Insulin Dependent Diabetes Trust

October 2009 Newsletter

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Government green paper

"Shaping the Future of Care"

IDDT has joined with other charities to raise serious concerns about the Government's green paper which reveals plans to abolish Attendance Allowance and leaves the way clear to end the care component of the Disability Living Allowance.

The proposals may not affect you, but they may affect you in the future and they will affect millions of people now, including some with diabetes. We are calling on you to help NOW – see inside for how to help!

Association between Lantus and Cancer

Professor Edwin Gale defends patients' right to know

"We acknowledge the anxiety and distress that these reports might have generated, but we also believe that people have every right to be informed of possible danger. Imperfect information is better than uninformed ignorance."

[The Lancet, Vol 373, August 15, 2009]

Consultation

should drug companies be allowed to supply information directly to patients?

Having lost the battle in the EU to allow drug companies to advertise directly to patients, there are now proposals that industry should be allowed to provide *information* directly to patients. The consultation documents suggest that the UK Government favours this move. IDDT has strongly opposed it, primarily on the basis that we, the patients need unbiased, independent information on which to make our treatment choices.

Free prescriptions for all long-term conditions

The Prescriptions Promise campaign, a coalition of charities, is campaigning for Gordon Brown to keep his promise of introducing free prescriptions for people with long-term conditions. People with diabetes receive free prescriptions, but there are many people with long-term conditions that do not. This is unfair and can lead to people not collecting all their medicines because of cost. The Prescriptions Promise campaign is easy to support if you have internet access. To sign the petition, just visit: www.prescriptionpromise.org

Hypoglycaemia

Hypoglycaemia is not caused by diabetes but by the treatment of it.
After meals insulin is produced by the pancreas to prevent the glucose in the blood from rising too high. In people with Type 1 diabetes, the cells in the pancreas do not produce any insulin, so blood glucose levels rise too high [hyperglycaemia] so insulin injections have to be given. The difficulty for people with diabetes is that as the insulin has to be injected, it does not exactly match up with food eaten, the exercise taken or the energy used. If the blood glucose drops below normal, whatever the cause, then this is hypoglycaemia [a hypo].

People with Type 1 and Type 2 diabetes are advised to keep their blood glucose levels as near to the normal blood glucose levels as possible, but this does mean that hypos can be quite common.

Normal blood glucose levels in non-diabetic people range between 4 and 7mmols/l. Hypoglycaemia is usually said to occur at 3.8mmols/l and so the recommended lower blood glucose level is 4mmols/l – hence the saying that “4 is the Floor”. Some publications say that hypoglycaemia does not occur until blood glucose levels are below 3.5mmols/l. However, there is research that shows that the ability to function may be impaired by blood glucose levels of 3.8mmols/l and lower. It is important that even mild hypos, or ‘lows’, are recognised as being hypoglycaemia so that they are treated to prevent blood sugars dropping even further.

Definitions of hypoglycaemia
Mild: a hypo that is easily treated by the patient by the intake of a sugary drink or food, often referred to as ‘being low’.
Moderate: one where someone else, spouse, friend or parent, has to intervene and give the sugary food/drink because the person with diabetes is confused or even losing consciousness
Severe: one that usually means unconsciousness and may be accompanied by a convulsion/seizure.

Hypoglycaemia is the main day to day concern of people who take insulin and sometimes people run their blood sugars higher than advised because of the fear of hypos, especially if they have reduced or no hypo warning signs. It is important that target levels are set for each person because their needs may be different eg someone living on their own may have to run their blood sugars a bit higher at night to avoid night hypos.

Diabetes and work – hypos at work are not that common
Researchers in the UK investigated the incidence of hypos in employed people with insulin treated diabetes. [Diabetes Care, June 2005] A 12 month survey of 243 people aged between 20 and 69 recorded the number of hypos and their severity. Over the 12 month period, the

results showed:

- A total of 1,955 mild hypos [self-treated] and 238 severe hypos [required help from another].
- Of the 238 severe hypos, 62% occurred at home, 15% at work and 23% not in the home or at work. 52% of all severe hypos occurred during sleep.

The researchers suggest that these results show that severe hypoglycaemia in the workplace is uncommon and seldom causes disruption. Therefore ‘restrictions on employment for most people with insulin-treated diabetes may be hard to justify’.

Working shifts
Working shifts can be difficult especially for people taking insulin and it is best to discuss managing this with your diabetes nurse. However, it has long been suspected that working shifts is not good for anyone’s health as it increases the risk of heart disease, ulcers, depression and sleep problems which carry on long after retirement. A study published in the New Scientist [April 2005] showed that off-shore oil workers on split rotas of 7 nights on followed by 7 nights off had a higher risk of heart disease, were more tired and inattentive. This resulted in increased risks of accidents.

This shift pattern was the more popular than permanent night shifts because the workforce adapted to night sleeping when they got home – but it was found to be the worst shift pattern for health. Tests showed that the levels of melatonin, the sleepregulating hormone normally secreted at night, did not become synchronised to new sleep times after shift changes.

Night shift workers also had abnormally high levels of fatty acids circulating in the blood after meals compared to day shift workers. This increases the risk of heart disease, diabetes and other metabolic disorders. One of the researchers suggested that workers should try to avoid split shifts and other changes that put their body clocks out of kilter. Perhaps easier said than done when employers play a considerable part in deciding shift patterns! We are moving to a 24 hour society and more than 20% of the working population work at least some time outside the 7am to 7pm day – perhaps another factor adding to the increase in Type 2 diabetes.

People with Type 1 diabetes may sleep through night hypos
Research carried out in Germany [PLoS Medicine 2007;4:e69] has shown that people with Type 1 diabetes often sleep through night time hypos. This increases the risk of prolonged hypoglycemia and is a possible cause of hypoglycaemia unawareness [loss of hypo warnings].

In the study on one night, the researchers induced hypoglycaemia to 2.2 mmol/l by infusing insulin over 60 minutes in 16 people with Type 1 diabetes and 16 non-diabetic people of the same gender, age, and BMI. On a separate control night, normal blood sugar levels were maintained in both groups. The results showed that only one of the 16 people with diabetes woke up when hypo compared to 10 non-diabetic people and none of the study subjects in either group woke up on the control night. We have known for some time that people often sleep through hypos but this study shows that the awakening response to hypoglycaemia is impaired in people with Type 1 diabetes. There was also an absence of counterregulatory responses to hypoglycaemia in the majority of people with diabetes.

The researchers suggest that because of the potentially harmful effects of nocturnal hypoglycaemia ‘restoring a proper awakening response to hypoglycaemia if a therapeutic goal of the utmost importance’ – a philosophy that most people taking insulin would agree with!

‘Imperfect Information Is Better Than Uninformed Ignorance’

Professor Edwin Gale, The Lancet [Vol 373, Aug 15, 2009]

When the European Association for the Study of Diabetes [EASD] journal, Diabetologia, published studies about the possible risk of cancer associated with the use of the long-acting insulin analogue, Lantus [glargine] at the end of June, Professor Edwin Gale, the editor of Diabetologia and Professor Smith, the president of the EASD, had the wisdom and foresight to ensur that summaries of the studies were written for patients in a language that we, the patients, could understand and they also wrote a patient advice leaflet.

The EASD and Professors Gale and Smith emphasised that the studies have limitations and are not conclusive but they are making an urgent call for more research to establish the safety of Lantus. While acknowledging that there is no cause for alarm, Professors Gale and Smith's say:

"People with diabetes do however have the option of using alternatives to using long-acting Lantus once a day [see below]... You may wish to consider this option if you already have a cancer, or, for women if there is a family history of breast cancer. You should not make any change without consulting your own doctor, and you should on no account stop taking your insulin."

This is a view which IDDT upholds

All IDDT's Trustees felt it was right to send the information to our members and we did so without any additional comment. It has always been IDDT's view that people living with diabetes should have a truly informed choice of treatment. We have been openly discussing this issue for the last 3 years and IDDT is funding research comparing cell multiplication in human and analogue insulins, so the new research was not a shock to our members. One member criticised us for being negative, but we have had several calls from people who have been grateful for the information and the choice.

So where do we go from here?

The European Medicines Agency [EMEA] press statement, 23.07.09:

"Due to methodological limitations the studies were found to be inconclusive and did not allow a relationship between insulin glargine [Lantus] and cancer to be confirmed or excluded." The Committee also stated that the present information does not provide a cause for concern and that changes in prescribing advice are not necessary. It has requested that Sanofi-Aventis develops a strategy for further research.

