Registered Charity No 1058284 - Issue No 52

Insulin Dependent Diabetes Trust

April 2007 Newsletter

Perhaps Hopeful Signs That Science Not Industry, Dictates

For watchers of the pharmaceutical industry, it has been an interesting few weeks. There has been a report showing that the public's trust in the pharmaceutical industry is at an all time low and warning industry to get its act together to restore its reputation. The Office of Fair Trading [OFT] in the UK has issued a report recommending an overhaul of the Pharmaceutical Price Regulation Scheme which sets drug prices. The OFT maintains that the Department of Health is not getting the best price for drugs and it identified several drugs where the prices were "significantly out of line with patient benefits".

Mike Penning MP a member of the Health Committee told the BBC: *"Hundreds of millions are being spent when they don't need to be spent, and it sounds to me as if they have exposed the taxpayer being ripped off."*

We are aware that the pharmaceutical industry produces very necessary drugs that generally benefit patients but government must also ensure that public money is being wisely spent. The OFT is rightly questioning the system where the price of a drug is based on a capped overall profit a company can make from the NHS on all its products which results in the price of an individual drug being unrelated to its actual price.

Industry's response is predictable - as a country we pay less per head for medicine than most European countries. This is open to wide interpretation and IDDT cannot make comment about drugs in general but we do know that in many other countries brand named insulins are less expensive than in the UK.

There is then the question of whether the NHS is funding expensive new drugs that have not been proven to be better than previous ones. In theory this is where NICE come into the equation - they look at the evidence for clinical and cost effectiveness of drugs and make recommendations about whether or not they should be funded by the NHS. So in theory, the science should dictate treatment availability. It is for this reason that IDDT is taking action to try to ensure that NICE assesses all types of insulin - first and foremost to ensure that people with diabetes receive insulin treatment that is safe, effective and most suited to their needs. But we also want to ensure that funds that could be better spent on patient care, are not being wasted by high prices of insulins.

NICE has not had the effect of forcing industry to lower the price of drugs but not so in Germany. As we reported in IDDT's October 2006 Newsletter, Germany's equivalent to NICE, the Institute for Quality and Efficiency in Health Care [IQWiG] concluded that there is no convincing evidence that rapid-acting insulin analogues [Humalog, NovoRapid and Apidra] are superior to regular human insulin for people with Type 2 diabetes. Based on this report, the German government refused to fund rapid-acting analogues unless their price was the same as human insulins. We waited with baited breath to see the outcome and it came 6 months later - all three manufacturers, Lilly, Novo Nordisk and Sanofi-Aventis announced that they were cutting their prices by as much as 30% albeit by discounts to health insurers. Reuters report that Novo Nordisk has said it is ready to stop delivering analogues to the German market, if the German health authorities push prices down too far. We will see...

While we do not want to see patient choice restricted, we do want patients to have reliable information, such as that provided by IQWiG, about the benefits or otherwise of all insulins. NICE could provide us with this in the UK, if they will respond positively to our requests and those of all the MPs who have supported our Early Day Motion in the House of Commons. We also want to see that government is not wasting money on unnecessarily high prices of drugs, including insulins, when they have no proven benefits. Possibly for the first time, in Germany we are witnessing a government standing up to industry on the basis of evidence rather than industry simply dictating prices irrespective of evidence. Surely this is the way it should be.

Sheer Determination Pays Off!

In the UK we are able to still obtain animal insulins despite the actions of the BIG THREE insulin manufacturers in removing the animal insulins some people need. The need is straightforward - because of adverse effects when using synthetic human and analogue insulins. If these adverse reactions to human and analogues insulins were 'imagined' or 'all in your mind' as has been suggested many times, then people would have taken the easy route, followed their doctor's advice and used synthetic insulins - indeed many people did and that's when the problems occurred!

As we know people in most other countries are not so fortunate, they do not have an alternative manufacturer to the BIG THREE and they have been left with no choice but to use synthetic insulin. Or have they?

The answer is that where there is a will, there is a way! If people are denied the insulin that suits them best and effectively forced to use one which seriously adversely affects both their health and quality of life, then make no mistake, they will find a way to obtain the animal insulin they need.

We can see their 'will' in action:

- people in several countries are importing animal insulins from Wockhardt in the UK
- in Germany people are importing affordable pork insulin from Argentina

- in Canada Wockhardt pork insulins have been given marketing approval
- in Australia it is highly likely that by the time this Newsletter is being read, affordable pork insulin will be available from within Australia
- in the UK animal insulins are still available and through determined and prolonged action, the Department of Health has agreed that this must remain the case because some people need them.

No one way of achieving accessible animal insulin has applied in these various countries but one thing is certain - sheer determination of people with diabetes and their families accompanied by the help of a few understanding, caring and independent doctors has won the day so far.

