linked to Type 2 diabetes. Each of the genes raises the risk of developing Type 2 diabetes by a small amount but the scientists believe that the combination of all six could be powerful. This discovery could help in the development of new forms of prevention and treatment.

Some of the disease variants are in 10% of the population and the one that's increasing the risk is the majority version which is in 90%. Inheriting a disease variant of any of the genes from either parent could increase a person's risk of developing Type 2 diabetes by 10%-15%. A few people will have many of these risk variants and they'll have a higher risk of diabetes than individuals who have a very few.

In the study 90 researchers from more than 40 European and US centres pooled genetic data gathered from more than 90,000 people. The researchers comment that none of the new genes were previously suspected of having a role in diabetes, so there is still a lot more research needed to work out what the genes are responsible for. Nearly all the genes found so far seem to be affecting the ability of the pancreas beta cells to compensate for insulin resistance. A surprising find was that one of the genes found linked to Type 2 diabetes was recently shown to play a role in prostate cancer.

### **Why some people may be more prone to complications**

I am sure many readers will have come across some people who don't seem to take a great deal of care of their diabetes but don't develop complications and yet others who try really hard, do. There may now be an explanation.

Researchers at Utah University examined over 600 people with diabetes for changes in the DNA and found that there was a genetic change associated with an increased frequency of severe eye and kidney problems. These two complications of diabetes are caused by excessive growth of blood vessels. The specific changes in DNA occurred near a particular gene which stimulates blood vessel growth and red cell production. Follow up studies in 1500 patients confirmed a strong relationship between people with diabetes and DNA changes and increased risk for severe kidney and eye complications despite their best efforts to control their blood sugars and their diet. [US Proceedings of the National Academy of Sciences, May 2008]

### **A warning about long-term planning**

US research has shown that the number of pregnant women with diabetes has more than doubled over the last 6 years. [Diabetes Care April 2008] Looking at 175,249 women, it was found that between 1999 and 2005 diabetes increased five fold in the 13-19 age group and doubled among women between 20 and 39.

The US has a different ethnic mix and higher rates of Type 2 diabetes than the UK but this trend of more young people with diabetes is being mirrored in the UK and other countries. Women with diabetes require pre-conception counselling and access to specialist services during pregnancy to reduce the risks of complications for themselves and their babies. Let us hope that this research acts as a warning to health service providers of the need plan ahead to increasing these services rather than finding in 10 years time that there is a shortage of trained staff and facilities.

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## **IDDT Bussines**

**If you are an internet user you can help IDDT to raise money every time you search the web.**

Everyclick.com is a great new search engine. It works just like other

major search engines but it also generates cash for charities and it doesn't cost you or us a penny so it is a great way to help IDDT. You can make Everyclick.com your homepage or every time you search the web, simply use <http://www.everyclick.com/IDDT>

IDDT receives a few pence every time you use it, so ask your friends to do the same or set your e-mails to automatically add the following at the end:

### **Search the web and raise money for IDDT**

<http://www.everyclick.com/IDDT>

**Don't forget IDDT's Annual Meeting** – Saturday October 11th 2008 at the Paragon Hotel, Birmingham. Further information from Bev at IDDT on 01604 622837 or e-mail [bev@iddtinternational.org](mailto:bev@iddtinternational.org)

**Going on holiday?** IDDT has a 'Holiday Information Pack' with information and advice about travelling at home and abroad. If you would like a Pack, contact IDDT on 01604622837, e-mail [bev@iddtinternational.org](mailto:bev@iddtinternational.org) or write to IDDT, PO Box 294, Northampton NN1 4XS

### **Can anyone help?**

One of our members would like to know if anyone has spare copies of a video of a programme called Same Difference on Channel 4 about 1990 and another on BBC Watchdog covering the human insulin debate. If so, please let Jenny know on 01604 622837 or e-mail [enquiries@iddtinternational.org](mailto:enquiries@iddtinternational.org)

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## **Insulins - There's Still Confusion!**

### **Pork insulin**

All readers of IDDT's Newsletter must now be aware that pork insulin continues to be available and that it is only Novo Nordisk that has

chosen to discontinue their pork insulins. However, confusion arises when a health professional wrongly says all pork insulins have gone. Here it is again - the following pork insulins are available on the NHS in vials and cartridges for pens:

Hyprurin Porcine Neutral [short-acting]

Hypurin Porcine Isophane [intermediate-acting]

Hypurin Porcine 30/70 Mix

Hypurin bovine insulins continue to be available as before.

