



# Insulin Dependent Diabetes Trust

October 2010 Newsletter



## **Novo Nordisk is discontinuing Mixtard 30 in the UK, for commercial reasons. This is bad for patients, bad for healthcare professionals and bad for the NHS.**

“The decision to remove Mixtard 30 will cause huge disruption and anxiety for people with diabetes, not least because it might take months to switch successfully to another form of insulin. And at a time of tight budgetary constraint, the added costs inherent in this move are an unwelcome blow for the NHS.” [Drug and Therapeutics Bulletin, Dr Ike Iheanacho]

“I am 6 years old and have been using Mixtard 30 for 5 years since I was diagnosed at 15months. I have had no problems with this and

sailed along good and why it is being discontinued is beyond my mum and dad??? Why change a good thing???” [A quote from the Drug and Therapeutics Bulletin petition]

The Mixtard 30 discontinuation also means that Innolet device will no longer be available. This affects the most vulnerable people – those with visual impairment and/or manual dexterity problems. Many will lose their independence and have to rely on others to help them inject their insulin – this has far-reaching consequences.

- Mixtard is currently used by 90,000 people in the UK. It is recommended by the National Institute for Health and Clinical Excellence [NICE] as a treatment of choice. Crucially, scientific evidence indicates that alternative analogue insulins, promoted by the company, such as NovoMix 30, are neither more effective nor safer.

- NICE states that any decision to start a patient on insulin analogues to treat diabetes should be balanced carefully against the lack of long-term safety data and increased prescribing costs. [National Prescribing Centre Report, August 2010]
- Although Novo Nordisk suggest that switching from Mixtard 30 to the company's biphasic [pre-mix] insulin analogue, NovoMix 30, represents an 'upgrade' in treatment, evidence suggests that human insulin and insulin analogues are similarly effective in controlling Hb1Ac. [UK Medicines Information, August 2010]

**But this is only the beginning.....**

Novo Nordisk has stated it is their intention to discontinue ALL human insulins to have an 'analogue insulin only portfolio' - an amazing decision given the lack of evidence that analogue insulins are neither safer nor more effective. So the withdrawal of Mixtard 30 is only the beginning. Novo Nordisk gave 6 months notice of this discontinuation – not long enough for patients or the healthcare professionals who have to carry the heavy workload. Yet we have been amazed at the acceptance of this decision by some patient and professional organisations, acceptance which will undoubtedly give Novo Nordisk the impression that their actions are OK. Well, no they are NOT OK!

They will discontinue other insulins with only 6 month's notice and by the company's own admittance, other human insulins will follow, again disrupting thousands of lives. And looking ahead, when they have successfully developed and marketed their new long-acting analogue insulin, will they then remove Levemir with only 6 months notice?

Quiet acceptance of this decision means they will do it again irrespective of the effect on people's lives, the effect on the NHS and the staff within it. And lest not forget the cost to the UK taxpayer, this helps to provide Novo Nordisk's increased profits.

**As an entirely voluntary and independently funded organisation, IDDT has no intention of merely accepting this decision or the way in which it was made.**

We are only too aware of the power and influence of the pharmaceutical industry. Maybe we won't be able to change a system where the NHS, the largest single purchaser of insulin in the world, has no teeth or influence but in the best interests of people with diabetes, we have to try. We want a time when changes in treatment are made because they are clinically necessary and advantageous to patients, not just pharmaceutical companies.

The reasons for meek silence of other organisations is open to conjecture but we hope they will reconsider. It is time for people with diabetes and those involved in their care to come together in an organised way to protect the best interests of people with diabetes, now and in the future.

IDDT will be contacting members and readers about our future actions and we hope that we will have your support. Even if you are not using Mixtard 30, please think about those who are and help us maintain the choice of insulin treatment. In the meantime, you can help - please sign the petition

We are working with the Drug and Therapeutics Bulletin [DTB] which has put a petition on its website objecting to Novo Nordisk's decision. Please help to give the message to Novo Nordisk that its commercial decisions are not acceptable. If you don't have internet access, ask someone who does to sign for you or go the local library and visit: <http://www.thepetitionsite.com/1/withdrawal-of-mixtard-30-from-the-uk-market/>



**Independent Information About Your Choices**

The Secretary of State for Health, Andrew Lansley, has assured IDDT that the information being sent by Novo Nordisk to health professionals would be 'non-promotional' and would advise them of the alternatives, including insulins from other manufacturers. However,

IDDT has already received reports of people being told they have to change to the analogue NovoMix 30 and of repeat prescriptions being automatically changed without discussion with the 'patient'. The first removes patient choice and the second is positively dangerous.

Independent information is the best as it is uninfluenced by other factors. The UK Medicines Information [UKMi] website provides independent information to health professionals and the public and can be accessed at <http://www.ukmi.nhs.uk/> Just search on Mixtard 30 and the information is very comprehensive. For those without internet access, here is the relevant information taken directly from the website.

### **Choosing an alternative**

When choosing a suitable alternative to Mixtard 30, both the type of insulin and the device for administration need to be considered. Decisions must be made on an individual basis, taking into account the patient's diabetes control and factors such as manual dexterity and patient preference relating to the choice of injection device. Where there is doubt about a patient's well-being or ability to use a new device related to this changeover, referral to a specialist diabetes service should be considered.

### **Choice of insulin preparation**

When switching from Mixtard 30 to another biphasic insulin, the options are to transfer to another human insulin preparation or to an insulin analogue preparation.

With all switches it is important that the patient be monitored carefully. The patient must be warned that the symptoms of hypoglycaemia may be different, or even absent, when changing from one insulin to another.

The preparations described below are those most similar to Mixtard 30 in terms of the proportion of short- and intermediate-acting insulin components they contain. Other biphasic preparations are available and are included in a chart of information prepared by Diabetes UK.

### **Switching to another biphasic human insulin**

The advantages of switching from Mixtard 30 to another biphasic human insulin include the possibility of switching dose for dose, and the fact that the timing of insulin administration in relation to mealtimes (about 30 minutes before a meal) is the same.

- Humulin M3 is near-identical to Mixtard 30; it contains 30% soluble insulin and 70% isophane insulin. When switching from Mixtard 30 to Humulin M3, no change in dose is required for patients with adequate glucose control. Some health professionals advise a 10% reduction in dose if hypoglycaemia is a particular concern. Like Mixtard 30, Humulin M3 is administered about 30 minutes before meals.
- Insuman Comb 25 contains the same constituents as Mixtard 30 and Humulin M3 but in a different ratio: 25% soluble insulin and 75% isophane insulin. It may be an option for some patients whose blood glucose is not optimally controlled on Mixtard 30. Like Mixtard 30, Insuman Comb 25 is administered about 30 minutes before meals.

### **Switching to a biphasic insulin analogue**

Patients switching from Mixtard 30 will require changes to their insulin dose and administration schedule. Although Novo Nordisk suggest that switching from Mixtard 30 to the company's biphasic insulin analogue, NovoMix 30, represents an 'upgrade' in treatment, evidence suggests that human insulin and insulin analogues are similarly effective in controlling Hb1Ac. Insulin analogues may, however, be useful for patients who are prone to hypoglycaemia at night. Insulin analogue preparations are more expensive than human insulin preparations.

- NovoMix 30 contains 30% insulin aspart and 70% insulin aspart protamine.
- Humalog Mix25 contains 25% insulin lispro and 75% insulin lispro protamine.

The timing of administration in relation to mealtimes is different to that of human insulins because of the more rapid effect of the short-acting

insulin component. Patients switching from Mixtard 30 will need to adjust the timing of doses so that they are administered immediately before a meal.

There is no direct dose conversion for patients switching from Mixtard 30 to a biphasic insulin analogue. It has been suggested that an initial dose 15-20% lower than the previous Mixtard 30 dose may be appropriate; the dose should then be titrated according to the patient's blood glucose control.

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## Reporting An Adverse Reaction To A Drug Or Insulin

*With the withdrawal of Mixtard 30 and change to a different insulin, some people may experience adverse reactions. An adverse reaction can occur immediately, within hours, days, months and even years.* If you think you have an adverse effect or reaction it is important that you report it through what is known as the Yellow Card Scheme. You only have to suspect that the symptoms are due to the drug or insulin you are taking, you don't have to prove it. Here's how to do it:

- ▶ You can make a Yellow Card report online by going to <http://yellowcard.mhra.gov.uk/> or by downloading the Yellow Card form to print and posting it to the address at the bottom of the form.
- ▶ You can obtain a Yellow Card form from pharmacies, GP surgeries or by phoning freephone 0808 100 3352 (available weekdays 10:00 and 14:00)
- ▶ You can make a report by phone on the Yellow Card hotline as above.