FDA [USA] Safety latest news, September 2009

"FDA is investigating the possibility that Lantus (insulin glargine) may be associated with an increased risk of cancer... All of the studies had drawbacks or inconsistencies that preclude drawing any firm conclusions about whether the drug is actually associated with an increased risk of cancer.

FDA is reviewing many sources of safety data for Lantus, including these four newly published studies, to better understand whether this drug poses a cancer risk. The agency is also deciding whether any additional safety studies will be needed. FDA will keep practitioners and patients informed as new information becomes available.

In the meantime, FDA is cautioning patients not to stop taking their insulin without consulting a physician, since uncontrolled blood sugar levels can have serious immediate and long-term effects".

Sanofi -Avent is, the manufacturers of Lantus

The company called upon an 'expert' panel to issue advice who 'agreed that the association between the use of glargine insulin and risk of cancer is an important question and should not be dismissed'. They recommended various studies that should be carried out.

Can we draw any conclusions?

Certainly not about the cancer risk with Lantus as the relationship between Lantus and cancer cannot be confirmed or excluded [EMEA].

Are the criticisms that publication caused anxiety and alarm justified? Interestingly all the major organisations and diabetes associations have chosen to issue advice without presenting patients with a choice, even though there is uncertainty. Only the FDA appears to have

recognised that patients as well as doctors need to be kept informed.

Several medical journals have openly made criticisms that publishing this information causes unnecessary alarm and anxiety to patients. Surely patients, the very people taking the insulin should be allowed to make decisions for themselves? Professor Gale very ably defended patients' right to know and the publication of the studies in the Lancet [Vol 373, Aug 15, 2009]:

"We acknowledge the anxiety and distress that these reports might have generated, but we also believe that people have every right to be informed of possible danger. Imperfect information is better than uninformed ignorance."

The reasons for concern
The patient information leaflet explained that Lantus has not been shown to cause cancer but that it is more mitogenic than human insulin which means it could cause cells to split into two so making tumours grow more quickly. This has been demonstrated in the lab but not in man. The German study, the largest, showed that out of every 100 people who used Lantus over an average of 1.5 years, one additional person was diagnosed with cancer compared to those using human insulin. It also showed that the increased risk of cancer was dose-dependent – the higher the dose, the greater the risk. The researchers explain that as analogue insulins do not control diabetes better than human insulin they suggest that these could be a safer option until there is more convincing evidence on the safety of insulin analogues.

Suggested alternatives:

- In Type 1 and Type 2 diabetes – using long-acting human insulin or a mixture of long- and short-acting human insulin twice a day instead of the once-daily analogue.
- In Type 2 diabetes – managing diabetes with short-acting human insulin before meals only.
- In Type 2 diabetes – losing weight so that less insulin is needed [or even none at all].

Neonatal Diabetes – Our Story
by Annemarie Davies

Our son, Matthew, was born in November 2005. We quickly adapted to parenthood and, to be fair, had it pretty easy. Matthew quickly slept through the night, took bottles of formula with no problems and was very cuddly.

Everything was going really well. I planned to end my maternity leave and return to work when Matthew was nearly 4 months old and we had found a childminder in the same street as us. However, things were not as they seemed. In February 2006 Matthew seemed too placid, didn't want to drink anything and didn't want any cuddles. Our Health Visitor suggested he was having a mild reaction to a routine childhood immunisation but as his temperature kept rising we called our GP. He came to visit us that afternoon and again suggested Matthew had some kind of virus and we should keep an eye on him.

People say mother's intuition is a great thing. Something still wasn't right. My husband and I took Matthew to our local A&E department that evening. He was admitted and on checking his blood samples he was found to have a blood sugar level of 66m/mol. Matthew was quickly transferred to ITU at Bristol Children's Hospital. He was in diabetic ketoacidosis and severely dehydrated. We were informed that, at 21/2 months old, Matthew was diabetic. We took him home on an insulin regime of Lantus twice daily and Actrapid as necessary. This averaged around 6 injections per day.

Despite all of this, there was light at the end of the tunnel. A baby being diagnosed with diabetes is pretty rare. The Consultant had told us about some research that had been carried out into diabetes led by the Peninsula Medical School in Exeter, involving a genetic mutation.

The hospital had sent off blood samples from Matthew, his Dad and me and six weeks later we were told that Matthew was suffering from a genetic mutation which caused diabetes in babies under 6 months old. Essentially he was born with it. The mutation came under the name of kir6.2 neonatal diabetes and the best bit was that research had shown it could be dealt with by tablet therapy. Two weeks later, Matthew was admitted to hospital and made the transition to glibenclamide, a sulphonylurea, and said goodbye to insulin injections. His control improved massively and his HbA1c levels have been between 5.6 and 7.2 ever since.

Three years after Matthew's diagnosis, we were invited to the Neonatal Diabetes Open Day in London. It was a great opportunity for us to meet the researchers, doctors and other families living with this. Until now we had found things difficult as awareness of this is very limited.

This discovery is the culmination of the work of Professor Hattersley and his team in Exeter, and Professor Frances Ashcroft and her team in Oxford. So far around 400 people worldwide have been diagnosed and some of these have made the transition to tablet therapy.

The Open Day was a great way of meeting other people, discussing treatment and finding out how other people has been affected. We became aware that we are incredibly fortunate that Matthew has a minor mutation and started tablet therapy so quickly. Other mutations may lead to some developmental delays but research into this is ongoing.

For further information, please look at www.diabetesgenes.org

Jenny: Thanks to Annemarie for telling us their family's experiences of neonatal diabetes. We are glad to know that her son is doing well.

By coincidence, there was an article [July 2009, Prac Diab Int] about a 38 year old lady who as a very young child was initially treated with tablets but at the age of 6 was changed to insulin. It was not until her daughter was diagnosed with neonatal diabetes that tests were carried out on her. She was found to have neonatal diabetes too and became the oldest person to change from insulin to glibenclamide. When on insulin her diabetes was poorly controlled but 18 months after transfer to glibenclamide, she is producing her own insulin and her HbA1cs are within the normal range.

Sharps Bins – Welcome To The UK!

An IDDT member from the other side of the world visited the UK recently. Here are her words: *"I thought I would do the right thing and obtain a sharps container. The chemist told me to go to a doctor, the doctor's surgery told me I would need a prescription or I would have to pay. OK, but then I was told that the friends I was staying with would have a problem disposing of the container! So I'll take my sharps back to Australia and dispose of it myself!"*

The situation with disposing of needles and lancets varies across the country but it shouldn't! For a visitor to the UK to have problems like this, really does make you feel ashamed of our system, or lack of system!

Here are the facts in a ministerial statement March 12th 2009:
"Those prescribed the Sharps bin should be advised that, because of the risk of needle-stick injuries, it should not be disposed of via the normal household refuse collection. Patients should correctly dispose of their Sharps bin by returning it to their GP for appropriate disposal (if so licensed). Alternatively, local authorities will make separate collections of clinical waste on request and patients should contact their local authority."
What this answer does not say is that some local authorities charge for the collection of sharps bins!

And getting rid of your used needles
The BD Safe Clip, available on an NHS presription, cuts off the metal

needles from syringes or pens and encases them inside the device so preventing accidental injury or damage. However, the manufacturers still recommend that used needles are put in a sealed rigid container or sharps bin and disposed of according to the local policy. They also recommend the same for the full Safe Clip which holds up to 1,500 needles.

New device may be on its way from the US – Safeguard Medical Technologies have developed a device specifically for people with diabetes that disintegrates the needle after an injection. The device, the Integrated Plus, is portable, hand-held and works by a plasma-arc melting the needle at 2,500F reducing it to a small ball at the end of the syringe. So the used syringe is made safe to be put in the household rubbish.

Disability Benefits – Action Needed Now!