### **Human insulin**

There is also confusion about which human insulins are available. People who have had adverse effects from analogue insulins and want to change back to their original human insulin have been told that these are no longer available. In some cases, only insulin in certain delivery systems has been discontinued so the insulin type is still available but not necessarily for the same delivery system. For example, Novo Nordisk discontinued Insulatard in pre-filled pens but it is available in cartridges for pens as well as vials and pre-filled dosers. If you have always used pre-filled disposable pens, using cartridges instead simply means using replacing the empty cartridge in the pen with a new one and not throwing the pen away each time – some would say more environmentally friendly!

So the commonly used Novo Nordisk human insulins and their delivery systems still available are:

| <b>Name of insulin</b>    | <b>Source</b> | <b>Delivery system</b>            |
|---------------------------|---------------|-----------------------------------|
| Actrapid [short-acting]   | Human         | Vial                              |
| Insulatard [Intermediate] | Human         | Vial, cartridge, pre-filled doser |
| Mixtard 30                | Human         | Vial, cartridge, pre-filled doser |

### **Important option – change brands!**

People who want to use Actrapid may not want to use a vial and syringe, in which case there is a simple option – change to a different brand of human insulin. Humulin S made by Lilly is very similar to Actrapid and is available in cartridges for a pen.

## Ask questions

If we have learned anything from the misinformation that has been flying about pork insulin availability, it is that we, as patients, cannot always assume that the information we are given is accurate so we have to ask questions and if necessary, do our own research on what insulins are available. Or just give IDDT a call on 01604 622837 or e-mail enquiries@iddtinternational.org

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## The End For Inhaled Insulin

After Pfizer stopped production of inhaled insulin, Exubera, and Novo Nordisk discontinued the development of their version, our April Newsletter questioned whether Eli Lilly would follow suit. Well they did – in March Lilly announced that they were abandoning it and stopping clinical trials. Again they said the decision was not based on safety issues but on “new uncertainties in the regulatory environment”, whatever this means!

At that time, there was still one more company developing its own inhaled insulin – Technoshere Insulin by MannKind Corp who said that they were still committed to developing their inhaled insulin. But all that changes...

### Cases of cancer with Exubera

On April 9th 2008 Pfizer announced that they had updated the US labelling on the inhaled insulin to include a warning with safety information about lung cancer cases observed in patients who used Exubera. An ongoing review of the clinical trials and post-marketing surveillance found that 6 of 4,740 Exubera patients compared with 1 of 4,292 patients not using the inhaled insulin developed lung cancer and another case was discovered after the drug was launched.

The warning states that all patients who developed lung cancer had a prior history of smoking, but there were too few cases to know whether the development of lung cancer was related to the use of Exubera.

Then on April 11th Mannkind announced that in the wake of the cancer findings for Exubera, it was suspending discussions with potential partners for its inhaled insulin. However, the independent Data Safety Monitoring Board has said the trials should continue on the basis that they have seen no adverse effects so far.

*But if it should ever reach the market, who's going to prescribe it and who's going to use it?*

### Lung function research

Part of a study known as the Atherosclerosis Risk in Communities [Diabetes Care, April 2008] found that people with Type 2 diabetes have decreased lung capacity when compared to people without diabetes. This happens to everyone with age but the reduction appears to be greater and declines faster in people with Type 2 diabetes. Apparently this link is greater than originally thought and further raises concerns about the potential use of inhaled insulin which may make lung function worse.

The unknown risk of long-term lung damage has been one of the concerns about inhaled insulin but one of the arguments in its favour was its advantages for people with Type 2 diabetes because of their fears of injections. In the light of this new research, the decision to discontinue inhaled insulin seems the safest one!