In Canada we see progress!
As readers may remember, Health Canada has fully acknowledged that some people cannot use synthetic 'human' and analogue insulins and therefore they must have access to the animal insulins they need. This is a very important and welcome step and one that is similar to that adopted by the UK Ministry of Health. Largely as a result of this, Health Canada encouraged Wockhardt UK apply for a licence to supply pork insulins in Canada and this was achieved in April 2006 although the Hypurin Pork insulins are very expensive, roughly $115.00 to $150.00 [£50 to £75] a vial - considerably more than Canadians were paying up to April of 2006.

Carol Baker, IDDT's Canadian Trustee, and Colleen Fuller of the Society for Diabetic Rights [SDR] have been working together to take all this further. In November 2006 a meeting was held with the Office of Consumer and Public Involvement [OCAPI] in Ottawa to discuss the problems with animal insulin access and the possibility of a National and International Insulin strategy - a very positive thought!

The OCAPI agreed to outline the directions for IDDT and SDR to pursue within the government. But most importantly, OCAPI said that the discussions have been started with Beta Labs in Argentina to begin the process of that company applying for a license in Canada for both beef and pork insulin.

The second meeting, held on December 12th was held with Dr Pierre Charest and Lindsay Blaney of the Biologics and Genetic Therapies Directorate (BGTD). Dr Charest confirmed that if Beta Labs applied for marketing authorisation for beef and pork insulins, this would be expedited. It was also confirmed that there has been discussion about setting up a panel of experts to discuss insulin needs - naturally both IDDT and SDR would be very keen to be involved.

Carol and Colleen proposed the development of guidelines to assist physicians in identifying severe and persistent hypoglycemia that may be linked to hypoglycemia unawareness. Such guidelines would also help educate physicians about human insulin related adverse events. Dr Charest and Ms Blaney were also informed of the concerns about possible mitogenic effect of analogues and the lack of evidence of their long-term safety.

So all of this looks very positive and clearly at last it is clear that people with diabetes who have adverse reactions to synthetic insulins are being believed - in Canada at least. IDDT and SDR will continue to work together to take forward these very positive steps.

Cost coverage for Hypurin Pork insulins
In order for part of the costs of Hypurin Pork insulins to be covered, each province in Canada gives its own individual approval and this has to be applied for by Wockhardt. The situation at the time of writing is as follows:

- British Columbia and Saskatchewan are covering Hypurin under Special Authority Program [SAP]. It is also stated that the person requiring insulin can apply to the SAP - it does not require a doctor's request.
- Quebec is covering it under Exception Patient Program
- Applications have been sent to Alberta and Manitoba but there has been no response yet

- Ontario has refused
- No applications have been made to Novo Scotia, Prince Edward Island, New Brunswick or Newfoundland because there appears to be no demand for pork insulin.

In Australia - pork insulin on Australian soil after 16years!
At the time of writing, we still have fingers crossed but it now looks highly likely that supplies of Hypurin Porcine insulins will be available from inside Australia. The Australian Quarantine Service and the TGA have given approval for Aspen Pharmacare to import Hypurin Porcine insulin from Wockhardt UK in quantity so that it can be supplied directly to people who need it. It will still be supplied through the Special Access Scheme [SAS] but without the high costs of importation and the problems of the insulin losing its effectiveness due to high temperatures during travel.

By the time you receive this Newsletter, I hope that we will have already written to our Australian members with the news that the insulin is in Aspen's warehouse and details of how to order it. We'll certainly keep you posted.

IDDT would again like to thank Aspen Pharmacare for taking this action on behalf of people who need pork insulin - care, kindness and consideration of one man has brought it all about. I think too tribute must be paid to IDDT's 'leaders' in Australia, Larrane Ingram, Michael Ginges, Kathie Strickland and Ian Kershaw, for their persistence and hard work in support of people with diabetes in Australia

And the US - just a note for people importing Hypurin insulins from the UK. There have been changes at JFK Airport and if insulin orders are going to a private address and not a business address, they will need to go through 'Planned Quarantine'. This process will cost $60. Once the order has been processed Planned Quarantine will telephone you, ask for your Social Security number and require payment of $60 without which your order will not be released. One way around this is to have the insulin sent your doctor's office, a business address. This is something that already happens in other countries.

Beware - Don't Believe Everthing You Read!

A letter in Diabetes Conquest [Dec 2006], the magazine of Diabetes Australia, criticised a previous article in Conquest that suggested that insulin was not related to weight gain. The writer states that he/she put on excessive and unexplained weight when on GM insulin and asked the key question: Can Diabetes Australia campaign to bring back pork insulin?