Reporting adverse reactions is an important part of ensuring the safety of medicines and making sure that medicines work properly and are safe.

## Thinking About Your Thyroid

People with one autoimmune disease, such as Type 1 diabetes, are more susceptible to developing other autoimmune conditions and thyroid disease fits into the category. According to Diabetes Spectrum [15:140-142, 2002] 31.4% of people with Type 1 diabetes have thyroid disease and only 6.8% of people with Type 2 diabetes have it.

### About the thyroid gland

The thyroid gland is situated in the lower part of the neck. It is part of the endocrine system and releases the thyroid hormone, thyroxine which controls how quickly the body burns energy.

When too much thyroxine is released, the body burns energy at a faster rate - this is called hyperthyroidism or an over-active thyroid. When there is too little thyroid hormone released, energy is burned at a slower rate - this is hypothyroidism or an under-active thyroid and tends to be more common than an over-active thyroid.

Symptoms of hypothyroidism [underactive thyroid]	Symptoms of hyperthyroidism [overactive thyroid]
Fatigue	Pounding heart
Sluggishness	Quick pulse
Slow pulse	Increased sweating
Depression	Shortness of breath after exercise
Feeling cold when others don't	Weight loss despite normal or increased appetite
Constipation	Muscle weakness or tremors
Weight gain unrelated to an increase in appetite	Diarrhoea
Low blood pressure	Difficulty concentrating
	Thickening of the skin on the knees, elbows and shins
	Change in menstruation

Hypothyroidism in particular also tends to give worsening blood sugars and increased insulin requirements.

## Testing for thyroid disease

According to the American Thyroid Association people with diabetes should have their thyroid tested once a year. There are two hormones that should be measured:

1. The thyroid hormone, Thyroxine [T4]
2. The Thyroid Stimulating Hormone [TSH]. This is the pituitary hormone that controls thyroid function and is a more sensitive test. A low TSH indicates hyperthyroidism and a high TSH indicates hypothyroidism.

There is also another test that is recommended and this is a test for Anti Thyroid Peroxidase Antibodies and this shows if there is a predisposition to thyroid dysfunction. If this test is positive, it indicates that the thyroid should be watched more carefully and regular T4 and TSH tests carried out.

Pregnant women should have their thyroid tested because undiagnosed hypothyroidism can cause still birth, premature delivery and high blood pressure at the time of delivery. Tests should also be carried out after pregnancy as this is a common time for thyroid antibodies to damage the thyroid.

## Treatment for underactive thyroid [hypothyroidism]

The treatment for an underactive thyroid is levothyroxine, which is usually referred to as thyroxine. The aim is to cure the symptoms by replacing the lack of thyroid hormones in the blood.

It is possible to have subclinical hypothyroidism which is where there are mild or no symptoms, in which case treatment may not be necessary but the GP will monitor the thyroid hormones every few months and will start treatment if the level falls below normal.

A blood test to measure the levels of thyroid-stimulating hormones [TSH] will help to establish the correct dose of thyroxine. High TSH levels indicate a low level of thyroid hormone. The dose is adjusted according to blood test results which are taken regularly until the correct dose is established which may take a while. Once this has

happened then normally a thyroid function test is carried out each year.

## Treatment for overactive thyroid [hyperthyroidism]

The treatment for overactive thyroid aims to return the thyroid hormones in the blood back to normal levels. Treatment may also be necessary for any associated conditions, such as the swelling of the thyroid gland [goiter].

## Subclinical overactive thyroid

It is possible to have subclinical overactive thyroid [no symptoms] and treatment may not be necessary. In most cases the reduced level of thyroid-stimulating hormone [TSH] will return to normal within 2-3 months. However, subclinical overactive thyroid can develop into fully developed overactive thyroid, so it is necessary to monitor the levels with repeat blood tests with the GP after one and two months.

If the TSH levels are still below normal after this time without raised levels of thyroid hormones, regular monitoring with blood tests is necessary. Further assessments to find out the cause of the subclinical overactive thyroid may be suggested.

## Fully developed overactive thyroid

If the thyroid function tests shows low TSH levels and levels of thyroxine are high, then overactive thyroid is diagnosed and referral to a specialist is necessary. The specialist will decide on the best form of treatment which could be the following:

**Thionamides** – drugs that stop the thyroid gland producing too much thyroxine. This has to be taken for 4 to 8 weeks before there is any noticeable improvement and the thyroid is under control. Once this happens, the dose of medication may be reduced but if the condition is not under control, it may be necessary to continue taking it for a long time.

**Beta blockers** – these drugs such as propranolol or atenolol, can relieve some of the symptoms of overactive thyroid such as shaking,

trembling, rapid heartbeat and hyperactivity. They may be prescribed to relieve symptoms while the thyroid is being brought under control with a thionamide.

**Radioiodine** – this is a form of radiotherapy that is used to treat most types of overactive thyroid. It contains radioactive iodine which builds up in the thyroid gland and reduces the amount of thyroid hormone it can make. Radioactive iodine treatment is given as a drink or a capsule. The dose of radioactivity is very low and not harmful. However, it is not suitable during pregnancy or breastfeeding. Women should avoid getting pregnant for at least 6 months after treatment and men should not father a child for at least 4 months after treatment.

**Surgery** – the aim of surgery is to remove all or part of the thyroid gland. It is a permanent cure for overactive thyroid and the specialist may recommend it under certain circumstances, for example, if the thyroid gland in the neck is severely swollen.

The aim of surgery is to remove just enough of the thyroid gland to lower the production of thyroxine to normal. In some cases too much thyroid gland can be removed which then produces underactive thyroid. If this happens, thyroxine tablets can be taken.

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## Artificial Sweeteners

In this article we will take a look at artificial sweeteners, what they are, how they can be used and the effects that they may have on people with diabetes.

Artificial sweeteners are chemicals or natural compounds that offer the sweetness of sugar without as many calories. Because the substitutes are much sweeter than sugar, it takes a much smaller quantity to create the same sweetness. Products made with artificial

sweeteners have a much lower calorie count than do those made with sugar.

People with diabetes may use artificial sweeteners because they make food taste sweet without raising blood sugar levels. But keep in mind that if you do have diabetes, some foods containing artificial sweeteners, such as sugar-free yogurt, can still affect your blood sugar level due to other carbohydrates or proteins in the food.

### There are four commonly used types of artificial sweeteners

**Saccharin** (brand name: Sweet 'N' Low, Sweetex) – this sweetener can be used in both hot and cold food and can also be used as a sugar substitute in cooking and baking. It is generally regarded as the safest artificial sweetener. However, it should not be used by women who are pregnant or breastfeeding and there is a possibility of allergic reactions including headaches, breathing difficulties, skin problems and stomach upsets.

**Aspartame** (brand name: Nutrasweet) – this sweetener can be used in cold and warm foods. It is not suitable for cooking or baking as it breaks down under high temperatures. It should not be used by people who have a rare genetic condition called phenylketonuria (PKU) and there have been reports of increased numbers and severity of allergic reactions, migraines and mood disorders, such as depression, especially among people who already have these conditions.

**Sucralose** (brand name: Splenda) - this sweetener can be used in both hot and cold food and can also be used as a sugar substitute in cooking and baking. It can also be found in processed foods.

**Acesulfame K** (brand name: Sweet One, Sunett) - this sweetener can be used in both hot and cold food and can also be used as a sugar substitute in cooking and baking. It is commonly found in processed foods and canned drinks.

### Labelling

Artificial sweeteners are often used in prepared foods and these

can be labeled in a variety of ways - no sugar, low-sugar, naturally sweetened, no added sugar – and this can lead to confusion, so here are the definitions of each of these terms:

- ▶ **No sugar** means the product does not contain sugar at all. It may contain sugar alcohols or artificial sweeteners.
- ▶ **No added sugar** means that during processing, no extra sugar was added. However, the original source might have contained sugar such as fructose in fruit juice. Additional sweeteners such as sugar alcohols or artificial sweeteners might have been added.
- ▶ **Sugar free** means that the product contains no sugars. It may contain sugar alcohols or artificial sweeteners.
- ▶ **Dietetic** can mean a lot of things. It's likely that the product has reduced calories.
- ▶ **All natural** simply means that the product does not contain artificial ingredients. It may contain natural sweeteners, such as sugars or sugar alcohol.

A final cautionary note about sugar alcohol sweeteners, such as sorbitol, mannitol and xylitol. These types of sweeteners contain carbohydrates so they do affect blood sugar levels. They are often found in reduced calorie sweets and chewing gum. So if you are in doubt check the nutritional information label. Under the Carbohydrate section, you can see how many carbohydrates the product contains. You can also see how much of these carbohydrates are in the form of sugar or sugar alcohol.