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## From Our Own Correspondents

### Article on statins – what a coincidence!

Dear Jenny,

The article on statins in the April Newsletter was a strange coincidence for me. I have taken statins for several years, but I have felt dreadful so I asked my GP if I could come off them. Although she was not keen, she said I could if I came back in 3 months for a cholesterol check

which was soon after the April Newsletter arrived. Although I have arthritis, I took up gentle exercise and changed to a healthier diet and guess what, when I had my cholesterol checked after 3 months, it was lower than it had been when I was taking statins. But the real benefit is that I feel so much better – the aches and pains have gone, I no longer feel depressed, I am much brighter and I am enjoying life again. So I shall keep up my healthy eating and exercise and avoid taking statins.

Mrs J.P.  
North West

### **Sexual dysfunction**

Dear Jenny,

Thank you for the excellent publication on sexual dysfunction in men and women which was most informative. I would like to comment of the limits on how many tablets, such as Viagra, that can be prescribed on an NHS prescription. In my case this is 4 tablets per month on the NHS and any extras cost £40 for 4 tablets. The tablets come in 3 strengths, 25mg, 50mg and 100mg. I asked my doctor to prescribe 100mg tablets and I then cut them to the required size with a serrated knife which is easily done while they are still in the packaging.

Name withheld

**Jenny's comment:** When Viagra first became available IDDT and many other organisations raised objections when the Dept of Health placed a limit of 4 tablets a month for the treatment of impotence. It was, and is, grossly unfair and has caused people to resort to these measures.

### **I'm appalled!**

Dear Jenny,

I was flabbergasted to read in the April Newsletter that people are still finding it hard to obtain animal insulin. It seems that things have not

changed very much. Some years ago I asked my consultant if I could change to Hypurin Porcine insulin and his reply was: "We don't have that insulin here." Another time when I needed an emergency doctor, she said: "I have never heard of it, how do you spell it?"

Thank you for all the good work you do for all of us.

D.P.  
South East

### **Americans finding it more difficult to import animal insulins**

Dear Jenny,

Thank you very much for the information and IDDT Newsletters you have sent me. I appreciate this very much. I have had Type 1 diabetes since 1961 when I started on beef insulin and have been on it ever since. I have worked hard to remain free from all the severe diabetes complications.

I have received my beef insulin from CP Pharmaceuticals since 2001 and my diabetes is well-controlled. When I tried so-called 'Human' insulin in 1998 I had terrible low blood sugars everyday followed by highs – it was a living hell. Although I am still well, I live under the tremendous stress of having to get the only insulin that works for me from half way around the world so the expense and the stress is dreadful. For those of us in the US Wockhardt UK has made it much more difficult to import animal insulin with higher costs and increased requirements from our doctors. I do not understand why they are doing this but it must be about money! Diabetes will not kill me but the ongoing stress knowing that I must struggle to get the beef insulin that I need everyday for my existence is what will kill me.

Thanking you for helping and for listening to all of us who still need animal insulins to survive. In the US we have no one to even talk with about what's happening – no one cares and no one helps us.

USA

**Jenny's comments:** As we reported in the April Newsletter Wockhardt has increased their requirements for people who need to import animal insulins and I have appealed to them to be more understanding of the needs of Americans who cannot use synthetic insulins. I am afraid I have made no progress. The new importation procedures can be found by visiting Wockhardt's website: [www.wockhardt.co.uk](http://www.wockhardt.co.uk)

### **Pumps and animal insulin**

Dear Jenny,

I would like to use an insulin infusion pump but as I have adverse reactions to all synthetic insulins and to pork insulin, I can only use beef insulin. My hospital clinic has told me that I cannot use pork or beef insulin in a pump. You did tell me that some IDDT members successfully use pork insulin in pumps and at least one uses beef insulin but still my clinic said that it was not possible.

I contacted the manufacturers of beef insulin and if any of your readers are in a similar position they will find this information useful. "Hypurin Bovine Neutral insulin, is a soluble, short-acting insulin which contains a phosphate buffer and is suitable for use in subcutaneous pumps. In the UK it is generally considered that the presence of a phosphate buffer in a short-acting insulin should render the product suitable for use in a continuous, subcutaneous infusion pump."

By e-mail

**Note:** Hypurin Porcine Neutral also contains a phosphate buffer and therefore on the basis of the above statement from the manufacturers, is suitable for use in pumps.