We are publishing this from Diabetes Australia for two reasons - because it is unbelievably misleading and to show that information even from national organisations has to be treated with caution and some scepticism! Their answer was:

"GM insulin, which is made industrially, is actually human insulin which is exactly the same as the insulin made by the pancreas and which controls the body's chemistry. Any insulin (beef, pig or human) can control the way our body uses the food that we eat, stop it being wasted and therefore regain the weight lost before insulin was used and food was wasted. Too much of any insulin can also lower blood glucose too much and cause hypoglycaemia, hunger and extra food intake. However insulin treatment does not need to increase weight beyond a healthy level. When people start insulin they should also review their lifestyle. A lifestyle plan – eating a bit less and walking a bit more – can help the balance between energy intake (food) and the energy used (activity)."

Let us put the record straight!
GM insulin is not 'exactly the same' as the insulin made by the pancreas - it is artificial/synthetic insulin produced from bacteria by genetic modification. The GM insulin molecule itself is identical but the insulin is not exactly the same - PVC might look like leather, but it's a copy produced artificially. Animal insulins are natural-produced insulins extracted from the pancreases of animals and when extracted so is a minute amount of glucagon. As glucagon triggers the warning signs of an impending hypo, it is the absence of this glucagon in synthetic insulin that is thought to reduce or cause the loss of hypo

warnings for some people using GM insulin.

While clearing all this up, insulin analogues [Lantus, Levemir, NovoRapid and Humalog], are made by a further genetic modification of the genetically modified GM synthetic human insulin.

Insulin has always been known to cause weight increase usually by a few pounds. Conquest has not made it clear that weight loss before diagnosis only applies to Type 1 diabetes, not Type 2 diabetes. However, we have reports from many people with both Type 1 and Type 2 diabetes who have had large weight increases when using GM human insulin regardless of the amount and type of food they eat and after changing to natural animal insulin they have lost the excess weight.

“Eat a bit less and walk a bit more” is unsafe advice in isolation. If people using insulin eat less and increase exercise this is likely to cause hypoglycaemia unless the insulin dose is reduced. Reducing the insulin dose itself may well aid weight loss.

Will Diabetes Australia campaign for pork insulin? The question was not acknowledged or answered leaving us with the age-old question of why national organisations that are supposed to care about people with diabetes only appear to care about those who use synthetic GM insulins - we can only guess the reasons! Never mind, thanks to IDDT and Aspen Pharmacare people in Australia should be able to obtain pork insulin!

Type 1 Diabetes May Not Just be an Antoimmune Disease

Scientists at Toronto’s Hospital for Sick Children working on the role of pain nerves in the cells that produce insulin, have prevented and reversed diabetes in mice. [Cell, Dec 14th 2007] They found that the pain receptors don’t produce enough neuropeptides [chemicals found in the brain] to keep the islet insulin-producing cells in the pancreas working normally. By supplying neuropeptides to non-obese mice susceptible to diabetes the researchers discovered how to treat this abnormality and even reversed diabetes in mice that already had the condition. The major discovery was that when they removed the sensory neurons in non-obese mice by injecting capsaicin, an active ingredient in hot chille peppers, it prevented islet cell inflammation and the mice did not develop diabetes in most cases. The islet cell inflammation cleared up in a day in the mice injected with the neuropeptide and reduced the raised insulin resistance normally associated with diabetes. The blood glucose levels stayed low for weeks to months after just a single injection of the neuropeptide and there are now 4 month old mice that used to be diabetic but are still non-diabetic - this is equivalent to 6 to 8 human years.

The researchers had been tracking links between the nervous system and Type 1 diabetes when they found an unexpected control circuit between the islet cells and the associated pain nerves. This means that Type 1 diabetes may be a disease of the nervous system and not just an autoimmune disease as has always been thought. Until now research has concentrated on the immune system and why it attacks and destroys the insulin-producing islet cells. Now research can be opened up into other areas of investigation and this seems like great progress.

There are immediate plans to move the research from mice to humans and a cllinical trial is expected to start in early 2007 to find out if people who have a high risk of Type 1 diabetes have the same sensory abnormalities. Studies have also been extended to Type 2 diabetes to investigate whether treating islet-sensory nerve circuits can normalise insulin resistance.

Macular Degeneration and Warning About Supplements

Macular degeneration affects the macula at the back of the eye and impairs central vision. The macular is a small area on the retina where detailed central vision takes place eg reading. The cells in the macula deteriorate and the central part of vision becomes blurred but what is seen around the blurred area is relatively clear because the peripheral area of the retina is not affected.

Who is affected?
Macular degeneration accounts for about 50% of all visual impairment in the developed countries. It usually affects people over 50years and so is known as Age-related macular degeneration [AMD].