On 14th July the Government published a new green paper "Shaping the Future of Care" in which it outlined its plans for the future of disability benefits. This green paper has caused widespread alarm as it reveals plans to abolish Attendance Allowance and also leaves the way clear to end the care component of the Disability Living Allowance. The plans are to stop paying these benefits to individuals and to hand the money over to Social Services instead and making it part of a "personal budget" for individuals who need support. This will leave millions of people worse off and will remove some of their independence. You can download the green paper at:

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_102338

IDDT is strongly opposed to these plans. Many of our members are in reliant on these benefits and have been in contact with us to express their worries and fears. One of our members wrote:

"I require DLA to help pay for the "normal" day to day living expenses as I amalso in receipt of Incapacity Benefit. Being at home the whole time is extremely expensive, especially during the colder months of the year. I need to be able to spendmy DLA on helping pay the increased price for a good diabetic diet of fresh fruit, extra heating during the day and the ever increasing household bills. I have never asked the council for any help and I feel that if it is left up to them my allowance would be drastically cut."

We understand that while you may not be in receipt of these benefits yourselves it may be worth remembering that diabetes can cause long term complications that can leave people reliant on these benefits. We have agreed to offer our support as strongly as we can and need to ask for your support too. The green paper is a consultation document and the consultation period ends on 13th November. It is likely that unless there is a strong show of opposition to these proposals before this date then the fate of attendance allowance and other disability benefits will be sealed.

We are asking all our members to write to their MPs expressing their concern at these proposals and to help you do this we have drafted a letter that you can use as a template if you so wish. You can download the letter on our website or call us for a copy If you write to your MP please address your letter to their constituency office. However if you are writing after 12th October then please address it to the House of Commons as the MPs have returned after their summer recess. You can find your MP's name and address at the following site:
www.writetothem.com

If you do not have access to the internet, your local council offices will give you the name and address of your MP.

These changes may not affect you but they will affect a vulnerable group of people within our diabetes community. Please help us to stop these proposals. Remember the consultation period ends on 13th November so we need to act NOW. For further information you

can contact us

e-mail: martin@iddtinternational.org
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write to us at:
Insulin Dependent Diabetes Trust
PO Box
294
Northampton
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Coenzyme Q10 & Statins

One of our long-standing members, David, phoned to say that one of the side effects for him of taking statins to lower his cholesterol, is tiredness and he had 'discovered' that taking coenzyme Q10 supplement everyday had given him a great deal more energy.

Many people have told IDDT that after taking statins they feel much more tired. The other common adverse effect from statins is joint and muscle aches, pains and weakness – myopathy and in its most severe form, rhabdomyolysis. All adverse effects should be reported to your doctor but we thought that we should look into Q10.

What is coenzyme Q10?
Coenzyme Q10 is a substance made naturally by your body. It is present in every human cell where it helps to produce energy and it is a natural antioxidant. It is also present in many foods, such as beef, liver, mackerel, sardines, soya beans and peanuts. Some sources of information say that young people [in their 20s and younger] almost always have adequate levels of Q10 but deficiencies of Q10 are common in people over 40 and very common in people with heart disease, high blood pressure, diabetes or low 'good' HDL cholesterol. Non-meat-eaters and long-distance runners also tend to have low Q10 levels.

Q10 and statins
Both Q10 and cholesterol are synthesised from the same substance in the body, so statins given to stop or slow down the production of cholesterol will also block the synthesis of Q10 in the body. This is not an adverse effect of using a statin but a direct action of the drug. The use of statins can reduce the body's production of Q10 by as much as 40%. This can then lead to a number of physical problems, the most common being muscle aches and weakness and as Q10 plays a critical role in providing energy, reduced levels can be the cause of the tiredness that people complain of when taking statins.

Q10 supplements
David found that taking Q10 supplement along with his statins gave him far more energy and reduced his tiredness. If you are having similar problems, Q10 supplements are something that you should discuss with your doctor before starting to take them.

By the way...
A study of 6462 people with Type 1 and Type 2 diabetes, carried out by the University of Dundee showed that only 41% of patients were still taking statins as prescribed after 5 years. This was a population-based study so people did not know they were being studied, which has the advantage that they don't alter their behaviour because they are beings studied. Basically it showed that adherence to statin therapy in people with diabetes was poor.

- There was a sharp decline in statin use during the first 6months.
- Younger people, non-smokers and people with higher HbA1cs were more likely to stop taking their statin.
- Older people and those with the most cardiovascular risk factors at the beginning of the study were more likely to continue to take statins.
- People who had a heart attack or stroke while taking statins were less likely to continue to take them. The big question is

why do so many people with diabetes stop taking statins when they are at a higher risk of heart disease and stroke than the general population?

Research News

Diabetes vaccine trials
Trials of a vaccine, Diamyd(r), are taking place to confirm andevaluate the ability of the vaccine to halt or slow the destruction of the body's insulin-producing cells. It is hoped that the vaccine will preserve the body's own ability to produce insulin in people with Type 1 diabetes.

So far the Phase 111 trials have involved 640 newly diagnosed 16 to 20 year olds but now the study has been extended to children between 10 and 15. The programme consists of one study involving nine European countries and one parallel study in the US. In addition, long-term follow up is also taking place in the children who were in Phase 11 trials to evaluate the long-term effects of the vaccine. Diamyd is hoping to receive marketing approval in 2012.

What happens to older teenagers and young adults with Type 1 diabetes?
There are plenty of studies of children up to the age of 15 that show that blood glucose control deteriorates in the early teens. In a Scottish study of 255 young people with Type 1, aged 15 to 25 years, researchers assessed glycaemic control, body mass index and insulin regimes in three age groups – 15 to 18, 18 to 21 and 22 to 25.

The results showed:

- The young people in the oldest age group had significantly better HbA1cs but higher average BMI than those in the youngest age group.
- HbA1cs were higher in the youngest age group and in women.
- Lower HbA1cs were associated with higher BMI in men only.
- Overall 74% used 3 or more injections a day and 60% of them were on basal bolus regimes. The proportion on basal/bolus regimes increased with age and duration of diabetes.

The researchers concluded that when compared with adolescents, young adults with Type 1 diabetes have better glycaemic control and higher body mass index and this was associated with lower insulin requirements. [Diab Med. 2008 Mar 25(3):360-4] Is there a message here? For parents of children going through the difficult early teens, there is – it does get better!

Near- normal blood glucose levels cut the risks of long-term complications by half
Research in the US looked at people who had lived with Type 1 diabetes for at least 30 years and concluded that getting blood glucose levels down to near-normal levels, aiming for HbA1cs of 7, can cut by half their risk blindness, kidney disease and heart disease. [Archives of Internal Medicine, July 27, 2009] They also found that treating Type 1 diabetes aggressively at the early stages worked better.

The comparison made was between people who were on intensivetherapy – taking insulin at least 3 times a day with at least 4 blood glucose tests a day – and people on 'conventional' therapy. Both groups had average HbA1cs of 9 between 1983 and 1989. The two groups were then followed for 30 years at which point it was shown that the complication rates were significantly less in the intensively treated group.

The researchers said that if people had stayed on intensive treatment for longer, the improvements may have been even greater. So one wonders why these patients did not stay on the intensive regime? Earlier research showed that patients could not keep up such an intensive regime with the increased numbers of severe hypos.

What the research doesn't tell us is, if people maintain near-normal blood glucose levels by other means, not 'intensive therapy', are the

complication rates still reduced by half? For instance, if near normal blood sugars are maintained by a low carb diet, which requires less insulin [and therefore less risk of severe hypos], are the risks still reduced? Is it actually the low HbA1c levels that result in the reduced risk of complications? If so, does it matter what regime or insulin is used to achieve them?

New Drugs For Type 2 Diabetes

New drugs for Type 2 diabetes have recently come on the market and like all new drugs, knowledge about them is limited and it is important that you report any adverse effects to your doctor.

Januvia [sitagliptin] is a once daily pill that lowers blood sugars by increasing the actions of a gut hormone known as glucagonlike peptide 1 (GLP-1). It should not be used with insulin. The most common side effects include upper respiratory tract infection, stuffy or runny nose, sore throat and headache.

A study in rats [Diabetes May 1 2009] showed that Januvia caused abnormalities in the pancreas that are known risks for pancreatitis. However, when Januvia was used in combination with metformin, this combination helped to preserve the production of insulin and increased insulin sensitivity. So the metformin seemed to counteract the adverse effects of Januvia alone. *But we must remember that the study was carried out in rats and may not affect humans in the same way.*

Victoza [liraglutide] made by Novo Nordisk, received European marketing approval in July 2009 for use in Type 2 diabetes. It has been approved for use on its own or with other Type 2 drugs when satisfactory blood sugar levels cannot be achieved. Again it is a glucagon-like peptide 1 (GLP-1) and is injected once a day. It lowers blood sugars by stimulating the release of insulin only when blood sugars are high. Novo Nordosk say it produces weight loss, possibly due to slower stomach emptying, so people eat less because they feel fuller for longer. It is similar to Byetta [exanatide] which has been on the market since 2007.