### **The change worked for me**

Dear Jenny,

If any of your members are worried about the discontinuation of certain pork insulins my experience may help. I am now 60 and have been diabetic since 1979. I have been on pork Insulatard and

Hypurin Porcine Neutral for many years and was very worried about changing to a new insulin but last October I saw a new diabetic nurse and she prescribed the GM insulin analogue, Levemir in Flexpens. Since then I have not had a single hypo, whereas before they were a regular occurrence, and now my general health and moods have greatly improved. The diabetic clinic doctors never offered me this new insulin regime and I cannot thank my diabetic nurse enough. My wife says I am a lot easier to live with now!!

Mr G.D.

By e-mail

**Note:** This is great news for Mr G.D. but what works for one person does not necessarily work for another so it is vital that the choice of natural animal, human and analogue insulins remains available.

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## **Strange History Behind Saturated Fats and Heart Disease**

Many older people like me, will remember life when we ate fats without thinking about whether they was good or bad for our hearts and plenty of butter on our toast was a treat. Of course life was different then and we all got a lot more exercise but I don't remember when saturated fats became bad for us.

However, according to an article in MSNBC Dec 2007, the first and influential condemnation of saturated fats was made in 1953 by Dr Ancel Keys. He compared fat intake with deaths from heart disease in 6 countries: Australia, Canada, England, Italy, Japan and the US. The Americans ate the most fat and had the highest death rate from heart disease and the Japanese ate the least fat and had the lowest death rate from heart disease.

This all sounds good enough to have the impact it has had – to change

the thinking so that recommended healthy diets were low in fats [and high in carbohydrates] but the statistics for 22 countries were actually available and these showed a different picture.

Analysis of all 22 countries showed that the link between fat consumption and death from heart disease disappeared. For example, the death rate in Finland was 24 times that of Mexico although fat consumption in the two countries was almost the same.

Just shows what manipulation of statistics can do!

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## Yoga and It's Effects On The Management Of Type 2 Diabetes

Some studies in people with Type 2 diabetes have shown that yoga positions can lower fasting blood glucose levels and also can increase nerve function in people. Certain postures and movements have greater effects than others by stimulating the endocrine glands in the body.

- The Yoga postures that induce relaxation and certain breathing exercises are thought to stimulate the pancreas – this could be due to the alternating contraction and relaxation of the abdominal muscles and increased blood flow to the pancreas making it more efficient.
- The rotation of the body and the holding and stretching positions increases circulation – thought to be because yoga increases the elasticity of the blood vessels.
- Meditation is an essential part of yoga to attain a relaxed mental state and this can have a calming effect and relieve stress. In people with diabetes high stress levels often cause high blood sugars, so it is important to remember that yoga meditation could cause unexpected low sugars.

In Type 1 diabetes the body does not produce insulin and stimulating the pancreas is not effective. It is likely that yoga will not have as big an impact on people with Type 1 as people with Type 2 diabetes.

Having said this, it is important that people with both Type 1 and Type 2 diabetes who attend yoga classes to regularly monitor their blood glucose levels, take their medication as directed and have emergency glucose available in case of sudden drops in blood sugars. Some people with Type 2 diabetes who regularly participate in yoga do end up reducing their medications.

### What do we know about the effects of stress?

**Short bursts of stress can be good for you** - scientists have known for a long time that stress can have a negative effect on the body. But researchers have looked at 300 scientific papers about stress involving 19,000 people and found that a short burst of stress, such as that caused by giving a speech, may strengthen the immune system. However, long-term, unrelieved stress such as that caused by living with a permanent disability or caring for someone with a long-term disability, may weaken the immune system making people less able to fight infections. 'Good' stressful situations that last only a short time appear to cause the 'fight or flight' adrenaline response and this boosts the body's natural defence against infections. The important factor appears to be knowing that the event causing the stress or anxiety will end soon.