There are other forms of macular disease that can affect younger people:

- macular dystrophy which is rare and tends to run in families
- macular disease caused by diabetes ie diabetic retinopathy

Two types of macular degeneration

- **Dry** - develops very slowly over a number of years with gradual fading of central vision
- **Wet** - develops more rapidly.

Symptoms of macular degeneration

- central vision is reduced and fine detail is difficult to see
- straight lines can appear wavy or misshapen
- judging distances and heights can be difficult
- colour perception may be affected.

Diagnosis
If your optician, or GP suspects that you have AMD, then you will be referred to the hospital where you will have one or more of the following checks:

- look at a grid test page to check for blind spots
- a colour vision test
- photographs of the back of the eye - the doctor then has an accurate record for future comparisons
- fluorescein angiogram is used only occasionally. Your pupils are dilated and a small amount of fluorescein dye is injected into a vein your arm. It circulates through the body and so the network of blood vessels at the back of the eye can be seen and if there are any leaks of the dye, then it shows the vessels are damaged or new vessels have developed. This occasionally causes nausea and the skin yellows for 3-6 hours and the urine for up to 24hours.

Treatment
So far there is no treatment for the dry type of macular degeneration. Laser treatment may occasionally halt the progress of the wet type if you are seen at the early stages of development.

Nutritional Supplements
There have been reports that nutritional supplements may help to treat AMD but they cannot restore vision. The Drugs and Therapeutics Bulletin [DTB] is an independent journal that provides independent evaluations of treatments and the management of disease for doctors and health professionals. The February 2006 edition expressed concerns that promotion of certain nutritional supplements that claim to improve or slow down macular degeneration may be medicinal and that these claims are aimed at people who are worried about macular degeneration.

In particular DTB has reported the claim that ‘Viteyes’ can ‘slow macular degeneration’. DTB says that there is some evidence to support the use of a specific combination of antioxidant vitamins and zinc, the so-called AREDS formula, in specific groups of patients with macular degeneration - those with advanced disease in one eye only but this formula can only be found in a few products - ‘VisiVite Original

Formula', 'Viteyes AREDS Formula' and 'Ocuvite PreserVision'. The use of other nutritional supplements, or use in other groups of people, cannot be recommended.

DTB's advice to people with macular degeneration includes to stop smoking and eat a healthy diet rich in green vegetables.

Warning note: manufacturers based outside the UK can continue to make inappropriate claims for their supplements because they fall outside the MHRA's jurisdiction.

Hypurin Pork Insulin May Not be on Your GP Database

IDDT has received several reports from people already using Hypurin Porcine insulin that they cannot obtain a prescription from their GP because "Hypurin Porcine insulin is not on the GP drug database".

One of the problems appears to be that sometimes it is listed under the name of Hypurin, sometimes under Wockhardt and sometimes under CP Pharmaceuticals, the old manufacturers name which is still on the insulin packs. However, it does appear that some Primary Care Trusts [PCTs] are removing Hypurin insulins from GP databases for some unknown reason. IDDT has looked into this and we are assured by both Wockhardt and the Department of Health that Hypurin animal insulins are listed on the four main GP drug databases which cover 95% of GPs.

Once again, we want to assure readers that Hypurin Porcine and Bovine insulins continue to be available.

If this happens to you, then clearly your first action is to tell your GP practice that you know that Hypurin insulin is available and you wish to continue to use it. If this fails, please let IDDT know as Wockhardt have offered to phone your GP and put the matter right. We also thank Wockhardt for responding to this problem by sending out another press release to GPs and PCTs advising about the availability of their animal insulins.

Note: we have received reports from Australian members that their doctors have informed them that Hypurin Bovine insulins are no longer going to be available. IDDT has checked this out and it simply is NOT true.

The Need to Revisit Proteins

Following Dr Morrison's article about proteins in the January 2007 Newsletter, IDDT received a number of comments and a certain amount of surprise that proteins could cause a delayed rise in blood glucose levels. Here is an example and Dr Morrison's response:

"I have a number of concerns about Dr Morrison's article about proteins. Very few [if any] persons suffered from any ill effects per sé from reduced fat and proteins during the decade of rationing during and after the war. I am no biochemist, but as far as I have read and understand, proteins do not normally end up as blood sugars, but are only converted to energy, essentially to the muscles, in the absence of readily available sugars. This is why the manufacturers of high concentrate protein supplements for athletes and body builders add a substantial amount of sugar substances to their products, so that the protein goes to the muscles, not used to replace energy. I and most insulin-dependent diabetics have always understood that to eat a meal with a high protein and/or fat content will delay the absorption of the carbohydrate in that meal, hence the delayed rise in blood sugar, from the carbohydrate, not the protein per sé."