*This article by Martin Hirst is also published in IDDT's October 2010 'Type 2 & You', our quarterly Newsletter for people with Type 2 diabetes who are treated with diet only or diet and tablets.*

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## News From Nice

- ▶ NICE issues new guidelines for the treatment of neuropathic pain in non-specialist NHS settings

This is the first time that NICE, the National Institute for Health and Clinical Excellence has outlined the most effective drugs that GPs and healthcare professionals in general and community settings should prescribe for adults with neuropathic pain. Neuropathy is caused by damage or change to nerves. The pain can come and go or be there all the time. People often describe the sensations and pain of neuropathy as shooting, stabbing, an electric shock, burning, tingling, tight, numb, prickling, itching or pins and needles.

Neuropathy and neuropathic pain is estimated to affect 1-2% of the UK population and diabetes is not the only cause - it can be present with stroke, multiple sclerosis, HIV and cancer.

Common painkillers such as aspirin, ibuprofen and paracetamol do not seem to have any effect on reducing neuropathic pain but there are other drugs which can help that are available on the NHS. As many people with neuropathy know, what helps one person, does not necessarily help another, so this is the first time that guidance has been issued to GPs and health professionals about which drugs should be used and in what order to try them.

### In brief, NICE advises the following:

- ▶ Amitriptyline, an antidepressant, or pregabalin, an anticonvulsant as first choice treatments or oral duloxetine, another antidepressant for painful neuropathy.
- ▶ If people continue to suffer neuropathic pain at the maximum dose of one of the above, then one of the other drugs above should be tried either by itself or in combination with the original drug.
- ▶ If the pain continues, then people should be referred to a specialist pain or condition specific centre for further treatment. If there is a wait for this referral, non-specialist health professionals can prescribe oral tramadol, an analgesic, alongside the ongoing second-line treatment, or topical lidocaine, an anaesthetic for localised pain when people are unable to take medication orally.
- ▶ Health professionals in non –specialist settings can prescribe other drugs but only provided that they are started by a specialist pain or condition-specific service.

This guideline can be found on the NICE website by visiting [www.nice.org.uk/CG96](http://www.nice.org.uk/CG96)

Alternatively, you can find all the NICE guidelines that relate to diabetes on the IDDT website <http://www.iddt.org/nice-guidelines/>

### ► **NICE to recommend Victoza**

Final NICE guidance on the use of Victoza also called liraglutide, is expected to be issued in October 2010 if there are no appeals against the draft guidance released in September. Victoza has to be injected once a day and is available in a pre-filled injection pen. It belongs to the same family of drugs as Byetta [exenatide].

The draft recommends Victoza 1.2mg daily for some people with Type 2 diabetes but does not recommend the larger dose of 1.8mg as available evidence does not suggest any additional benefit. However, the recommendation places restrictions for use and it is recommended only as follows:

**For dual therapy** [means in combination with another tablet]:

- Only if people are intolerant of either metformin or a sulphonylurea or if there is a reason why these drugs should not be used.
- Only if people are intolerant to the glitazones or the gliptins.

**For triple therapy** in combination with metformin and a sulphonylurea, or metformin and a glitazone only when blood glucose control is inadequate – an HbA1c of 7.5% or greater but the person must also have:

- a body mass index (BMI) of 35 or more and specific psychological or medical problems associated with high body weight, or
- a BMI of less than 35 kg/m<sup>2</sup>, where insulin therapy would have significant occupational implications, or weight loss would benefit other significant obesity-related conditions.

Treatment should only be continued after 6 months if:

- the person's diabetes has shown a benefit, defined as at least

1% reduction in HbA1c at 6 months in dual therapy

- and in triple therapy, a reduction of at least 1% in HbA1cs and a weight loss of at least 3% of initial body weight at 6 months.

### **Adverse effects**

The most frequently reported adverse effects of Victoza are liraglutide are nausea, diarrhoea, vomiting, constipation, abdominal pain, and indigestion. These usually reduce within days or weeks of starting treatment. Hypoglycaemia [low blood sugar] is also common, especially if used in combination with a sulphonylurea.

**From a patient perspective** – both Victoza and Byetta cause weight loss, which has got to be good. They also have the advantage of another treatment option before insulin has to be prescribed and this can be helpful for people who may lose their commercial driving licences or taxi driving licences, in some areas, as a result of going on to insulin.

### ► **NICE calls for ban on trans-fats and salt intake**

In June this year, the National Institute for Health and Clinical Excellence [NICE] called for a ban on trans-fats from food to help prevent deaths from cardiovascular disease [heart disease and stroke].

Trans-fats are artificial fats that can be found in some dried foods, biscuits, cakes and fast foods. They have no nutritional benefit but are used to make foods taste nicer or to increase their shelf life.

NICE is also calling for further reductions in salt and saturated fats and believes that this alongside the banning of trans-fats would save the NHS £1 billion. Experts at NICE say 40,000 of the 150,000 annual deaths are 'eminently preventable' by people eating better and taking more exercise.

The British food industry said it was already leading the world in promoting healthier production but they could do more - for instance, Denmark has already banned trans-fats.

**By the way...a small drop in salt intake reduces blood pressure**  
UK research has shown that modest, easily achievable reductions in the amount of salt we eat can significantly lower blood pressure. The study looked at 44 people with Type 2 diabetes or pre-diabetes who were not on any medication for blood pressure or diabetes. They all received advice on how to reduce salt intake to below 6gms a day. After 6 weeks cuts in salt intake reached 2.9gms per day which led to a reduction in systolic blood pressure of 4mmHG, from 135mmHg, and in diastolic blood pressure of 2mmHG, from 81mmHG. The researcher points out that this certainly supports the advice that people with diabetes [and other conditions] should be on a reduced salt diet to at least 6gms a day.

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## The New Coalition Government On Health

***“We will enable patients to rate hospitals and doctors according to the quality of care they received, and we will require hospitals to be open about mistakes and always tell patients if something has gone wrong..... We are committed to the continuous improvement of the quality of services to patients, and to achieving this through much greater involvement of independent and voluntary providers”.***

**HM Government, The Coalition: our programme for government, May 2010**

### There's a long way to go

► The National Diabetes Audit for 2008/9 shows that just 32% of people with Type 1 and 51% of people with Type 2 diabetes received all 'care processes' recommended in the diabetes national service framework, such as blood glucose and cholesterol checks.

► The number of complaints about the NHS has reached its highest rates in 12 years, according to a report by NHS Information Centre. 101077 complaints were recorded in 2009-10, a 13.4%

increase from 2008-09. Almost 45% of complaints were about the medical profession.

► The green paper about benefits – yes, many of us expressed our concerns about changes in the benefit scheme and in pensions in the Green Paper the last government put forward. Well, decisions on all this have now been delayed until 2013.

### And what it's not going to do in future.....

#### Targets to be scrapped but new 'standards' to appear

Under the last government targets were used to drive improvements but many of these are to be scrapped. The Health Secretary wants the NHS to measure itself against quality standards.

The first target to go was the requirement for GPs to see patients in 48 hours, instead GPs will be able to prioritise patients. The 4 hour A&E target is being lowered from 98% of patients to 95%. The new guidance makes it clear that hospitals will be expected to see patients in 18 weeks but they will not have to prove it local managers, meaning less paperwork.

Over the next 5 years there are likely to be standards published for 150 different areas of care in the NHS in England. They are supposed to be advice to the health service, not targets. Unlike the last government's targets there will be no need for hospitals and other services to report these to government or whether they have met them and if not, why not.

Patients may also use the standards to demand they get the best quality of care. No doubt this will become clearer over time, but if meeting, or not meeting, standards is not reported locally or to government, how do we as patients, know which hospitals or GPs are offering the best quality of care? Are our rights to choose where we receive our care being eroded because we will not be able to make an informed choice without this sort of information? Isn't this what NHS Choices is about?

### **NHS Direct to be scrapped**

Rather quietly over the August Bank Holiday weekend, Health Secretary, Andrew Lansley, announced that NHS Direct, the 24 hour health advice phone line, is to be scrapped. It is to be replaced by a new non-emergency number 111. Apparently the new number aims to make it easier for patients to 'access care' without having to go through busy urgent call lines. If the situation is not a life threatening emergency, then calls are to be made to 111 which will hold information on who is best to call for help. 111 is supposed to cut down on A&E visits and make more ambulances available. At the moment, it is unclear if the evidence-based health information offered by NHS Direct will still be available to the public. NHS Direct costs £123 million per year but has been estimated to save £200 million a year on unnecessary hospital and GP visits. The 111 number is already being used in some areas and trialled in others but for the moment NHS Direct is still available on 0845 46 47.