**Short bursts of stress and diabetes** - a study published in Diabetes Care, June 2007, looked at the effects of short-term mental stress in people with Type 1 diabetes with fairly good blood glucose control. It found that both in a fasting state and after a meal, mental stress had little effect on blood glucose control although heart beat, blood pressure and salivary cortisol levels increased. [Salivary cortisol is a hormone produced in response to stress.] This study only looked at short-term stress and not chronic stress and it only looked at people with 'fairly good control' - the results may be different for people with long-term mental stress or in people with 'poor' control.

**Stress may raise cholesterol levels** - studies in the past have shown that stress is linked to increased heart rate and weakened immune systems. Recently a team from University College London has found that stress also appears to raise cholesterol levels over the long-term in some people.

199 people were given stress tests and cholesterol tests three years apart. Cholesterol levels had gone up over time in everyone but some people showed large increases even in the short-term while others showed very little response. After three years, those people whose cholesterol levels had risen the most had high levels of LDL [bad] cholesterol compared to those who showed the smallest rise in cholesterol. [Health Psychology August 2007]

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## Generic Drugs

As part of government policy to save NHS funds, GPs often prescribe generic drugs rather than brand-name ones people may have been using. This makes economic sense but often causes people concern because they have been used to a brand-name drug. In many cases the generic drugs work just as well as the brand named ones. However some people get adverse effects from the generic drug that did not occur with the brand-name drug, which they have been told is the same.

The differences between brand-name and generic drugs can sometimes affect how a drug works, particularly in cases where the exact dose is critical. Certain conditions require people to maintain a constant and precise level of medication in the blood over long periods and switching drugs for certain conditions may upset a delicate balance eg epilepsy, asthma, diabetes and thyroid problems.

### What are generic drugs?

Once a brand-name drug has run out of patent, it is allowed to be made

by other companies and can be sold much more cheaply. Generic drugs have to have the same quality, strength, purity and stability as brand-name drugs but they may differ in the inactive ingredients eg preservatives.

A drug can be chemically exactly the same but not bioequivalent which means that they may not get into the body in exactly the same way. Bioequivalence depends on how a drug is formulated and how it is absorbed and eliminated by the body. The inactive ingredients, products which allow a drug to be formulated into a pill or a capsule, may be different from the brand-name drug and these can affect the absorption of a drug. The differences between people can also affect how a drug is absorbed eg age, weight, kidney and liver function.

If you experience difficulties with a drug, discuss these with your doctor and if necessary your drug can be changed.

**Note:** in an online survey of 781 registered nurses in the US, 41% reported that generic drugs are less effective than their equivalent brand-named drugs but we have to be very wary of such surveys because it could be that only nurses who had noted some differences responded to the survey.

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## Spare A Thought For The Carers...

It is recognised that caring for someone with a physical disability or an illness can be and is stressful and tiring but so often diabetes is a 'hidden' condition – not obvious to people around. It is sometimes hard for people with diabetes to understand or recognise that their diabetes can be a worry for their partners, spouses or parents [their family carers]. Indeed, some people would resent the suggestion that their families have to do any 'caring' from them. But family carers may have their own fears and worries that are quite different from those of the people with diabetes they love. For example:

- carers often have to handle hypos, especially in the night and then they may live with the fear of having to handle another hypo.
- If they are the person who does most of the cooking, they may feel their level of knowledge is not adequate and worry about the food they are preparing.
- They may worry about the risks of long-term complications.
- Carers can feel, and sometimes are, excluded from clinic visits despite having to know about their loved one's diabetes. We are pleased to see that the NICE Guidelines for Type 2 diabetes state that 'if the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.'

In 2006 a survey showed that there are 6 million carers in the UK and a survey of 5,000 of them showed that 79% of them admit that caring has made their health worse which in turn has adversely affected the person they care for. Only 1 in 4 has been offered a health check by their GP but 9 out of 10 carers wanted an annual health check.

So if you are a carer, think about your own health and ask your GP for a health check that includes a blood pressure check, diabetes check and a mental wellbeing check.



## NHS News

**Prescription charges** - in April prescription charges in Scotland were cut by 25% to £5.00 as part of phasing them out altogether. At the same time in England, prescription charges rose to £7.10 per item. In Wales prescriptions are free. It was interesting to read about this in a US newspaper report which referred to this variation of charges in 'the so-called United Kingdom'!