Dr Morrison's response:
The method of using rapid acting analogues for carb and regular

insulin for protein was refined by an Alaskan called Dave “Iceman” from Dr Bernstein’s forum. His tried and tested method worked not just for him but for others. I don’t think this is necessarily the only way to use different insulins effectively but the more techniques we have to experiment with the better results certain individuals are likely to get.

Proteins are indeed broken down into amino acids and these go to the muscles. The muscles are recyling amino acids all the time and return them mainly to the liver, but also to the kidneys and intestine where they are transformed through the process of gluconeogenesis into glucose. Please don’t ask me to explain how this happens. I’m only a General Practitioner! I had to memorise Krebs cycle in first year at medical school and it has left me with post traumatic stress disorder.

The upshot is that the body can also convert dietary protein into glucose but only to an efficiency of up to 38%. This happens if the blood sugar goes too low, if there is not enough insulin available or if the body’s need for amino acids have been met. People with Type 1 diabetes who are low carbing have great respect for gluconeogenesis. In the absence of much dietary carbohydrate it is their main source of glucose for certain brain functions. They are much more susceptible to low blood sugars if they take more than very low amounts of alcohol which suppresses gluconeogenesis.

Report Suggests The Pharama Industry Must Clean Up Its Act

A report published in January 2007 compiled by Pricewaterhouse Coopers (PwC) concludes that the growing decline in the pharmaceutical industry’s reputation poses a threat to its long-term success unless the industry takes steps to rectify this AND sooner rather than later.

A PwC spokesman said that it is hard to understand how an industry that has saved so many lives should be held in such low esteem with the public is questioning industry’s motives and practices from sales and marketing to drug development. In view of the recent scandals with some of the block-buster drugs and the cover up of adverse reactions, perhaps it is PwC’s comment that is hard to understand!

The report says that no other industry’s reputation has suffered as badly during 1997-2003. In 1999 79% of those surveyed believed that industry was serving its customers well but by 2003 this had dropped to 44%! Consumers’ greatest concerns were:

- that industry does not focus enough on important unmet medical needs, only 55% believe companies really consider true medical need when making drug development decisions
- the transparency of the clinical trial process, 62% believe drug companies often manipulate or suppress negative clinical trial results to maximise sales. 92% said that drug companies need to do more to ensure clinical trial results are reported accurately and completely, and 96% believe there is a need to increase transparency in reporting the results.
- the focus and approach of sales and marketing activities, 94% agree that drug companies spend too much money on promoting their drugs, including direct-to-consumer advertising, physician education and other sales initiatives.
- there is a battle between pharmaceutical companies and generics manufacturers, 73% believe that drug companies spend too much money and effort trying to prevent generic drugs competing with their branded products and this is money that could be spent developing life-saving drugs.
- when deciding which pharmaceutical product to use, 78% of consumers surveyed said they would consider the drug company’s reputation when choosing a product.

The authors of the report suggest that much of the consumer’s distrust in pharma companies is based on a belief that industry has deviated from its original vision of improving public health to simply increasing company profits. They also said that there was a misunderstanding

and knowledge of industry and its workings by consumers that contributed to their negative views.

Nevertheless, in the report PwC stated, ”Whether consumers and stakeholder group perceptions are accurate or are based on misconceptions is to some extent irrelevant. The realities are that perceptions drive people’s behaviour and that in recent years the pharmaceutical industry has, for a myriad or reasons, lost the trust of its key stakeholders…As such the industry can and should act to restore trust as the central tenet of all its relationships.”

An old saying worth thinking about!
The trouble with the world is that the stupid are cocksure and the intelligent full of doubt.

More on Driving...

Diabetic Retinopathy and Fitness to Drive
As regular readers are aware, we have discussed the problems of visual fields tests for people with retinopathy who have had laser treatment and in some cases, lost their driving licence as a result of failing visual field tests. This has been particularly unfair for people who had laser treatment some years previously and continued to drive because their retinopathy had stabilised and then despite no deterioration in their eyes, have suddenly had their driving licences removed by the DVLA. Long processes of appeal against such decisions have taken place and the inadequacy of relying solely on field tests using instruments never designed to give such definitive results, has been raised with the DVLA many times.

A DVLA Expert Consensus Workshop [March 2006] made various recommendations that have yet to be adopted officially but if you are facing this situation it is well worth using them in the meantime. The new recommendations show greater understanding that [a] retinopathy is not always progressive and can stabilise and [b] that some people can learn to adapt to field loss without being unsafe drivers. If/when adopted this will ensure that people are treated more fairly than in the past.