The most common adverse effects with both drugs are diarrhoea, indigestion, nausea, vomiting, common cold and headache. Hypoglycaemia is a common adverse effect and very common when Victoza is used in combination with a sulphonylurea, so a dose reduction of this drug is recommended.

According to the NHS drug tariff, Victoza costs £78.48 per patient per month compared to the similar drug, Byetta which costs £63.69 per patient per month. Both drugs are significantly more expensive than all other drugs for Type 2 diabetes including various insulins, such as Insulatard and Mixtard cartridges which cost £14.99 per patient per month.

Victoza [liraglutide] has not been approved in the US as experts were split on whether it is sufficiently safe. When considering thyroid tumours found in tests on rats and mice, they voted 6-6 and one panel member abstained. Novo Nordisk told the panel that there was no evidence liraglutide would cause thyroid tumours in humans. The experts said the company had not presented a convincing case to entirely dismiss the concerns. It is difficult to understand why there is a difference between views of the experts in Europe and in the US when they are looking at the same studies and evidence.

Pharmceutical News

Best new product award
The OmniPod Insulin Management System, designed and produced by Insulet Corporation, has won a 2009 Edison Best New Product Award. The OmniPod(R) Insulin Management System is the first and

only continuous insulin delivery system of its kind because it has no tubing and features automated, virtually pain-free insertion. There are two wireless components – the Pod which is a compact, lightweight, self-adhesive insulin delivery device worn on the skin beneath clothing; and the Personal Diabetes Manager — a wireless, menu-driven, handheld device that programs the Pod.

Warning about painkillers

Sept 2009: the Medicines and Healthcare products Regulatory Agency [MHRA] has issued a warning that over-the-counter painkillers containing codeine can become addictive in just 3 days. It has been reported that 30,000 people have become addicted. 27 million packs of codeine-containing painkillers are sold every year.

The medicines will have to carry prominent warnings about addiction. Advice will be given that they should only be used for pain not relieved by simple painkillers, such as paracetamol and ibuprofen. Suggestions that they should be used for colds, flu and sore throats will be removed. People will be warned not to take them for more than 3 days and pack sizes will reduced to a maximum of 32 pills, although the All Party Drug Misuse group want the pack sizes to be reduced to 18 which is more than enough for 3 days.

Ocean coral "of fers pain therapy"

A compound harvested from soft coral off the coast of Taiwan could provide a new treatment for pain from intractable nerve damage. It is estimated that about 1 in 100 people in the UK have persistent neuropathic pain and many of these are people with nerve damage occurring as a complication of diabetes. Traditional painkillers like aspirin and even morphine often do little to take the edge off neuropathic pain but research in the British Journal of Pharmacology suggests that the coral, Capnella imbricate, could provide relief. Initial studies have shown positive results and now more studies are needed to see if this could offer a new way to treat the condition.

Warnings about anti -smoking drugs

US drug regulatory agency, the FDA, has decided that Chantix and Zyban, anti-smoking drugs must receive boxed warnings to highlight the risks of serious mental health events including changes in behaviour, depressed mood, hostility and suicidal thoughts. The FDA also advises health professionals who prescribe these drugs to monitor patients carefully for any changes in mood or behaviour after starting the drugs.

Pfizer to pay fines of $2.3 billion for the illegal promotion of drugs to doctors

In September, Pfizer one of the world's largest drug companies, was fined the largest ever sum of $2.3 billion for illegal drug promotions involving expenses paid consultant meetings for doctors at resorts with free golf, massages and holidays. Authorities called Pfizer a repeat offender as this was the company's fourth such settlement in the last 10 years, already costing them $11 billion. Even when Pfizer were negotiating settlements on past misconduct, they were continuing to break the same laws with other drugs. Pfizer will be specially monitored for the next 5 years.

One analyst commented: "There's a kind of mentality in this sector that settlements are the cost of doing business and it is OK to cheat." Interestingly, there do not seem to be any comments about the ethics of the doctors who took the freebies!

Novo Nordisk settle Oil - for -Food breaches

Novo Nordisk reached a settlement with the Danish Public Prosecutor for Serious Economic Crime regarding the company's sales to Iraq during 2000 to 2003 under the United Nations Oilfor- Food programme. Novo Nordisk will pay back past profits of 30 million Danish kroner. Novo Nordisk also reached settlements on the same issue with the US Securities and Exchange Commission and Department of Justice.

News From Abroad

Australia

Beef insulin to continue
The Pharmaceutical Benefits Advisory Committee has recommended retaining Hypurin Bovine on PBS and for it to be funded at a higher price – so it will continue to be available. Thank you to all our members in Australia who wrote letters expressing the need for Hypurin Bovine insulin to continue to be available on prescription.

4% increase in children with Type 1
New figures in Australia show that Type 1 diabetes in children under 14 has risen at the rate of 4% a year since 2000. The figures also show a link between where they live and the likelihood of them developing Type 1 diabetes – the more remote the location, the lower the risk.

Canada

Testing and Type 2 diabetes
In August, the Canadian Agency for Drugs and Technologies in Health [CADTH] issued recommendations about blood glucose testing by people with Type 2 diabetes who do not use insulin. The key recommendation states:

- Routine self-monitoring of blood glucose by most adults with Type 2 diabetes using oral anti-diabetes drugs is not recommended / suggested.

It is noted that the primary reason was cost effectiveness. The Canadian Diabetes Association [CDA] view is that there are significant limitations in the studies that were cited so they do not provide conclusive evidence for the recommendation. In addition, CDA does not agree with the cost effective analysis as it undervalues safety and clinical issues including hypoglycaemia and complications. The CDA view is that blood glucose testing should be individualised depending on glycaemic control and type of treatment.

Levemir "useful addition" in Saskatchewan
Saskatchewan has increased access to the insulin analogue, Levemir [determir]. It has been added to the Saskatchewan Drug Formulary, under Exception Drug Status with effect from July 1, 2009.

Air Canada has recently hired a pilot with insulin-dependent diabetes
Although the company already employs several pilots who became insulin dependent while employed by them, this is first time a major airline has taken on a pilot who was already taking insulin.

India

Animal insulins no longer available in India
There are 41 million people with diabetes in India, many of whom need insulin. For many years locally manufactured and more affordable animal insulins were used, but following the introduction of synthetic insulins by international insulin manufacturers, animal insulins are no longer available in India. However, as in other countries, there are people in India who have adverse effects with synthetic insulins but personal importation from the UK is generally not an option because of the cost.

Looing after your health

Here's a variety of information to help you look after your health, know what care and treatment you should receive and make treatment choices.

NHS is failing 852,000 people with diabetes
An audit by the NHS Information Centre has shown that the NHS is failing to deliver proper care to 852,000 people with diabetes. It found that a range of vital health checks, such as cholesterol, blood sugar levels and body-mass index, were not being carried out, as recommended by the National Institute for Clinical Excellence (NICE).

It also showed that the number of people who have diabetic complications is subject to wide regional variation. More worryingly, the failure to follow the NICE guidelines mostly involves people with type 1 diabetes. NICE guidelines lay down nine sets of checks, including eye and foot examinations, blood pressure and cholesterol checks, blood glucose monitoring and smoking history. To find out what care and checks NICE says you should receive, you can download guidelines by visiting:
www.nice.org.uk/ If you do not use the internet, you can telephone NICE on 0845 003 7780.

Only half of patients have enough information to manage their condition

A study of 4500 patients with three chronic conditions – asthma, Type 2 diabetes and heart disease – in 8 European countries and the US, showed:

- Nearly half of patients in the UK are concerned that they do not know enough about their condition and its treatments to confidently manage them and about half of them felt that a lack of knowledge might be worsening their conditions.
- When patients did receive health information on how to manage their condition, only 49% made proactive changes in their behaviour based on the information they received. 74% of those who did change their behaviour reported health benefits.
- There were significant differences in knowledge between the European countries but US patients had the greatest knowledge.
- UK patients use a wide number of sources of information – pharmacists, books, TV and radio and the internet [10%] with 91% looking to doctors and nurses as the main source of information.