**Nurses have called for in-house cleaning in hospitals** - at the Royal College of Nurses conference in April, there was an overwhelming vote to bring hospital cleaning back in house in a bid to tackle

hospital bugs. 40% of hospitals contract out their cleaning but the Dept of Health maintain that there was no evidence of a difference in infection rates between hospitals that contract out and those with in-house cleaners.

**Specialist nurses could save the NHS could save money** - research has shown that introducing diabetes specialist nurses [DSNs] into emergency medical units could save the NHS £100million a year. In a trial lasting a year DSNs made daily weekday visits to the emergency unit of Leicester University Hospitals and found 111 people with diabetes of which 47 were discharged within 24 hours compared with the average stay of 11 days. The number of hospital days taken with caring for people with diabetes was cut by 42% which saved the hospital £111,155 during the year. If this system was implemented throughout the country, the NHS could save £100million a year.

**Choice of hospitals expands** – from April 2008 people in England having non-emergency treatment can choose any hospital in the country which now includes local hospitals and some private health providers. Hospitals are allowed to compete for 'business' through advertising and sponsorship deals. Research from the King's Fund suggests that this choice could increase health inequalities as more educated people are more likely to shop around than people from deprived backgrounds.

It appears that there has only been a luke-warm response to this policy of choice probably because it relies heavily on the GP electronic 'choose and book' system. This is currently only used for about half of all referrals so patients and doctors have to phone round to hospitals.

**Re-think on electronic patient records** – a National Audit Office report [May 2008] said that the single NHS electronic patient records system is likely to be delayed until 2014, four years later than planned. A second report from University College London says that the government is being forced to re-think the plans for computerised patient records because there is great confusion amongst patients

and new fears over the security of the electronic patient record. When gathering evidence for the report, not one patient felt confident that their electronic 'Summary Care Record' was 100% secure.

Some experts say that the system should be scrapped in favour of local IT systems.

One of the problems is that the system uses implied consent by patients whereby patients' records are automatically on the IT system unless they specifically opt out. This latest report recommends the opposite – to protect patients, they should have to give explicit consent every time their electronic 'Summary Care Record' is viewed, as happens in Wales and Scotland.

**New polyclinics are flawed according to expert** - polyclinics are planned as part of the NHS reforms. These are super-surgeries housing many GPs who will carry out relatively minor hospital treatment - dermatology, physiotherapy, social services and importantly for our readers, diabetes care.

As we have heard in the news, the government has announced the setting up of 150 polyclinics which they maintain are additional new capacity. Apparently they will not be forced on local primary care trusts [PCTS] yet an article in the British Medical Journal [14.3.08] said that PCTs have already been told to start setting up polyclinics even where there is no need for them.

The argument in favour? According to Health Minister Lord Darzi, polyclinics will suit people's needs because people want "more personalised and convenient healthcare" and "this is about the local NHS making changes that suit people's needs: clinically led, locally driven and putting the public first." I must be missing something here! Large polyclinics seem a far cry from personalised treatment from a GP practice that has known us and our family for years!

The arguments against? Professor Martin Roland, of Manchester University has studied 30 pilot polyclinics and maintains that focusing

GP care in polyclinics will harm patient choice and when this was tried in the 1990s, doctors did less work because of increased travelling time and lack of access to resources such as blood testing labs and scanners. Importantly he pointed out that there are no mandatory training standards set out for doctors and nurses taking on the new responsibilities of polyclinics. So what does this mean for patient care and diabetes care in particular?

We don't know but we need reassurances that the level of care will not fall, that doctors and nurses staffing polyclinics will be trained, especially for specialist conditions such as diabetes.

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## Testing For Ketones - Just A Reminder

Ketones are substances formed when the body breaks down fats and carbohydrates for energy or food and this occurs if there is not enough insulin present and therefore blood sugar levels are very high. If untreated, this can lead to diabetic coma and ketoacidosis [DKA].

When there are too many ketones in the body they spill over into the urine. So ketones in the urine occur with loss of diabetes control and this can a sign of other illnesses eg 'flu. Unusual physical or emotional stress can also cause ketones.