The recommendations state:

- Before having the Esterman field test, you should be given full information on the procedure and appeals system. You should also be familiarised with the Esterman test before taking it and if you fail, you should be offered a repeat test on the same day.
- If you fail the Esterman test you could be offered a Goldmann test [a different instrument].
- If you fail the Goldmann test but you could show that you meet the criteria to be considered an exceptional case, you could be allowed to re-apply and have the chance to demonstrate that you have compensated sufficiently for your field loss by taking an on-road driving assessment. To be classed as an ‘exceptional case’ you would need to supply a medical opinion that your condition has stabilised and that you have learned to compensate sufficiently for your field loss.
- These alternatives should be made available so that people do not have their driving licences removed unnecessarily. However the burden of proof in showing that the retinopathy has stabilised rests with the person and not the DVLA.
- Visual fields should not be re-tested for at least 3 months after laser treatment as vision may be affected immediately after it.
- The current 3 yearly visual field testing may be too frequent for some people where there is evidence of a stable condition and a mechanism would need to be in place to identify the people where this applies.
- There is a need for more evidence and further research.

Insulin and Driving Taxis

The Department of Transport has issued new guidance for insulin users who hold licences for driving taxis. Up to now whether or not a taxi driver using insulin is allowed to drive a taxi has varied according to local authorities with some having automatic bans. IDDT is aware that some people with Type 2 diabetes have avoided going on to insulin in order to keep their taxi driving licence - not good for their long-term health but understandable when they have a family to support.

The new guidance for England and Wales published in October 2006 recommends that 'best practice is to apply the C1 standards'. CI licences are issued annually but only after applicants have successfully been through a strict medical assessment. Hopefully local authorities will now follow this guidance and the standards will not vary from one area to another and nor will people whose diabetic control is satisfactory be denied their livelihood. For taxi drivers who do receive an automatic ban, this new guidance can be used to argue their case.

Trials With Lantus in Pre-School Children

Researchers in Wisconsin carried out a study in pre-school children with Type 1 diabetes using a flexible multi-dose daily regime of pre-meal Humalog and bedtime Lantus [glargine].

35 children with an average age of 4.8 years were monitored for two years. They all received multiple injections for one year before being changed to the flexible multi-dose regime with Lantus and Humalog. The results showed that overall blood glucose control as measured by HbA1cs improved and there was a reduction in the overall rate of severe hypoglycaemia. However, this improvement only applied to children of normal weight and there was no improvement in children who were overweight. The researchers words were "Excess body weight status appeared to preclude a desirable therapeutic response in the group of patients". [Pediatrics, May 2005]

Notes from the UK Specific Product Characteristics documents accessed December 2006:

- **Lantus** is not licensed for use in children under 6 years old
- **Humalog** - 'may be used in children when an advantage is expected'.
- **Levemir** - '6month trials have taken place in children between the ages of 6 and 17 but it has not been studied in children under 6 years'.
- **NovoRapid** - 'no studies have been performed in children under the age of 2 years. NovoRapid can be used in children when a rapid onset of action might be beneficial.'

Restless Leg Syndrome

Restless leg syndrome is a condition where there is an urge to move the legs which occurs or gets worse when at rest and is improved by activity. It is common in people with Type 2 diabetes and can cause sleep disruption. Research carried out in 2005 [Diabetes Care, Nov 2005] studied 100 patients with Type 2 diabetes and 27% had restless leg syndrome and 45% of these had poor sleep quality. It can be associated with peripheral neuropathy in people with diabetes.

The reported symptoms of restless leg syndrome are sensory:

- shock-like feelings
- jittery
- internal itches
- an uncomfortable feeling inside the legs
- tiredness during the day
- difficulty going to sleep and frequent waking during the night.

There can also be similar symptoms in the arms.

People with the symptoms of restless leg syndrome are advised to consult a doctor especially of the symptoms are frequent, such as 3 nights a week. Treatment is usually with a one of 4 drugs, the choice being based on individual need taking into account clinical benefits and adverse effects.

The Lancet Reports Allergies to Insulin Analogue, Levermir

As we have reported in previous Newsletters that allergy reactions fall into 4 categories, unsurprising called Type 1 to Type IV, with the latter being the most severe with dangerous symptoms such an anaphylactic shock. Allergies to insulin are classed as vary rare, estimated to be less than 1% of those using insulin, and they are usually skin reactions at the injection site.

A letter by French doctors published in The Lancet [Feb 24,2007], reports 6 cases of allergic reactions to the long-acting insulin analogue, Levemir [determir] which has only been available in France since September 2005. Four of the cases were type IV allergy [delayed-type hypersensitivity] and two were type I allergy. The patients were tested for allergic reactions to 12 other commercially available insulins as well as latex [for the vial bung] and protamine.

- The patients with type I allergy had immediate sensitivity to all insulin preparations including Levemir.
- None of the patients with type IV allergy had immediate reactions to the other 12 insulins tested but one patient also reacted to some regular insulins as well as to Humalog and Lantus but not to NovoRapid or isophane.
- One of the patients with type I allergy to Levemir continued on Levemir and a few weeks later was able to stop the antihystamine drugs given for the allergy but the other returned to his previous insulin.
- All patients with the more serious type IV allergy to Levemir stopped taking it.
- None of the patients were allergic to latex and protamine.