### **Food Standards Agency to disappear**

It is planned that the Food Standards Agency [FSA] will be removed. Does this give more power to the food industry so that less restrictions are placed on unhealthy food and drinks?

### **Clamp down on government websites**

In June this year, the Minister for the Cabinet Office, Francis Maude, pledged to scrap hundreds of unnecessary and expensive government websites and slash the cost of the remaining sites. In the autumn of 2006 the then government made a commitment to drastically cut back on the number of websites but in March 2010 there were still 794 and in June there were 820!

All 820 government funded websites will be reviewed and no new websites will be permitted except those that pass a stringent exceptions process. It is expected that 75% of the existing sites will be shut down and the aim with the remaining sites is to cut their costs by 50%. A report from the Central Office for Information found that across government £94 million was spent on the construction and setting up of just 46 sites and £32 million on staff costs in 2009-2010!

### **Online database of information about medicines shelved**

Plans for an online database of information about medicines have been shelved despite public support for the project. The Medicines and Healthcare products Regulatory Agency [MHRA] site would have allowed the public to access regulatory information about medicines. Information about medicines is available elsewhere but how much of the 'regulatory information' that would have been available is unclear. Two sources of information are:

- ▶ Electronic Medicines Compendium which provides both Patient Information Leaflets [PILs] and the Summary of Product Characteristics [SPCs] for all drugs is a useful site at <http://www.medicines.org.uk/emc/>
- ▶ NHS Choices <http://www.nhs.uk/Pages/HomePage.aspx> also gives information about medicines and health conditions.

### **Healthy living - Change4Life will continue to be a focal point but.....**

In answer to a Parliamentary Question [08.09.10], Health Minister, Paul Burstow confirmed that the Change4Life programme 'will continue to be a focal point', but it is to be changed from a centrally directed campaign and to 'a genuinely social movement, owned collectively by communities' and driven locally.

Does this mean that it will no longer be funded centrally? If it is funded locally will it be at the mercy of local budgets?

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## **At Last - The Scandal Of Avandia Is Out**

An article about Avandia in the British Medical Journal [BMJ, 06.09.10] was covered by the national papers. Panorama also covered the story, or perhaps scandal is a better word.

Studies have shown that Avandia [rosiglitazone] causes increased risks of stroke and heart failure. GlaxoSmithKline [GSK], the

manufacturer, continues to defend Avandia despite already paying millions of dollars in settlements to patients or relatives in the US.

### **The British Medical Journal: “Avandia should never have been licensed”**

The BMJ article states that the UK drug regulator, the Medicines and Healthcare Products Regulatory Authority [MHRA] was advised to withdraw Avandia last July because its “risks outweigh its benefits.” However, it has remained on the market apparently because the European Medicines Agency has yet to reach a decision.

The BMJ goes even further in claiming that Avandia should not have been licensed 10 years ago as there was a lack of evidence about the long-term risks and benefits during the European approval process. The BMJ report also raises broader concerns about the lack of publicly available trial results and a lack of transparency in the European system and calls for “more robust regulatory processes and better access to raw data used to license drugs to allow scrutiny by the scientific community”.

### **Where are we now?**

- ▶ The European Medicines Agency [EMA] review is expected to be finalised by September 20/23rd [after we go to print]
- ▶ In the US, the advisory panel to the Food and Drug Administration [FDA] voted by the narrowest of margins to recommend that Avandia should stay on the market but with increased safety warnings. The FDA has yet to come to a decision.

In the meantime, what are patients supposed to do? IDDT has kept readers up to date with news about this drug and again we warn that if you have concerns, you should not stop taking Avandia without talking to your doctor. Actos [pioglitazone] belongs to the same class of drugs and some concerns have been expressed about its safety, so again talk to your doctor if you are worried.

### **Can we have faith in the system?**

The Avandia experience shows serious flaws with the system of drug approval and regulation. It also shows how little doctors and patients are told, even when dangers do show up – can there be a justifiable reason why the MHRA did not go public in July when they made the decision that Avandia should be withdrawn? If the health and safety of patients is to be protected, then major changes to the system have to take place.

**It is worth remembering** - troglitazone [Rezulin] was the first of this class of drugs to be introduced in 1997. It turned out to be associated with adverse liver problems, but it was immediately removed from the market - by the end of the same year in the UK.

But going back even further, the approval process for human insulin took only 6 months, yet it was the first GM drug to ever reach the market so one would have expected a very rigorous approval process. It was known to cause reduced hypo symptoms before it was licensed but no one was told and patients’ reports of loss of warnings were not believed!

### **But no one asks about the people who have been damaged by Avandia**

People have been damaged by Avandia and some have died but no one in the UK is talking about what has happened to them. They have not been allowed to join the US legal case against GSK and there appears to be no easy legal way that people can bring a case in the UK. Lives have been damaged and possibly lost, so surely these people deserve some compensation.



## **Injections And Lipodystrophy**

Lipodystrophy is disorder of the subcutaneous layer of the skin associated with insulin injections.

The subcutaneous tissue is the third layer of the three layers of skin. It contains fat and connective tissue that houses larger blood vessels and nerves. This layer is important for regulating the temperature of the skin and the body and its size varies in different parts of the body and from person to person.

There can be two types of lipodystrophy: **lipoatrophy** which is a depression in the skin and **lipohypertrophy** which is a thickening or raised area. It can occur anywhere on the body where you inject.

**The most common causes are:**

- ▶ Not rotating the injection sites.
- ▶ Excessive reuse of needles.
- ▶ It can sometimes be due to incorrect injection technique.

It is not always easy to see lipodystrophy so sometimes it can be easier to feel it. Injection sites should be regularly examined for any swelling, lump or indentation and this is better carried out when you are standing up and relaxed.

Injecting into an area where there is lipodystrophy can cause insulin to be absorbed erratically by your body. This can lead to large and unpredictable changes in blood sugars resulting in hypoglycaemia or hyperglycaemia because the insulin is not absorbed very well through the thickened tissue.

**Avoiding lipodystrophy**

- ▶ Rotate your injection sites to avoid injecting into the same site.
- ▶ Rotate within injection sites.
- ▶ Use a new needle every time.

If you already have lipodystrophy, to try to reduce the size, stop injecting into the affected area, leave it to recover and carry out the above. If necessary, check out your injection technique with your nurse.

## There's More To Living With Diabetes Than Numbers

*As many of us know, there is much more to living with diabetes than just controlling blood glucose levels. Yes, achieving target blood sugars has become the main focus at the clinic and blood sugars are treated as the main measure for how 'good' or 'bad' your control is, although sometimes it can feel like how good or bad you have been! If the numbers are judged as bad, it may be what we expected as we may know the reason – a stressful time at work or home over the last few weeks - but we're not always asked what we think!*

There is more to life than measuring blood sugars and sometimes as we all know, however much we stick to the rules it just doesn't work out right. Sometimes too, we know that we don't always stick to the rules and it is not just because we don't want to or that we are simply being 'naughty' - sometimes we have just had enough. If you have had Type 1 diabetes since childhood, by the time you reach 40 you have been living with it, and all that goes with it, for a very long time! All too often people who don't live with diabetes think you just get used to it but it's not that simple – sometimes you have just had enough of it and yes, you stop trying and don't do all the things you should do.

And there are things other than diabetes going on that affect our lives. People with diabetes are like anyone else, they have happy times and sad times. They go through marriage, divorce, bereavement, children starting school, problems at work – just like anyone else. But they have to also deal with their diabetes and sometimes it's just too much.

In many ways, today's technology has made this worse, so busy with tests and numbers, that the whole person behind may seem forgotten. We understand that from the perspective of a doctor or health professional the numbers are important and probably take priority over everything else because blood glucose levels can affect our future health. But even when we know diabetes is taking a back



seat in our lives, it's not that blood sugars aren't important to us too. 'Poor' or variable blood sugars are just yet another worry on top of whatever the problem is in the first place - we do know what they could mean for the future!

- ▶ Sometimes we just need support through the difficult times and recognition that we are more than just a faulty pancreas.
- ▶ Sometimes we just need to talk and be listened to. It's not always easy to talk to the people closest to us for a variety of reasons, one of which could be that they live with diabetes too!
- ▶ Sometimes we just need to be praised for doing a good job, even though our blood sugars do not meet the targets – we have doing our best given our circumstances at the time.
- ▶ And sometimes we just need to 'offload'!

### **Unexpected worries**

All of this was highlighted in a call to IDDT from a lady with Type 2 diabetes who has two adult children and she is happy for me to explain her concerns. Firstly, she was upset because she felt her children thought she was making up the seriousness of her diabetes and what she has to do to manage it. This is difficult enough for her but her second worry was that her two adult children would develop Type 2 diabetes themselves. Her sons are already overweight but they are not modifying their lifestyles to try to reduce their risks and they don't want to talk about it.