### When to test for ketones

A warning sign of ketones is sweet smelling breath, like the old fashioned pear drops but the general advice is to carry out ketones checks if your blood glucose levels are above 13mmols/l on two consecutive occasions. If ketones are present, then you should seek the advice of your doctor. Testing for ketones in the urine is usually carried out with strips [Ketostix] which can be obtained on a GP prescription.

### Correction

The ACCORD study referred to on page 5 of the April Newsletter is

associated with the National Institute on Diabetes and Digestive and Kidney Diseases (NIDDK) at NIH, not the Heart Institute.

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## Snippets...

### **Being obese is more dangerous than smoking**

According to the Foresight Report being obese may reduce a person's life expectancy more than smoking. Having a body mass index [BMI] higher than 30 decreases life expectancy by 9 years and men with a BMI of more than 45 by 13 years. Being a smoker reduces life expectancy by 10 years. The report warned that the obesity crisis is exacerbated by the fact that being overweight is coming to be seen as "normal."

### **Sleep can keep you slim**

A new study found that people who sleep significantly more or significantly less than 7 hours were overweight or obese. It is not clear which is cause and which is effect but it appears that the ideal amount of sleep to aim for is 7 hours every night. People were more likely to be overweight if they slept for 5 hours or less or 9 hours or more. [Am J Clin Nutr;87:310-6] A separate survey in 4 States in the US has shown that adults are not getting enough sleep – the blame is being put on late night television and internet surfing. People who are retired had better sleeping habits than working people.

### **Men think they are slimmer than they are**

Men perceive themselves to be more than three inches slimmer than they really are with most of them under-estimating their waist size by an average of 2.7 inches. These were the findings from a study in Leicester of over 500 men and women asked to estimate their waist size. Men underestimated by 3.1 inches [7.9cm] and South Asian women were the most accurate. Women in general got their waist measurements wrong by 2.2 inches [5.5cm]. People from white European backgrounds were worse than people from

South Asian backgrounds when estimating measurements, with an average 2.9 inches [7.4cm] error compared to 1.6 inches [4.1cm] for South Asians.

Having a large waist is one of the main risk factors for developing Type 2 diabetes so it is important that we don't fool ourselves about our size.

### **Hospital food in Australia a problem too!**

It seems that hospital food is not just a problem in the UK but in New South Wales, Australia too. A year-long inquiry found that over half the patients were malnourished and that malnourished patients stayed in hospital twice as long as others. It also found that the Dept of Health had not involved dietitians in hospital menus and that there should be more flexibility for individual dietary needs.

### **Japanese consumers opposed to GM foods and agriculture**

As long ago as 1997 nearly 500,000 Japanese signed a petition opposing GM food and demanding proper labelling and by 2002 the petition had grown to 2 million signatures. Their concern is about GM contamination of crops. Japan does not produce any GM crops but imports GM canola from Canada and it appears that contamination has already occurred. Over 80 consumer groups and farmers groups have visited Australia, Canada and the US to protest against GM foods. One wonders how they feel about GM insulin????

### **Conflicting evidence about cinnamon**

As we have reported in previous newsletters, some studies have suggested that cinnamon added to the diet may help to lower blood glucose and cholesterol levels in people with Type 2 diabetes. Now a recent study of 43 people with diabetes has found that cinnamon did not change either blood glucose, insulin or cholesterol levels over 3 months [Diabetes Care, Sept 2007].

Laboratory research suggests that cinnamon may make body cells more sensitive to insulin, so the connection is that Type 2 diabetes develops when cells lose their sensitivity to insulin. There is also

evidence that cinnamon slows down digestion which may tend to lower the blood sugars after a meal. However, this new study suggests that cinnamon does not have any beneficial effects, so why the difference? It could be that in this latest study the participants were taking various diabetes drugs but in previous studies, the participants were not taking any drugs.

**Kisses are good for the soul but...**

Doctors have found out that they have the same effect as strain on the body. Thyroid activity increases, blood sugar levels rise, the body starts to produce insulin and each time we kiss someone our heart beats faster. Kisses are also good for your teeth as they increase the flow of saliva which in turn decreases acid levels in the mouth so reducing the risk of tartar and decay.

**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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NN1 4XS

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**From Your Editor – Jenny Hirst**

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