The authors say that they do not have a clear idea of the frequency of allergy to Levemir but *“it is striking that we have seen only 15 patients with confirmed allergies to common insulin preparations within the past 10 years, whereas these six observations of local allergy to detemir [Levemir] were recorded within the past 6months.”*

Eight further cases of allergy in patients treated with Levemir have been reported to the French regulatory agency. There were two previous published reports of type III or type IV allergy to Levemir although allergy tests were not carried out so it is not clear whether the cause was Levemir or the preservatives etc.

What does the information from Novo Nordisk say about Levemir?
The Special Products Characteristics document for Levemir [prepared by the manufacturers when a drug is approved] says:

- Injection site reactions are seen more frequently during treatment with Levemir than with human insulin, These reactions include redness, inflammation, bruising, swelling and itching at the injection site.
- Injection site reactions are classed as common - affecting between one in 10 and one in 100 people using Levemir.
- Allergic reactions, from urticaria, rash and eruptions through other symptoms to anaphylactic reactions are classed as uncommon - affecting between one in 100 to one in 1000 people.

What do you do if you have these adverse reactions?
Talk to your doctor and discuss changing your insulin. Don’t forget to report these problems as an adverse reaction through the Yellow Card Scheme - details are in this Newsletter.

A Big Thank You to Jessica...

In December 2006, IDDT received an e-mail from 13 year old Jessica Wynne which said *" I have type 1 diabetes and a while ago I decided that I didn't want to receive any presents for Christmas but instead to give all the money normally spent on my presents to a charity. I have not decided yet which charity to give it all to but I am considering this charity as it does affect my life quite a bit. I was just wondering how this money will affect the charity as I do want this money to make a difference."*

I wrote back to Jessica and explained about the work IDDT does to help children with diabetes at Dream Trust in India whose families are so poor that they cannot afford insulin or the medical care they need. I am delighted to say that Jessica chose IDDT as the charity she wanted to help and in January Jessica sent us £155 for the children at Dream Trust.

As Jessica says, she is 13 years old and has had diabetes since she was seven so I asked her how she felt about having diabetes. Here are her comments: *"Basically I'm not too bothered by it and I try to keep on top. My friends are great but probably don't know as much as they should :) but they do know what to do when I go low. I used to live in the USA when I first got it and they have different ways of dealing with it so when I moved over here when I was about 8 it all changed, but I still call hypos lows and things like that. In February I am going on a school ski trip to Quebec in Canada so this will be a hopefully good test on my ability to keep my numbers under control!!*
Overall I do lead a normal life but do have the odd differences to others. But I try to stay sane."

Perhaps this last sentence speaks for so many of us! So a huge thanks to Jessica for giving up her Christmas presents to help the children at Dream Trust and for her words of wisdom.

MediPal - a medical ID Card
MediPAL is a credit-card-sized medical ID card made from hard-wearing plastic and displays a distinctive green cross. It allows for 10 prescriptions and up to 8 areas to show your medical history. It also includes your GP's details, as well as your name and an Emergency contact number. There are no call centres so there is instant access to your medical details.

The card costs £11.99 if applied for online or £14.99 via an application form and the price includes 2 free updates. There are no annual fees to pay.

Tel: 0845 603 4604 for an application form or apply on line at www.medipal.org.uk

All About Eating

As we have said many times before, there are three cornerstones to the management of diabetes - insulin [or diabetes medications], diet and exercise. For many people dietary advice is both confusing and conflicting.

In the UK prior to 1986, people with diabetes used a carbohydrate-controlled, sometimes called a carbohydrate restricted diet, where carbohydrates were counted in 10 gram portions [often called exchanges] and the insulin dose was matched to the number of carbohydrates eaten. We all had books or lists of carbohydrate values of foods and drinks and we were taught how to match carbs and insulin doses.

Then in 1986 the UK recommendations became 'healthy eating' - high carbohydrate, low fat and plenty of fruit and vegetables. It remains a mystery to many of us how these recommendations ever came about because the evidence to support them is difficult to find. People in the UK were no longer taught to count carbohydrates but still recommended to match their insulin dose with the food they

ate - a very difficult task, if you don't actually know what amount of carbohydrates are in the food you are eating.

It is worth noting that America, Canada and many other countries never went down the 'healthy eating' route but stayed with carb counting and indeed, the American Diabetes Association [ADA] Clinical Practice Recommendations for 2006 state:

"Both the amount of carbohydrate [in grams] and the type of carbohydrate in a food influence blood glucose level. The total amount of carbohydrate consumed is a strong predictor of glycaemic response and thus, monitoring total grams of carbohydrate, whether by use of exchanges or carbohydrate counting, remains a key strategy in achieving glycaemic control."