This survey demonstrates that patients need more and better information but it also showed that having information does not necessarily produce a change in behaviour. It is essential that along with better education programmes, patients with chronic conditions must be provided with support and help to enable them to make behavioural changes.

The study was commissioned by drug company, Pfizer, so it is reasonable to question why they wanted the survey. Could it be to help their case for the EU to allow them to provide information directly to patients? There certainly is a great need for more and better information for patients, but the sources of such information must be reliable, accurate and uninfluenced by anything other than the patients' best interest. The pharmaceutical industry has an understandable vested interest in the promotion of their drugs, so they have no place in the provision of information.

Education for everyone promised from January 2006

In June 2005 the Department of Health [DoH] announced that all Primary Care Trusts [PCTs] will need to implement NICE Guidance on patient education for everyone with Type 1 and Type 2 diabetes from January 2006. Structured patient education has to be made available to all people with diabetes at the time of initial diagnosis and then as required on an ongoing basis, based on a formal, regular assessment of need. The following principles are recommended:

- Education should reflect established principles of adult learning and use a variety of techniques to promote active learning.
- Education should be provided by an appropriately trained multidisciplinary team to groups of people with diabetes, unless group work is considered unsuitable for an individual.
- These teams should be tailored to the needs of different groups of people with diabetes and should at least include a diabetes specialist nurse who has knowledge of the principles of patient education [or practice nurse with experience in diabetes] and a dietician.
- Sessions should be accessible to the broadest range of people taking into account culture, ethnicity, disability and geographical issues and could be held either in the community or at a local diabetes centre.

Some areas already have these educational programmes in place but educational programmes should be available in your area and you should have a regular, formal assessment of your educational needs.

If you are not receiving this level of education, ask when the NICE guidance is going to happen for you. If it is not, then it is something that should be taken up with your local Primary Care Trust.

By 2010 you should have a care plan – if you want one

The Government has made a commitment that everyone with a long-term condition who wants a care plan should be offered one by 2010. A care plan is defined as a patient-friendly 'roadmap' that records treatment and social support that someone with a long-term condition needs. It is meant to be developed with the patient and to be flexible to adapt to any changes in the patient's circumstances. The 3 main aims of care plans are:

- To improve efficiency and co-ordination among health professionals and social services, where applicable.
- To improve patients' experiences of these services.
- To improve patients' health outcomes.

Care plans for diabetes

As part of the 'Year of Care', 103 GP practices ran a programme which has shown the benefits of a more systematic approach to the treatment of people with diabetes. If the results from this programme could be reproduced nationally it would mean:

- 35,100 fewer patients would have diabetic complications.
- 28,500 fewer people with diabetes would suffer heart attacks or strokes.
- 11,600 fewer deaths every year.
- In just 10 months the programme demonstrated that simple changes can have dramatic effects, these include:
- Creating and maintaining an accurate record of patients with diabetes.
- Calling patients in for regular checks – blood sugars, cholesterol and blood pressure.
- Training them to become experts at managing their diabetes.
- Creating a network of care that included GPs, primary care trusts and hospitals.

The next step is to develop and deliver a care plan training package for health professionals. NHS Diabetes has contracted Diabetes UK to develop and deliver this training package through regional sessions and practical workshops. So you should have a care plan by 2010, if you want one.

The legal right to hospital choice

From April 2009, you have a legal right to choose the organisation that provides your NHS care when referred for your first outpatient appointment. However, a recent Mori survey of 93,000 people carried out for the DoH found that the government has made little progress in improving patient awareness of their rights to a choice of hospital for their first outpatient appointment. In March 2009:

- Only 47% of patients recalled being offered a choice of hospital compared to 46% in December 2008.
- 50% were aware of their rights to choose before they visited their GP, the same as December 2008 but only 62% of them could recall being given a choice compared to 61% at the end of 2008.
- 74% of patients who did make a choice said that hospital cleanliness and low infection rates were important influences on their choice.

So be aware that you should be offered the choice of where you receive your treatment. The only exception to this is when speed is important to the patient's health, eg heart attack.

Putting Feet First – new foot care guidelines

In May 2009 NHS Diabetes issued guidance for PCTs to commission hospital foot care services for people with diabetes. The aim is to make improvements across the country in the care of foot ulcers in people with diabetes and reduce the number of amputations. There is no new discovery, but the guidelines make recommendations for best practice. Make sure you get the foot care you need – some time ago research in Wolverhampton showed that:

- 25% of those thought to be at high risk of amputation were not being offered any kind of specialist care.

- 40% were not being educated on how to prevent and treat infections.
- Over 30% did not have any kind of diabetes review to assess how they managed their condition to ensure they did not develop any other complications prior to amputation becoming a risk.

Glucose test kit reduces hospital stays
Bristol Royal Infirmary has trialled a glucose testing 'toolkit' which aims to help hospital staff improve the care of people with diabetes admitted to hospital. It is called the ThinkGlucose toolkit and includes a credit card-sized referral guide, advice on insulin treatment, audit tools and staff prompts. Results show that the ThinkGlucose kit can reduce hospital stays by as much as 4 days, so its use is being rolled out across the UK.

Foody Facts

Pizza can affect blood sugars for up to 8 hours
This suggests that people with Type 1 diabetes need a slow steady dose of insulin to keep control of the blood sugars after a pizza which is high fat and high carbohydrate. Researchers in the US asked 24 people with Type 1 diabetes to eat a pizza with different insulin regimes. The same total amount of insulin was given and the regimes used were:

- An entire dose of insulin immediately.
- Half the dose immediately and programmed an insulin pump to continuously administer the rest of the dose over 4 hours.
- Half the dose immediately and the second half as a slow release dose over 8hours.

This last regime gave the best control of blood sugars suggesting that the pizza affected the blood sugars for up to 8hours! The researchers suggest that other high fat/high carb foods were likely to have similar effects raising blood sugars for much longer than expected.

Garlic's Claim to Lower Cholesterol not true
A study [Archives of Internal Medicine, Feb 26, 2007] has shown that fresh garlic and garlic supplements do not lower cholesterol levels as has been thought previously. The idea that garlic is one of nature's answers to all sorts of health problems dates from Egypt around 1500BC.

Vegetables are good for the brain, but not fruit!
Research suggests that eating vegetables may slow mental decline in older people and help to keep the brain healthy and young. In almost 2,000 elderly people in Chicago those who ate more than two servings of vegetables each day were mentally sharper than those who ate few or no vegetables. They were given mental function tests three times over six years including short-term memory and delayed memory tests. Those who ate more vegetable showed about 40% less mental decline, and their test results were similar to what would be expected in people about five years younger. Green leafy vegetables seemed to be the most beneficial which may be due to the fact that they contain significant quantities of antioxidant vitamin E. Eating fruit did not show a similar slowing down in mental decline. Vegetables usually contain more vitamin E than fruits and are also often eaten with the fats found in salad oils, which help the body absorb vitamin E. [Neurology, Oct 24, 2006]

Now it's mustard – mustard is tasty but it is now reported that it is also good for you. Mustard seeds contain magnesium which is a mineral that may help to regulate cholesterol levels and blood sugar levels in people taking insulin. One tablespoon of ground mustard seed contains 33 milligrams of magnesium – about a tenth of the daily recommendation. By comparison, cooked oatmeal which is considered a good source of magnesium, contains only 28 milligrams per half cup. Adding mustard to marinades, vinaigrettes, and sandwich spreads is probably healthy as well as tasty.

The Insulin Ball

This is the title of a case study reported in the Lancet [Vol 373, Jan 10, 2009] and it describes a man with Type 1 diabetes who had been taking Lantus and NovoRapid for several years. His dose was gradually increased to 94 units a day because his blood sugars were high and poorly controlled.

He was taken into hospital for suspected insulin resistance but all the tests proved to be negative. However, re-examination of the lower abdomen found two hard lumps, one at each side under the skin about 3-4 cm in diameter. He had noticed the lumps several months earlier and had been injecting into them because it was less painful. He was given insulin in a different part of his stomach and he immediately went hypo. His dose was reduced to 24 units a day and he maintained good control.

This may sound as if he was injecting into fatty lumps which can develop if the injection sites are not rotated but in fact, these lumps were not fatty. A biopsy showed that they were amyloid deposits – in this case consisting of insulin. For the amyloid deposits to consist of insulin is very rare, although the authors report that they have seen 4 cases recently, all in people using non-human insulins ie analogues. They suggest that the amyloid lumps may be caused by the amino acid difference between analogue insulin and the insulin the body naturally produces – analogues are more different than synthetic human insulin.