As a mum, she naturally worries about her sons - it's just part of being a mum. Mums with children with Type 1 diabetes often worry about their other children developing diabetes - but this is not quite the same worry. Type 1 diabetes cannot be prevented but the risks of developing Type 2 diabetes can be reduced with changes in lifestyle.

This is not a worry that could be discussed at the clinic but it is one that could be discussed with IDDT. This lady wonders if any of our members have similar worries and if so, would they like to write to her – having a pen friend might help. If so, just contact Jenny at IDDT, PO Box 294, Northampton NN1 4XS or call 01604 622837.

### **IDDT hopes to expand its listening role**

IDDT has always been determined to maintain its personal touch - real people answering the phone who listen and give time. We don't offer medical advice and neither are we counsellors but we are good listeners! If there are problems with your diabetes, then we will talk these through with you and hopefully help you to work through what you should do. If there are other worries and concerns, we will try to do the same.

But as IDDT has grown, so have the number of calls we receive – and we don't want these to stop! We have been running 2-week trials with an experienced and trained listener, Kevin, taking some of the calls and it works well. In the near future we hope to expand in this direction, so do give us a ring, whether you need information, pointing in the right direction for help, or you just want to talk.

### **Here is Kevin's view of his times with IDDT**

For several reasons I have found myself in a new and unfamiliar role for two weeks; it is a temporary role within a small charity organisation called Insulin Dependent Diabetes Trust (IDDT)

It was suggested on the second morning that I write an article for publication; my initial reaction was this was way out of my comfort zone and something I am not used to doing; but quickly realised that this may be of use to the charity and some of their clients.

Let me try and explain myself a little better and further by starting to tell you a little about myself. I have never considered myself as academic; I know very little about diabetes and certainly have no medical training background.

I am currently a self employed builder and have been for thirty plus years. I have had the privilege to have been trained in listening to people and worked for another charity as a volunteer for some years. Further to this I am currently heading towards the end of my second year part time at college that may lead me on to a course in counselling. I find both roles very rewarding and I am certainly aware

that within our increasingly insular society there are a lot of people that are alone with their thoughts and feelings.

As you can see I am not a trained counsellor but just someone who at times can listen to people and offer them some support and reassurance; that they are not alone and that there are people and organisations that do care.

I and the founder of IDDT have been talking for several months about how to better support and help people, carers, and their families having to live with diabetes.

I have been honoured to be asked to take part in trials of setting up a telephone listening help service on a two week basis. This initially involves me taking calls from people who have read a news paper article and are after further information regarding diabetes. My role is to take the callers details so the relevant information packs can be distributed to them. Further to this I am trying to offer them a listening ear and offer them what support I can.

As I write this I have just finished my second week and have taken in the region of 220 calls; the majority of these calls have come from people having to live with Type 2 diabetes. What has become apparent to me is that a high percentage of people have found themselves being left by medical professionals with very little information regarding their disease. This in turn leaves them feeling somewhat on their own and not knowing quite what to do; especially with their diets.

I have had the pleasure to talk to some wonderful people in the last two weeks and hope that they have managed to receive the information and support that they are entitled to.

Thank you.

To those people that haven't found the service satisfactory; I apologise, but please don't give up on us as we do care and want to help in any little way we can.

My warmest wishes to IDDT and you all for the future.

## Blood Glucose Test Strips

In August 2010, IDDT received a letter from Health Secretary, Andrew Lansley, which again made the point that the Department of Health has not put any restrictions on the number of strips that can be prescribed. So any restrictions or refusal to prescribe strips is a local decision either by the Primary Care Trust or the GP practice.

Yet the most common complaint IDDT receives is about the restriction or refusal to prescribe blood glucose test strips. Some people taking insulin can't get enough strips and others with non-insulin treated Type 2 diabetes are refused strips altogether, even when the tablets they take can cause low blood glucose levels. We were asked to raise awareness of this again by one of our members. He has Type 1 diabetes, has no hypo warnings and a locum GP recently refused to give him the 100 strips he normally has every month - on the grounds that testing 3 times a week was sufficient and he was just panicking!

**Testing and Type 1 and insulin treated Type 2 diabetes** – it is widely accepted that people using insulin need to test their blood glucose levels. Sometimes though people are not prescribed the number of strips they require to manage their diabetes. Testing is very individual and there should not be a blanket policy on how many strips people should have, it should be on a case by case basis.

**Testing and non-insulin treated Type 2 diabetes** – this is usually where the problems arise and it is frequently said 'research does not show a benefit from testing' but usually the research has not taken into account the benefits to patients. Providing they have received education in understanding the results and what action to take, if people feel safer testing, then they should be provided with test strips.

### **IDDT's advice if you don't receive the test strips you need**

Firstly discuss your needs with your GP practice manager and explain why you need tests strips and how many. If this doesn't work, then take the matter to the local Primary Care Trust [PCT]. If you need to quote the NICE Guideline for Testing and Type 2 diabetes the gist of

which says:

- ▶ Testing should be offered to newly diagnosed people with Type 2 diabetes only as an integral part of diabetes education [which everyone is supposed to receive].
- ▶ Testing should be available to those treated with insulin, those taking tablets that lower blood glucose levels
- ▶ To assess changes in lifestyle, times of illness and to ensure safety during activities, including driving. [If people on insulin follow the driving guidelines, then this can use more than a tub of 25 strips in a month!]

If that all fails it is worth noting that the argument 'research doesn't show any benefit' has been somewhat blown out of the window by a randomised controlled trial in 522 patients with Type 2 diabetes at the University of California. This showed that a programme where patients and doctors interpret self-monitored blood sugars results improves blood sugar control.

Patients were taught how to test and the GPs were trained in suggested medications in response to the blood glucose patterns over the previous 3 months. After 12 months patients who self-monitored had an average HbA1c level 1.2% lower than at the start of the study and significantly greater reductions in HbA1c over time compared with the control group not on the programme. Over the year of the study, both groups showed significantly less distress and depression and a significant increase in wellbeing.

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## Apologies For Error

Apologies for a typing error in the July 2010 Newsletter on page 10. The telephone for Autonomed Ltd, the company which makes Seal-Tight dressings should have been 0870 041 0150.

## And another apology...

### Changes to Driving and Type 2 diabetes treated with tablets, diet or both

The articles on driving and diabetes in IDDT's July Newsletter and Type 2 & You state 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 hypoglycaemia. 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 or discuss this with your health professional. This situation places the responsibility with you to inform the DVLA if or when it becomes necessary.

### Informing your insurance company

In the same article we also stated that you should always inform your motor insurance company. Some people have told IDDT that their motor insurers do not want to know if they have Type 2 diabetes. However, an article in the magazine of the International Diabetes Federation [Diabetes Voice, June 2010] states: *“It is always advisable to report diagnosis to an insurer in order to avoid refusal to pay out in the case of an accident.”*

Myth it may be but insurance companies have a reputation for finding a reason not to pay out in the case of an accident. Not informing them of your diabetes could be one of the reasons they find as it can be classed as a 'material change in your health'. Our advice is to keep a copy of the letter you send or if you telephone the company and they say they don't need to know, keep a record of the date you called and the name of the person you spoke to, just in case.

### **Just a note....**

A new EU Directive on driving licences was issued in August 2009, replacing the 2006 EU Directive. A Directive is binding on all Member States but they can choose the method they adopt according to their own legal system as long as the objectives are achieved. This is one of the reasons the driving regulations with diabetes differ from country to country within the EU.

Generally the UK standards are higher than those required by the new EU Directive. The EU Commission has stated that Member States can rely on their existing standards if they are stricter than the new Directive, so there is no obligation to relax the rules. However, the DVLA is considering amending the UK medical standard for driving with diabetes, epilepsy and poor vision.

In September 2010, John Thurso MP asked a Parliamentary Question asking when the Secretary of State for Transport plans to publish his consultation paper on the minimum standards for drivers with diabetes, epilepsy and vision required under EC Directive 2009/113/EEC.



## **Winter's Coming**

### **Winter and blood glucose levels**

Perhaps just a reminder or a tip for people new to using insulin – very cold weather can result in blood sugars falling and so more hypos. Very cold weather requires extra energy to keep warm and therefore blood glucose levels may drop.

### **'flu jabs**

Just a reminder that people with diabetes are treated as a priority for 'flu jabs. They are also entitled to a free pneumonia jab.

### **The common cold**

We all know what we mean by 'the common cold' and that it is a major cause of absence from school or work. It is usually caused by viruses and so antibiotics are useless.