They also suggest that amyloid lumps may be go undiagnosed partly because the use of non-human insulin is increasing and by being mistaken for fatty lumps [lipohypertrophy]. So what's the difference? Amyloid lumps are harder and less obvious so an MRI can help with diagnosis. Injecting into fatty lumps can reduce the effectiveness of insulin but as amyloid lumps are harder, this reduction is greater.

Bits & Pieces

Glucose game – the Didget
In the UK and Ireland, Bayer have launched a blood glucose monitor that is compatible with Nintendo DS handheld games consoles. The Didget is aimed at children between 5 and 14 years old and offers two testing levels. It rewards consistent testing and meeting personalised glucose targets with points which can be used to unlock new game levels and for buying in game items. It is made by Bayer.

Acupuncture for bad backs
The National Institute for Health and Clinical Excellence [NICE] has approved the use of acupuncture, exercise classes and massage as part of routine treatment for people with persistent non-specific lower back pain. NICE recommends the use of these therapies over the current practice of radiographs and spinal injections.

Diabetes inpat ient audit day
It seems to be with great pride that on August 18th NHS announced that it is carrying out the first ever audit of diabetes services in hospitals. This is designed to take a snapshot of inpatient care and patient experience in all acute hospitals in England. However, the announcement gave the date of the audit – the week beginning September 21st. While this is to be welcomed, forgive the cynicism, but the audit would provide much more typical evidence if hospitals were not warned of the date! Even the press release almost acknowledged this, as it was entitled *"The First Ever National Diabetes Inpatient Audit – Get Ready"!*

Heparin & Hypurin Are Not The Same

From a long-standing IDDT member
I gave birth to my gorgeous healthy baby girl 2 months ago and I wanted to update you on my experience while I was an inpatient.

While pregnant I tried to see my consultant about using animal insulin when I gave birth but despite several requests, I didn't manage to get to see him – I was told I didn't need to see him as I had seen the diabetic nurse! After pushing the diabetic nurse, I finally got my "birth plan", but sent to my home address so I had no opportunity to discuss it. It looked in order and a copy had been sent to the delivery suite and one in my maternity notes. It highlighted that I use "Hypurin Porcine Neutral" several times, so I felt reassured.

I had to have an emergency Ceasarean at 37 weeks. My blood sugars were 13 mmol/l, so they stated they would put me on a sliding scale to get them down to 8 mmol/l before the c section. I stated several times that I was to have Pork Neutral insulin as per my birth plan. They said it would take too long to get pork insulin from the pharmacy so they would use my insulin I had taken in. They went out of the room, another nurse came in to start setting up the sliding scale. Again I re-iterated that it was my Pork Insulin they would be using to which the reply was "Yes". She went out and another 2 nurses came in so I just mentioned YET AGAIN that it was Pork Insulin they were using, to be told "No it's Actrapid"!!

I immediately shouted that I was not to have this. I could see the panic in the nurse as she quickly started pressing buttons on the machine and told me "Not to worry as it hadn't gone through just yet"!

As well as my birth plan, I had also been given a "red wrist band" to alert staff to the fact that I was "Hypersensitive to Human Insulin" – but nobody had checked this. After all these precautions, I was just gobsmacked that they had still tried to give me human Actrapid! It seems that you cannot relax at all on this issue!

I had my baby girl and I was able to self-administer again. But this wasn't the end! The day after having my baby I was told that I needed to have Heparin injections to help prevent blood clots. I hadn't had this done when I had my first daughter but I assumed this was now standard. After the 3rd day, a nurse went to double check that I should be having Heparin injections. She returned to tell me that the doctor had written up a new drug chart and he had mistaken Hypurin for Heparin! To say my confidence in the doctors and nurses has shot right down is an understatement! I didn't feel safe or that I could relax which should not be the case in a hospital. Mine is a very simple request – NO HUMAN INSULIN!

I hope this helps other members of IDDT who need animal insulin to be aware that they need to double, triple and quadruple check that they are being administered the correct insulin when in hospital.

Note: It is worth noting that the number of medication errors reported to the NHS has more than doubled from 2005 to 2007, from 36,335 to 86,085, in two years according to a report from the National Patient Safety Agency [NPSA] in September 2009. The rise was put down to more staff reporting errors, although, the NPSA said that only 10% of errors are actually reported. Among the top 5 errors were; patients being given the wrong dose; medicines being missed or delayed; the wrong drug being used.

Anger At Proposal To Close Diabetes Centre

IDDT member, Len Ralph has written to his local paper following proposals to close Ipswich Hospital Diabetes Centre. Here's what he says:

"There is no such thing as uncomplicated diabetes, and it has very complicated side effects that need constant monitoring over the years in order to maintain an acceptable level. Sadly even with good care, the situation can go very wrong in a very short space of time. Having had Type 1 diabetes for over 50 years, although control has been generally very good, complications set in and were only picked up by the Specialists at the Centre. If the PCT take away the "Specialist Centre" and farm us out to the GPs, who is going to spot the problems that can and do arise? At the GPs there is no guarantee that we

will ever see the same doctor or nurse twice in a row as you can't book in advance to see a particular doctor. The old adage "If it ain't broke – don't fix it" comes to mind, but I guess the matter comes down to someone thinking they can save money. I suggest they recalculate – the cost of undiagnosed complications will easily outstrip any savings they are trying to make, to say nothing about the stress caused trying to find trained GP staff who can provide answers to the problems."

IDDT has received similar comments from people in other parts of the country. Even when they do not have complications, their reactions are very similar to Len – at a time in their lives when they are more likely to develop complications, they are removed from the specialist care of a diabetologist. The logic of this defeats most of us!

Swine Flu & Diabetes

Dr Laurence Ger l is, IDDT Medical Adviser
July 30th 2009: Swine flu was affecting 100,000 people per week in the UK. It is an illness characterised by fever, sore throat, cough, fatigue, headache, muscle aches and sometimes vomiting and diarrhoea. People generally recover after 3-5 days. In people with diabetes, the blood sugar will be elevated during the infection and it is important to keep insulin doses up even though you may not be eating – it is also vital to drink plenty of fluids as dehydration will increase the risk of ketoacidosis. Regular blood testing is important during the illness. The chest infection may be quite severe and patients with diabetes should be given priority by their doctors. Tamiflu and paracetamol are safe to give in diabetes and will shorten the illness by 2-3 days.

September 3rd: Estimated new cases of swine flu in the UK were 4,500 last week compared with 5,000 the week before, according to figures released by the Health Protection Agency.

From our own correspondents...

Here is a selection from the many letters we have received and which the writers have kindly allowed us to reproduce:

Learning something new is always good!
Dear Jenny,
It's always a pleasure to learn something new and more so when you're not expecting it. After 15 years 'managing' my daughter's diabetes, I wasn't really expecting new ideas from your excellent little booklet 'Understanding Your Diabetes', but I did. Page 9 'it is important to have the correct sized needle...'.

Gosh!
My daughter was having days when the insulin just didn't appear to work. We had tried different sites and had discussions with the doctor and nurse, but no improvement. After reading your booklet and then reading more, we changed from 5mm needles to 8mm several months ago.

Her daily insulin total has gone down from 85 units to 60 units and HbA1c from over 9 to 7 point something and most important, we now hardly ever get the 'insulin isn't working' days. Brilliant and Thank You Very Much.

You would think that such a critical piece of basic, old fashioned 'best practice' should be more widely known, especially by the specialists who look after us? But then... Thanks again and keep up the good work.

By e-mail

Correction about natural thyroxine
Dear Jenny,
In the July 2009 Newsletter, there is an article about thyroid conditions and it mentions that there are cases where thyroxine alone is not suitable for some people and talks about natural thyroid medication.

At the end you suggest if people want more information they contact The British Thyroid Foundation but there is an other excellent organisation which is more in line with the aims of IDDT. It advocates for the choice of patients to have natural thyroid medication if they cannot get well on thyroxine alone. In fact I think this is the only organisation that does this, and therefore I would have hoped you would have included this organisation as another contact. It is a web-site and internet thyroid support forum, Thyroid Patient Advocacy – UK [TPA], www.tpa-uk.org.uk

Your article gives the impression that it is easy to obtain natural thyroid medication in the UK, even though not licensed. Here you are wrong and if you had spoken to the organisations you quote you would have discovered this. My experience is that as far as the British Thyroid Foundation is concerned, if you cannot feel well on synthetic thyroxine then you either have another condition or it is all in your mind. There is no problem for those people who fit inside the box but those who do not are completely disregarded.

The aim of TPA is trying to do for thyroid patients what IDDT is trying to do for people with diabetes – for patients to be given the choice of the best treatment for them.

By e-mai l

Jenny's response: I apologise for not knowing about the TPA and for implying that it is relatively easy to obtain natural thyroxine. Obtaining any unlicensed drug on a named patient basis is not simple and we know from experience with the adverse reactions to synthetic insulins, that all too often people are not believed. We did also receive another response about this issue asking for our advice on how to lobby for natural thyroxine as it appears that supplies from the US are under threat of discontinuation.

Children under stress

Dear Jenny,

I have had Type 1 diabetes since I was 16 years old and I am now 54 and the article about the rising incidence of childhood diabetes [July 2009 Newsletter], made me think of my diagnosis, probably triggered by the stress of my GSEs. My mother and father were told that I should avoid stress as much as possible because of the adverse effects it could have on my diabetic control. This was not easy to do but I think it is harder for today's children, with or without diabetes.

I never underestimate children's ability, or inability, to deal with stress but we do need to protect and nuture our little ones as much as we can in this fast paced, target driven life we all have to lead.

J.C. North West

Face cream and blood glucose tests

Dear Jenny,

After reading the article in the April Newsletter about how important it is to wash your hands before testing, I thought I should let you know that when I was using a Avon Vitamin c face serum, my readings went through the roof, until from trial and error [so many hypos] I realised it was the face cream. After applying to my face I took readings, which were always very high, but after washing my hands the readings were normal. This was about 4 years ago, hence I stopped using it altogether. I wonder how many facial creams also have an influence on blood sugar levels and how many people are unaware of this possibility – it's not something that my health professional ever warned me about.

Mrs L. I , By e-mail

My experience may help others

Dear Jenny,

I have Type 2 diabetes and have been taking metformin tablets for 15 years but in December 2008 I was put on Lantus insulin. I have developed blurred vision which has got very bad and I am convinced it is the insulin that is causing it.

My vision was OK until my daily dose was between 26 and 38 units when my left eye went blurry. Four days ago my doctor told me to

increase my dose to 48 units and my right has now gone blurry too. My doctor said it was coincidence and nothing to do with the insulin but I'm not a believer in coincidence! I have stopped taking the Lantus and gone back to my tablets and what do you know, 4 days later my vision came back to where it was before I increased my dose.

I went back to my doctor and expressed my concern to him and showed him the information that one of the adverse reaction to Lantus is that it can cause oedema [fluid retention]. He agreed that stopping the Lantus was the right thing to do. In addition, since stopping Lantus my blood sugars have been between 6.2 and 10.1 whereas they were all over the place on Lantus. With a little work on my diet, I should be able to get it a little lower. I have since had my eyes photographed and it has been confirmed that I have oedema which hopefully will dissipate over time.

My experience makes me wonder how many other people are having similar problems but don't know it could be the type of insulin they are using. I have reported my adverse reactions to Lantus to the Department of Health on their website.
Thank you for your website – it has been a godsend to me.

Adam Dawkins, By e-mail

Note: adverse reactions to a drug or insulin can be reported by patients. You only have to suspect, not prove, the adverse reaction is caused by the medication.

If you have access to the internet: go to www.yellowcard.gov.uk and CLICK on submit a Yellow Card report. [On this site you can also check the adverse reactions reports already made.] If you prefer to use a paper Yellow Card reporting form: telephone the MHRA on 0207 084 2000 or e-mail patientreporting@mhra.gsi.gov.uk and ask for a form to be sent through the post.

Changes In The Reporting Of HbA1c

Just to remind you, HBA1cs will be reported in units of 'mmols/mol' and not the percentage figure we are used to. If this looks a little familiar it is because our home blood glucose test results are measured in 'mmols/l' which is not the same. From June 2009, HbA1c results in the UK will be given in both percentage and mmol/mol to give everyone time to get used to the new units. From April 1st 2011, the results will be reported only in mmol/mol.

The relationship between the old and the new measurements

Old HbA1c New HbA1c	[%] [mmol/mol]
6.0	42
6.5	48
7.0	53
7.5	59
8.0	64
9.0	75

- So if you are aiming for HbA1c targets of 6.5% and 7.5%, the new units will be 48mmol/mol and 59mmol/mol.
- Normal blood glucose [in someone without diabetes] is 4 – 6% but in the new units it will be 20 – 42mmol/mol.

New Insulin Delivery Systems In The Pipeline

Inhaled insulin – not finished yet...
A study published in May 2009, after the discontinuation of inhaled insulin, Exubera, has shown that in people with Type 2 diabetes, using higher doses of it before meals reduces overall blood glucose levels more effectively than injected long-acting insulin analogue, Lantus. Having said this, the number of hypos was 8.7 per month for Exubera

compared with 2.4 for Lantus.

The only inhaled insulin for adults with Type 1 and Type 2 diabetes still undergoing development is Afresa, made by MannKind. So how does it differ from previous inhaled insulins that did not succeed? The manufacturers say that it is an 'ultra rapid-acting insulin' that immediately dissolves on contact with the lung surface releasing the insulin rapidly into the blood stream. It peaks within 12 to 14 minutes of administration. We have to wait and see whether this one receives approval in the US and if so, will doctors prescribe it and will patients want to use it?

Oral insulin a step nearer
Spray Insulin is approved in another country
Generex Oral-lyn is meal-time spray insulin delivered to the oral cavity and absorbed through the lining of the mouth. It is not deposited in the lungs. It is for sale in Equador, India, Algeria and now Lebanon for people with Type 1 and Type 2 diabetes. Studies are going on in 22 other countries. So far over 300 people have enrolled and 60 people have used it for 6 months. It appears not to be inferior to injectable insulin [one of the approval requirements] with no significant or serious adverse events.

PatchPumps

- SteadyMed Ltd, an Israeli company, is developing a device called PatchPump, described as a 'light patch-sized miniature infusion pump'. It promises to be able to inject both basal rates and boluses of insulin. It sits directly on the skin and uses a solid-state battery cell which gradually expands in a stable way under electronic control and merges the two major components – the power source and the motor into one simple miniature part that is flat.
- A company, Medingo Ltd, has recently received approval in the US to market the Solo MicroPump Insulin delivery system. This consists of an insulin delivering patch and a remote control device that increases or decreases the patch's rate of insulin secretion. The only other patch pump on the US market is the OmniPod made by Insulet.
- Another device in the pipeline is V-Go, made by Valeritas. This uses a small adhesive machine-like patch to deliver both basal and bolus insulin dosages. V-Go is a once-daily, disposable, waterproof device that provides a continuous set basal rate of insulin and on-demand bolus dosing of rapid-acting insulin analogue to cover meals. It is intended for people with Type 2 diabetes. A protective adhesive layer is peeled from the back of the device and applied to the body eg the abdomen area. With the push of the start button, a micro-needle is inserted into the skin and supplies a basal flow of insulin. At meal times the bolus button is pushed in to administer the rapid-acting insulin. On removal of the device, the micro-needle retracts, limiting the needle injury risk.

Intranasal insulin phase 2 trials completed. Bentley Pharmaceuticals has completed Phase 2 trials in 80 Type 2 patients in India to establish the safety and efficacy of intranasal insulin spray [Nasulin] in combination with oral anti-diabetic medications. So far it appears that people using Nasulin for 3 months had reduced post-meal blood sugars and a reduction in HbA1cs of 0.7% – similar to people on oral anti-diabetic medications only. It appears to have been well tolerated with no nasal symptoms and in contrast to insulin given by injection, there was no overall weight gain.