Since the 1930s it has been thought that vitamin C would help with respiratory infections and it became particularly popular in the 1970s when Nobel laureate Linus Pauling concluded from earlier placebo-controlled trials that vitamin C would prevent and alleviate the common cold. Since then, it has been widely sold for preventative and treatment.

A Cochrane Review has looked at 30 studies comparing a placebo [dummy pill] and 0.2 gms a day, or more, of vitamin C.

- ▶ Taking regular vitamin C regularly had no effect on the number of colds people had but it did have a modest effect in reducing the duration and severity of the symptoms.
- ▶ In 5 trials where people carried out short periods of extreme exercise, physical stress, vitamin C halved the risk of getting the common cold.
- ▶ High doses of vitamin C administered therapeutically starting after the onset of symptoms, showed no consistent effect on either duration or severity of common cold symptoms but only a few of these trials have been carried out and none in children.

So although many people take vitamin C to 'boost their immune systems', this Cochrane Review suggests that there is no evidence that taking extra vitamin C wards off colds. The effect for the vast majority is so minute it is not worth the expense.

The current guidelines recommend a daily intake of about 60mg of Vitamin C and just one 220ml glass of orange juice contains more than that - about 97mg, so no need to take extra.

Cochrane reviews on many topics can be found at <http://www2.cochrane.org/reviews/>

## News From The American Diabetes Association Conference

The American Diabetes Association [ADA] Conference, where the latest research is presented, is probably the largest in the world and is attended by researchers, doctors and health professionals from all over the globe. Here is some of the news from the 2010 ADA conference.

### **Inhaled insulin for Type 2 diabetes, a step further**

AFREZZA, an ultra-rapid mealtime human insulin powder, is now the only inhaled insulin under trials for adults with Type 1 and Type 2 diabetes. According to a 2 year study in people with Type 2 diabetes, it provides long-term glucose control comparable to that of usual injected insulin but with less hypos and less weight gain.

AFREZZA is administered at the start of a meal and dissolves immediately after being inhaled and delivers insulin quickly to the blood stream. Peak insulin levels are achieved within 12 to 14 minutes so mimicking insulin production in people without diabetes.

AFREZZA is being used in a study being funded by the Juvenile Diabetes Research Federation as part of its Artificial Pancreas Project.

### **New more-rapid-acting insulin**

An early trial designed to compare a new more-rapid-acting human insulin, VIAject®, with regular human insulin in combination with Lantus for use in people with Type 2 diabetes was presented.

The reduction in HbA1cs was similar in both groups but rates of severe hypoglycaemia were significantly reduced in people using VIAject® and there was less weight gain. However, injection site pain / irritation was higher, although this got less during the course of the study. Trials have also taken place in people with Type 1 diabetes. Based on the results of further studies, the FDA will accept VIAject® for review later this year.

### **Insulin analogue with an ultra-long duration**

A new ultra-long insulin analogue is under development by Novo Nordisk, called insulin degludec. In trials traces of it have been detectable 96 hours after injection. Early 'proof of concept' trials have shown that it was safe, well tolerated and provided similar glucose control to insulin glargine [Lantus]. It has been studied using two dose regimes, once daily and three times weekly and compared to once daily insulin glargine. After 16 weeks, patients achieved HbA1cs of 7.3% with once daily and three times weekly degludec versus 7.2% with once daily insulin glargine. The most common adverse events were headache, diarrhoea and nasopharyngitis - most were mild to moderate in severity.

Novo Nordisk is planning to launch the new insulin 2013 with forecasts of combined peak sales in 2020 of at least \$2 billion. This compares with total group sales in 2009 of around \$8.2 billion for Novo Nordisk.

### **Tight control did not delay risk of complications in people with Type 2 diabetes**

This presentation at the ADA conference was also published in The Lancet [June 29, 2010]. The Action to Control Cardiovascular Risk in Diabetes [ACCORD] trial provided evidence that lowering blood glucose to near normal in people with longstanding Type 2 diabetes by intensive treatment did not delay the combined risk of diabetic complications compared to standard treatment.

The first findings from ACCORD were published in 2008 when it was shown that although intensive treatment produced some beneficial effects, it also increased death rates and rates of severe hypoglycaemia. The study was stopped at this point and people on intensive treatment were changed to standard treatment.

Further analysis of the results of the study has shown that in a group of participants with longstanding Type 2 diabetes and some of the risk factors for cardiovascular disease, intensive lowering of blood sugars reduced some markers of eye, nerve and kidney damage but there was no difference between the progression to kidney failure, nerve

disease and major vision loss between those on intensive treatment and those on standard treatment.

Earlier, well conducted trials have shown that in people with newly diagnosed Type 1 and Type 2 diabetes lowering blood sugars to near normal reduced eye, nerve and kidney disease but ACCORD has shown that this does not apply to people with longstanding Type 2 diabetes over the 3.7 year period of the study. ACCORD is continuing follow up of the participants because prevention of complications needs to be followed up over many years. Meanwhile, the recommendations from these findings are that doctors and patients should be aware that increasing treatment to achieve near normal blood glucose levels provides some benefit but this could increase the risk of adverse effects in people with Type 2 diabetes and additional risk factors for heart disease or who already have heart disease.

### **Increasing Omega-3 in women with Type 1 diabetes does not provide heart benefits**

According to a US study, eating higher amounts of omega-3 fatty acids does not appear to lower heart disease risk in women with Type 1 diabetes. Omega-3 fatty acids, primarily found in fish, promote healthy hearts by preventing the build up of cholesterol but no one has looked at their specific effect on people with Type 1 diabetes.

The study involving 601 men and women with Type 1 diabetes began in 1986 and generally their consumption of omega-3 was low. During the course of the study, 27% developed cardiovascular disease. Although the men consumed the highest amounts of omega-3, the incidence of heart disease was lower compared to the women.

So although omega-3 is typically associated with a decreased risk of cardiovascular disease, this may not be the case for women with Type 1 diabetes. The authors also highlighted the point that it should not be assumed that men and women are the same!

## **From Our Own Correspondents**

### **Accu-chek testing plasma blood**

Dear Jenny,

I was interested and grateful for the information regarding Accu-Chek meters now testing plasma blood. I have been using these meters since they were brought out and had no idea of the change to the strips. I have checked the strips I have and they are the plasma ones. My wife uses the empty containers and I checked those, they were the plasma strips too. So I have been using them, unknowingly, for at least two months. Nobody has told me and in that time, I have been to my diabetes clinic, seen my GP and my diabetes nurse and of course, my pharmacist. Not one person has told me. I suppose I should have read the insert but a box of strips is a box of strips...or so I thought! I have had slightly higher readings than I expect and when I work it out on the basis of the readings for plasma being 11% higher than my usual glucose readings, my control has been good. Maybe this is why my HbA1c test was 6.2 as I have tried to get my levels lower because of the slight increase in readings. On reading your article, I thought much the same as your reporting member and was prepared to change my meter but after using these strips without knowing and without bad side effects, there seems little point now!

Howard Glansfield  
By e-mail

**Comment:** This has worked to Howard's advantage and caused him to try to lower his glucose levels but for some people with lower glucose levels, it could cause apparently unexplained hypos because their readings are 11% higher. So if a test result reads 4mmols/l with the new strips, it is actually around 3.5mmols/l and in the hypoglycaemic range with the old strips.

### **After 46 years of Type 1 diabetes I have become more insulin sensitive**

I had awful problems with human insulin back in the 1980's when we

.....

were put on it en masse. My diabetes specialist nurse put me back on pork and yes I got my hypo warnings back again. I was told analogues may cause the same problem, however, 18 months ago my control was poor and I had nocturnal hypos as the old intermediate insulins peaked causing night time lows. I asked my GP for Lantus and Apidra. I have had type 1 diabetes for nearly 46 years and I am becoming insulin sensitive and sometimes need little or no short acting insulin. However, on my new analogue insulins I still have hypo warning and feel a lot better. So if your pork insulins are causing problems do not despair there may be an alternative but be wary of which insulins you choose.

L.K  
North West

### **Are we living in the world of wealth and not health?**

Dear Jenny,

I read with interest about the grant for pregnant women to enable them to eat a healthy diet. It is great that pregnant ladies are looked after in this way but as someone with Type 2 diabetes on diet only, I must point out that it is very hard to manage to buy all the right food on a minimum wage. As I am not on medication for my diabetes, I also have to pay for prescriptions. When I can afford to pre-pay for 3 months, I do but this is not always possible. So are we living in a world of wealth and not health?

Mr M.A.  
West Midlands

### **Driving licence – my experience**

Dear Jenny,

I've just got your newsletter about DVLA and licence renewal and I would like to share with others what I tried and I got one without too much hassle! When I go to the hospital to see my diabetes consultant

he writes a letter just before the DVLA are due to contact him and sends it to my GP with a copy to me.

On the letter I asked him to put a line in about how good my HBA1c's were (6.6 last one!) and how he had no concerns about my eyes and my driving. On the letter there is also a chart for the last 4 appointments detailing my kidney function/thyroid and diabetes control readings.

I enclosed a copy of the letter in the DVLA renewal questions forms (although they hadn't asked for it), and I was sent a licence on the eye test alone, they didn't even write to my consultant.

By e-mail

**Just a cautionary note:** There seems little consistency in the way the DVLA respond, so just because it worked for this person, it does not mean that this will work for everyone but well worth a try!

### **Got my life back and my hypo warnings!**

Dear Jenny,

I just wanted to thank you and IDDT for the amazing information packet you shipped to Canada for me last February.

I've been battling with constant fatigue, fuzzy-headedness and feeling out-of-sorts for several years. Once I got my toddler's sleeping through the night, got my Celiac Disease diagnosed, and started getting some rest, the problems still didn't go away. So I had to turn to blaming my Humalog insulin which I've been on since the 1990s and no noticeable problems. But both Lantus and Levemir had given me identical problems.

Why would Humalog suddenly give me problems now? The only change in my care has been using an insulin pump since the winter of 2009. I've concluded that getting hourly doses of the insulin instead of meal boluses was just more than my system could process.

Armed with your materials, I approached my doctor about making a change to Hypurin pork insulin. "WHAT? Are you NUTS?" she said, and gave me a referral to Canada's leading endocrinologist.

In the meantime, my fatigue was growing worse and the thought of trying to care for two young children each day was really becoming intimidating. So after 42 years of dealing with my diabetes under medical supervision, I marched into my pharmacy, told them to order me a vial of Hypurin pork insulin and gave it a try.

I have my life back! It took 24-hours to get my fuzzy-headed, numb brain back to feeling functional. A week later I was energetic enough to be working into the evening, whereas in the past I'd be ready to quit by 10 AM each day.

After two months I am still adjusting my doses to find an ideal, but I do feel my sugars are more stable. On Humalog I'd bounced all day from 3.5 to 16.5 to 4.6 to 12.7. It was exhausting! Now, even if I'm too high, at least I stay at one number for awhile and then slide back into my target range. The ricochet effect is missing, fortunately.

Also, when my sugars start to drop, I break a sweat now!!! I'd been labelled a brittle diabetic 20 years ago and have had no warnings of low blood sugars for so many years. I still don't get the shakes, but I do sense when things are starting to go awry and have to mop my brow - so this has been a good thing. Another great change is that my average daily blood glucose went from 10.5 to 8.5 in the first week. And it stayed there. Hopefully with continued "tweaking" I can finally bring my A1c's down to a proper level.

Life will never be perfect without a cure, but I'm back to raising free-range chickens, canning homemade tomato sauce, reading, visiting, landscaping yet more gardens on our acreage, and of course, raising two wonderful children. All were so monumental before and I'd just get into a depression trying to figure out how to get anything worthwhile done in my day. Now? Nothing is too big to tackle!

Thanks so much for your efforts to keep the animal-based insulins available. I just wish we could get them manufactured here in North America again. I have to pay three times more per vial than I do for the Humalog. So I'll just keep spreading the word and hope that demand can drive someone to get it produced on this side of the Atlantic again.

Lisa  
Ontario, Canada

Just a note: Insulin is still available over-the-counter in Canada, so Lisa was able to purchase her insulin without a doctor's prescription, unlike the UK.

### **National Database**

Dear Jenny

I thought I should let you know my experience with this so far. I received a notification that my GP was going to enter my details on the database and if I had any objection or questions to get in touch with him.

Fortunately I decided to make sure that the information on the red stickers IDDT provided some years ago was transferred to this new system. When I called I was told that the record showed that I was allergic to Humulin (the insulin I was put on to in the early 1980s) and the adverse reaction was hypoglycemia! I wondered whether any doctor would take that as a serious problem!

I explained that this was totally insufficient as all insulin users were liable to suffer hypos and it gave no idea of the problem I have, or the severity of having no hypo warnings at all! I explained that I was not prepared to receive treatment from any GM insulin, but it was essential that I received insulin. I was then asked whether the reaction was potentially fatal and when I replied that it was I was taken a bit more seriously. She then told me there were about 100 different insulins on the database and I would have to specify which ones I was allergic

to! My reply was that nobody would read that long a list, and in any case the way things were going there would be new insulins produced quite frequently in the future and these were all produced by GM. The initial answer was that I could not, but then they suggested that they could enter a warning in a pop up window which apparently appears when my record is entered. This sounded a good idea so I specified that I must only be treated with Porcine or Bovine insulin. I asked for a copy of my record and I was told they could not print it out (that is understandable!) and I was not allowed to see my record on the screen.

I wonder whether other members are having the same problem.

By e-mail



## Product News

### Human Insulin and KwikPen manufactured by Eli Lilly

Lilly Diabetes has confirmed that it is committed to continuing their supply of human insulin. They have also confirmed that the KwikPen will be available for Humulin M3 [the nearest equivalent to Mixtard 30] and Humulin I from September 2010. This pre-filled pen was introduced in 2008 for use with their Humalog range of insulins and so they are now making it available in these two human insulins. Unlike Novo Nordisk who did not produce their latest pre-filled FlexPen for Mixtard 30 users, Lilly is producing their latest pre-filled pen for the 'older' insulins.

### SoloSTAR and ClikSTAR

Sanofi-aventis is expanding the range of insulins available in their latest pen devices in line with guidance from the National Patient Safety Agency on reducing insulin-related errors. No insulins are being discontinued but all the company's insulins will be available in their most modern pen devices – the SoloSTAR [prefilled pen] and the

ClikSTAR [re-usable pen].

### Insuman Comb 25 will be made available in the SoloSTAR(R) from November 2010 [which will be a help to those changing from Mixtard 30].

The older pens, Opticlik, Optiset, Optipen Pro 1 will be discontinued by December 31st 2011. Sanofi-aventis will no longer supply the Autopen but the Autopen 24 and Classic will continue to be supplied on an NHS prescription, or can be purchased directly from Owen Mumford, customer helpline 0800 731 6959.

The announcement has been made 15 months in advance to give doctors and patients plenty of time to manage the changes. So, even people who only see their doctor once a year will be able to wait until their next routine clinic visit to change their pen. At least one company has learned lessons from the anger expressed at Novo Nordisk's short period of notice for the withdrawal Mixtard 30 – good PR!

### Byetta

Byetta [exenatide] made by Eli Lilly, is an injectable treatment of Type 2 diabetes in a pre-filled pen. The Summary of Product Characteristics [SPC] has been changed and it can now be used in combination with metformin, sulphonylureas; thiazolidinediones; metformin and a sulphonylurea; or metformin and a thiazolidinedione.

There is no increased risk of hypoglycaemia expected when Byetta is added to metformin and/or thiazolidinedione treatment so the existing doses can be maintained.

### The world's smallest meter

Home Diagnostics have brought out what they say is the world's smallest blood glucose meter – it twists on to the top of a new vial of test strips and is called the 'TRUEresult twist'. Results are in 4 seconds, there's no coding, it only requires a tiny sample of blood and it stores up to 99 tests. Customer service telephone number for Home Diagnostics Ltd is 0800 08 588 08.

### **Smallest needle ever**

Becton Dickinson in the US announced the launch of the world's smallest pen needle. According to their press release, the BD Nano pen needle has been shown to be as effective as longer needles for all body types and less painful. The needles is 4mm long and thin gauge, 32 G.

### **Glucagen stocks low**

European stocks of GlucaGen, the injection used to treat severe hypoglycaemia, have been limited due to a manufacturing problem. According to Novo Nordisk, this has now been resolved but it will take a few months for stocks to be replenished. Novo Nordisk says that the shortage is unlikely to affect people with diabetes directly but as a precaution, the company is limiting supply to wholesalers to prevent reducing stocks too far. If your pharmacy cannot obtain GlucaGen to meet your prescription, they should contact Novo Nordisk Customer Careline - 0845 600 5055.

In the UK there are no quality or safety problems with the GlucaGen products already in the supply chain but the situation is different for our Canadian members. Health Canada has informed Canadians that Novo Nordisk has voluntarily withdrawn two lots of GlucaGen Hypokit currently on the market – the lots are YW60335 and YW60351. Novo Nordisk Canada is requesting that wholesalers, pharmacies and hospitals immediately stop sales and recall the affected lots. People in Canada who have concerns about these products should consult their health professionals or contact Novo Nordisk at 1-800-465-4334

### **Roche Accu-chek meters and plasma**

In the July Newsletter we warned that Roche Accu-chek meters are now measuring plasma blood which results in readings that are about 11% higher than when measuring whole blood. As we said the new strips can be identified by a yellow circle with black lines through it. One of our members received one pack with the yellow circle and one with a green square with lines through it. On checking with Roche it appears that both these symbols mean that the strips measure plasma blood.