Nanoparticles insulin pill
Scientists in India have developed an insulin pill using nanoparticles [minute particles] of insulin designed to be taken twice daily. The nanoparticles breakdown in response to the acidity levels of the blood and allow insulin to be released into the blood stream. Tests in pigs and rats have shown that after entering the bloodstream, the insulin ended up in organs such as the liver and kidneys. Other experiments in pigs showed that their blood glucose was controlled after taking a pill. Human trials are expected to take place in the next few months

World Diabetes Day

World diabetes day takes place on November 14th and is lead by the International Diabetes Federation [IDF] and the World Health Organisation [WHO]. It is an official United Nation's Day and is represented by a blue circle logo – the global symbol for diabetes. The Day aims to raise awareness of the serious impact of diabetes and how, where possible, to avoid or delay the condition and its complications. 2009 is the first year of a campaign that the IDF hopes will raise awareness for the need for diabetes education and prevention programmes and this year's theme is 'Understand diabetes and take control'. People are getting involved by lighting up buildings in blue across the world. IDDT has joined forces with other UK diabetes organisations in this and to have accompanying press coverage. IDDT's role in the first year of this theme will be to widely publicise the availability of our free booklet 'Understanding Your Diabetes'. Clearly only some types of Type 2 diabetes can be prevented, so we believe that as the first stage of this campaign, it is vital that the public receive a very clear message – the difference between Type 1 and Type 2 diabetes.

IDDT has a reason to celebrate 2009 – we are 15 years old!
To celebrate our 'Birthday' and the theme of World Diabetes Day, we are holding a Birthday Debate'. This is being chaired by Lord Clement Jones CBE, and is entitled: 'Do attitudes need to change for people with diabetes to have a real choice of treatment?' It is being held at the London Marriott Hotel, County Hall, Westminster Bridge and the audience will consist of MPs, decision makers in diabetes and of course, people with diabetes. And the Marriott Hotel will be lit up in blue!

NHS News

Martin Hirst reports
Give Feedback on your GP Practice
The British Medical Association's GP committee has confirmed that it is working with NHS Choices to enable patients to rate and review their GP practices, covering aspects such as access and courtesy. Since its launch the NHS Choices website has offered patients the facility to rate their hospital experience. It is now hoped that, by Autumn 2009, the website will offer the facility for patients to be able to post comments about their GP practice as well.

NHS must cut child care errors
The National Patient Safety Agency (NPSA) has said that the NHS must cut down on the number of errors made while treating children. The NPSA collected data which showed that last year alone there were 70 deaths and 20,000 cases of harm in which a lapse of care contributed. The NPSA say the figures are too high and that standards need to be improved.

Worryingly mistakes with medication were the most common error, cited in 16% of cases, but mistakes with hospital transfers, discharge, incorrect treatment, slips and falls were also noted. However, these figures are likely to be just the tip of the iceberg, if the errors where no harm resulted were counted, the total rises to 60,000. Add to this, the fact that the reporting scheme is only voluntary, the true figure is likely to be much higher.

As a result the NPSA has produced a good practice guide, explaining

what NHS trusts can do to tackle the problem, including tips on training, prescribing and communication.

Superbugs decreasing
The number of deaths caused by hospital superbugs has fallen for the first time since records began in 1999. Between 2007 and 2008, the number of deaths from MRSA fell by 23% and from C difficile by 29%. These figures are based on death certificates mentioning the two infections.

Care Quality Commission urges NHS trusts to meet essential standard
The Care Quality Commission (CQC) has expressed its concern that only half of NHS trusts in the UK met all the current quality and safety standards against which performance is measured. It also expressed concern that, while 9 out of 10 trusts met 90% of the standards, not all trusts are meeting the core standards, five years after they were first introduced.

More trusts said they were meeting standards relating to decontamination, equality and diversity, and choice and access. However, there were declines in compliance relating to child protection, implementing patient safety alerts, learning from safety incidents and ensuring confidentiality of patients' information.

The CQC has a new range of enforcement powers which range from fines to closure and has warned NHS trusts that they face strict conditions being imposed on their licence to operate if they fail to meet essential standards.

Free prescriptions in Wales
Although prescription charges have been abolished in Wales, Welsh people who have to receive prescriptions in England have had to continue paying. Under new rules which come into force in the autumn, Welsh people who have to receive their treatment in England will be able to reclaim the prescription charges.

Indigestion

Indigestion also called dyspepsia is very common and most people have it from time to time. Usually it is mild and goes away on its own or with medicine bought over-the-counter but for some people it is very frequent and painful. This group need to see a doctor for a more powerful drug. These drugs are proton pump inhibitors [PPIs], such as omeprazole, and work by stopping the stomach from producing acid.

However experts claim that at least £100 million of NHS money and almost £2bn worldwide is being wasted each year on these indigestion drugs [King's College London published in the BMJ 4.1.08]. They maintain that in up to 70% of cases there was no reason for the prescription and accused doctors of ignoring prescribing guidelines and say that cheaper but still effective drugs can be given. They blamed hospital doctors of prescribing PPIs too frequently and GPs of failing to take people off the drugs when they are no longer needed.

If you are taking a PPI, be assured that the experts say that they are incredibly safe and effective for indigestion but "it's a bit like giving morphine for a headache". Having said this, like all drugs PPIs have side effects – research suggests that they increase the risk of C difficile infection and people taking them for over a year are at increased risk of hip fracture.

What does the National Institute for Health and Clinical Excellence [NICE] say?
A NICE spokesman said that for many patients PPIs should only be used for a short period of time until the underlying cause of the dyspepsia can be identified and treated.

So what's the advice for indigestion?
Chairman of the digestive disorders charity, Core, Dr John Bennett advised people with indigestion to look for causes which can easily be remedied such as over-eating, excess alcohol intake, heavy smoking or rushed meals. Obviously for persistent and painful indigestion,

people need to see their GP.

Just Another Reminder – Animal Insulins Are Still Available

We are still finding that some people are being told that pork and beef insulins are no longer available. Wockhardt UK [formerly CP Pharmaceuticals] are still supplying pork and beef insulins. It is only Novo Nordisk that chose to discontinue pork insulin. Wockhardt UK's pork insulin continue to be available in vials and cartridges.

Snippets...

The Budget – high earners could help charities
Raising income tax for those earning over £150,000 may have been a political move but charities could benefit. If people who fit into this category don't want to pay the extra tax, they can donate it to charity and claim tax relief on 30% of the donation! A survey of this group suggests this tax relief gives nearly a third of them the incentive to donate to charity – let's hope that some of them think of IDDT! In the meantime, we are grateful to everyone who helps IDDT by donating through Gift Aid as it gives IDDT an extra 28p for every pound you give.

Deodorant that stops underarm hair growth!
From January 2009, Unilever are marketing roll-on and spray deodorants under the names of Dove and Sure that will slow down the rate of underarm hair growth and make it finer! Uniliver says a change is apparent after 4 weeks but normal hair growth will return quickly if the product is not used. These 'hair minimizing' products are expected to generate £10 million in sales in their first year!

Be warned – adverts deceive us!
Back in February 2008, Pfzer ran a TV advert in the US for its anti-cholesterol drug, Lipitor. In the adverts, a well-known US scientist Robert Jarvik who invented the artificial heart endorsed Lipitor. Wearing a white coat, Jarvik tells viewers that Lipitor can lower "bad" types of cholesterol by between 39% and 60% and goes on to say "I'm glad I take Lipitor, as a doctor and as a dad". The final shot shows him rowing in healthy, muscular fashion across a sun kissed mountain lake. Nothing wrong with this you may think! But Jarvik, 61, isn't qualified to practice medicine and he has admitted that he wasn't actually taking Lipitor at the time the adverts were filmed. Finally, he doesn't know one end of a boat from another, so the advertising agency used a stunt double with an impressive late middle-age physique. Dr. Jarvik was paid 1.35 million dollars.

Delay with generic medicines costs 3 billion Euros
A preliminary report from the EC says there is evidence that drug companies have deliberately delayed or blocked competing drugs from entering the market. The report looks at drugs that lost their exclusivity in 17 countries from 2000 to 2007 and estimates that 3billion Euros could have been saved if generic medicines had entered the market sooner.

A Big Thank You!!!

Here at IDDT we wanted to take the time to say a big thank you to some of our friends who have been raising money for us. First of all, a big thank you to everyone who took part in the British 10K Run in July. They managed to raise over £535, so thanks to them for all their time and effort and thanks to everyone who supported them. Guys you did brilliantly!

We also need to give a special thank you to Jason Ritchie. Jason runs a website that auctions memorabilia. Jason was given a signed

script by actor Chris Barrie (Red Dwarf, The Brittas Empire) to auction and even by his own admission, Jason was staggered when it finally sold for £857. So thank you to Jason and thank you to Chris Barrie for nominating IDDT as the beneficiary.

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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