## **Humour And Laughter – Try It**

With so much serious stuff around in the world generally and possibly in our own lives, it is worth remembering that humour and laughter can do us good.

- ▶ Laughter boosts the immune system – it decreases stress hormones and increases immune cells and antibodies that fight infections.
- ▶ It triggers the release of endorphins, the body's natural feel-good chemicals, which increases the overall sense of wellbeing and can temporarily relieve pain.
- ▶ It protects the heart by increasing the blood flow and improves the blood vessels which can help to protect against a heart attack.
- ▶ It relaxes the whole body – a good hearty laugh relieves physical tension and stress leaving your muscles relaxed for up to 45 minutes.

If things are difficult, it may seem hard to laugh or find humour but here are some tips:

- ▶ Laugh at yourself – share your embarrassing moments with others rather than taking yourself too seriously.
- ▶ Try to laugh at situations rather than moan about them.
- ▶ Have things around you that make you smile – a funny poster, photos of family or friends having fun, a funny screensaver.
- ▶ Keep things in perspective – many things are beyond our control, especially other people's behaviour, so don't take the weight of the world on your shoulders.

If you live alone, as I do, it's not always possible to share humour so a personal one for me, is to watch TV programmes that make me laugh  
- Dave is good for this!



## Reports

### People with diabetes not receiving all the tests they should

According to latest figures from the National Diabetes Audit, thousands of people with diabetes are still missing some of the 9 key tests recommended by NICE which should be carried out at an annual review with their GP. These include weight measurement, blood pressure, smoking status, HbA1c, urinary albumin, serum creatinine, cholesterol and tests to check the eyes and feet. The audit found that in 2008/9:

- ▶ Only a third of people with Type 1 diabetes received all 9 tests.
- ▶ Just over 50% of people with Type 2 diabetes received all 9 tests.
- ▶ Measuring urine albumin creatine ratio, which detects early kidney disease was the least likely to be carried out while blood pressure measurement was the most frequently recorded test - 88.8% for people with Type 1 and 96.5% for those with Type 2 diabetes.
- ▶ Social deprivation did not affect the likelihood of all the tests being carried out.
- ▶ Age did have an effect with younger people receiving tests less frequently. Of people aged 16 to 39, just over 20% with Type 1 and just over 35% with Type 2 diabetes received every process compared with just over 34% and just over 51% respectively in the 40–84 age group.
- ▶ 90% are in contact with their healthcare teams at least once a year but the audit showed that the high level of contact with healthcare teams are not always being converted into effective care. Half of people do not meet blood pressure treatment targets, a third have 'poor' blood glucose control, particularly younger people.

There have been improvements from 6 years ago when the audit was carried but the latest figures are still below NICE recommended targets. Worryingly younger people and those with Type 1 diabetes seem to be missing out more on the care they receive. Maybe it would be wise to take the initiative at your next annual review - make a list of the tests described above and ask if they have all been carried out.

### The cost and number of drugs prescribed to treat diabetes increases

The cost and number of drugs used to treat diabetes in England has increased by over 40% in the last 5 years according to a recent report, Prescribing for Diabetes in England [NHS Information Centre].

Over 35.5 million prescription items were dispensed in 2009/2010 at a cost of £650 million compared to 24.8 million items in 2004/5 at a cost of £458.6 million. The number of people diagnosed with diabetes increased from 3.3% in 2004/5 to 4.1% in 2009/10 showing that the increased cost is not just due to an increase in numbers of people with diabetes. The relatively high costs of some of the newer drugs and insulins has had a large impact.

- ▶ Prescriptions for Metformin [recommended by The National Institute for Health and Clinical Excellence for Type 2 diabetes oral therapy] increased by 73% to a total of £60.5 million.
- ▶ Prescriptions for thiazolidinediones drugs [Actos and Avandia] increased by 90% to a total of £78.6 million.
- ▶ Prescriptions for analogue insulins increased by 116% to a total of £255.2 million.

Clearly, IDDT believes that treatment choices should be based on evidence of benefit from research and people with diabetes should have an informed choice of all treatments which should not be restricted by cost. However, as yet, evidence of benefit of insulin analogues for the majority of people has not surfaced, so again we have to ask if this £255.2 million is justified and could the money be more wisely spent, for instance on increasing the number of diabetes specialist nurses or dietitians?

### Personal Health Budgets

We previously reported the [last] government's plan to give patients personal health budgets, so that with the help of health professionals we can choose how we spend our health budget. Over a cup of coffee in the office, it didn't take us long to work out that [i] such a system may benefit some people but for many others, it would be difficult to understand and operate and [ii] that extra time and staff would be

necessary to help people make decisions. And can the NHS afford this? But pilot schemes went ahead, including for diabetes, and an interim report has been produced for the Department of Health, 'Early experiences of implementing personal health budgets'. It says that while early adopter sites were 'enthusiastic' about the potential of personal health budgets, fears have emerged that specific groups of patients may benefit more than others. One site felt that "self-selecting [white middle class]" people would be more likely to access personal health budgets and there was reluctance by other groups such as elderly patients who "may find it too much". And concerns about the cost and time implications of the whole process have also been expressed!

Dear me, whoever thinks these ideas up and who do they consult? Certainly not people with basic common sense - 10 minutes during IDDT's coffee break came to the same conclusions! But meanwhile, the pilots continue and the costs mount.....

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## Just Had To Call.....

**Is there any wonder that people are misinformed!**

One of IDDT's members, who is a nurse in a hospital, went on a Diabetes Study Day for health professionals in Shropshire. One speaker was a rep for the insulin manufacturer, Eli Lilly and when he was asked about animal insulin, he said it was not made anymore because there was a shortage of animal pancreases! She phoned IDDT in amazement and thought that this story should be published to show the nonsense that is sometimes 'taught' to health professionals.

What is worrying is that misinformation like this is actually told to health professionals on a Study Day designed for them to learn and then enable them to offer people with diabetes information and support!

► *Animal insulins made by Wockhardt UK are available on an NHS prescription. There never was a shortage of pancreases – animal*

*insulin wee stopped for 'commercial reasons'.*

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## Snippets

### **Speaking to a real person on the phone**

Do you get frustrated when you ring up large companies, or your bank, when you can't speak to a real person? Well, according to a study [BMC Public Health] this is because 'interacting with the general public can cause employees psychological distress' which raises the chances of 'mental disorders'. What about the mental distress of customers trying to talk to a real live person and not an automated machine?

### **University stops pharmaceutical industry funding**

Michigan University has become the first US medical school to stop receiving drug and medical device company funding to pay for continuing medical education coursework. Pharmaceutical industry funding for postgraduate medical education has come under scrutiny because of the potential bias of promoting drugs and devices over patients' best interests.

### **US campaign to encourage doctors to blow the whistle on bad adverts**

America is one of only two countries in the world where prescription drugs are allowed to be advertised to the public. Now the US Food and Drug Administration [FDA] has launched a campaign to encourage doctors to recognise and report adverts that are inaccurate, not supported by evidence from clinical studies, unbalanced in terms of risks and benefits or are inconsistent with prescribing information.

### **France and Denmark ban Bisphenol- A from babies bottles**

Remember the publicity about one of the plastics in baby's bottles? Well, from the beginning of July 2010 France and Denmark have banned the plastic Bisphenol-A from babies bottles – the French ban is permanent. In Denmark it is a temporary national ban on Bisphenol

A in materials that are in contact with food for children aged 0-3 years of age. The reasons are that numerous studies have raised health concerns. Some studies have shown a link between Bisphenol-A and prostate and breast cancer, obesity, diabetes and thyroid dysfunctions, as well as behavioural and reproductive problems.

Canada and several US states have already banned it. Although the British Plastic Federation have said that the ban is unjustifiable and the UK is unlikely to follow suit, some UK manufacturers of babies bottles have already stopped using Bisphenol-A.

**Americans think that drug companies have too much influence**

More than two-thirds (69%) of Americans currently taking a prescription drug say drug makers have too much influence on doctors' prescribing decisions and half say that doctors are too eager to prescribe a drug when other non-drug options are available for managing a condition. Those are just some of the concerns raised in a new prescription drug poll by the Consumer Reports National Research Center.

The nationally representative poll found that nearly half (45 percent) of Americans take at least one prescription drug on a regular basis, and on average, they take 4 medications routinely. Another key point made was that they did not receive enough information about possible adverse effects to drugs.



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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