Then there's the glycaemic index…….
With no more counting of carbs came dietary recommendations whereby we were supposed to choose our food by its glycaemic index [GI]. For some of us, this always was difficult to understand, the name alone is enough to frighten us off because it sounds so technical. Basically the glycaemic index ranks carbohydrates according to the effect they have on blood glucose levels - high glycaemic index foods raise the blood sugar more quickly and low glycaemic index foods do it more slowly and therefore are better for you. Well, that's the thinking anyway but it turned out that the glycaemic index of one food was not always the same because it could vary according to what other foods were eaten with it.

Once again the evidence is not definite and again, according to the ADA Clinical Practice Recommendations for 2006:

"A recent analysis of the randomised controlled trials that have examined the efficacy of the glycaemic index on overall blood glucose concentrations have shown that the use of this technique may provide additional benefit over that observed when total carbohydrate is considered."

Research by Elizabeth Mayer-Davis published in the British Journal of Nutrition [March 2006] suggests that the glycaemic index is hard to understand and is so flawed that it hardly ever results in weight loss. Radical thinking!

Mayer-Davis' study analysed information from more than 1,000 people in a national study on diabetes risk factors. The results showed that while low glycaemic index foods tended to be higher in fibre and thus healthy, basing a diet on glycaemic index ratings has no clear benefits, especially for weight loss.

One reason for this is the difference between laboratory established glycaemic index levels and how people eat in real life. Laboratory ratings that we see on a packet of food are established in people who fasted and then were tested. These ratings are different from the real life situation where the glycaemic index is influenced by when you eat, what you eat with the food, whether your stomach is empty or full, medications being taken and other factors.

Mayer-Davis knows that people will disagree with her findings but says that for people trying to lose weight, it's also a big mistake to pore over glycaemic-index figures while not paying enough attention to overall calories, fat content and exercise. She also says that even for people with diabetes there is more to consider than glycaemic index - blood sugar levels, meal patterns, medications and so on.

So perhaps the simple way is to do what we have always done - some foods contain fast acting carbohydrates eg cakes and fruit juice and some contain slower acting carbohydrates eg brown bread.

Then came the low carb diet...
And along with it came a debate that has never satisfactorily been settled. Part of the problem is that the opponents of low carb diets automatically assume that low carb means high fats - it does not and they forget that some fats are 'good fats'. IDDT has debated this in the Newsletter in the hope that it makes people just wonder about the amount of carbs they are eating

Recent research has actually shown that low fat/low carb diets are as good or better than traditional diabetes diets! A literature review [Nutr Metab 2005;2:16] found that low-fat/low-carb diets were as good as or better than traditional diabetes diets for managing weight, improving the dyslipidaemia of diabetes and metabolic syndrome, and controlling blood pressure, postprandial glycaemia and insulin secretion. The reviewers said that objections to low-carb diets had little scientific basis and clinicians associated low-carb diets with the controversial Atkins diet [less than 30Gms a day] which could not be recommended without further study.

Commenting on the review and low carb diets, leading endocrinologist, Professor Joseph Proietto, head of the weight control clinic at Austin Health in Melbourne said: “There’s enough evidence now to suggest that it helps glucose control if you can limit the carbohydrate load. It makes sense.” He advises his patients to eat little bread, pasta, rice and potato, and to eat more lean meat, fish, vegetables and salads. Professor Proietto said that the next time guidelines are written, this issue needs to be looked at very carefully.

And high carb diets may affect blood pressure in people with Type 2 diabetes

A study [Diabetes Care, Nov 2005] in people with Type 2 diabetes, showed that 14 weeks of a high-carb diet modestly raises blood pressure compared to a diet high in monounsaturated fat.

The study compared the effect of two diets with the same total calorie content, the first was a high-carbohydrate diet with 55% of calories as carbohydrate, 30% as fat and 10% as monounsaturated fat. The second was a high-monounsaturated fat diet with 40% of calories from carbohydrate, 45% from fat and 25% from monounsaturated fat.

The 42 people in the study ate each diet for 6 weeks, with about 1 week between the two periods and with the order of the diets randomly assigned. They were also invited to continue the second diet for an additional 8 weeks and 8 people continued on the high-monounsaturated fat diet and 13 continued on the high-carbohydrate diet. The results were interesting:

- after the first 6-week periods, on both diets there were no significant differences in systolic or diastolic blood pressure [the upper and lower numbers of blood pressure measurements] or in heart rate.
- however, after the 8 week-extension, the high carbohydrate diet [55%] was associated with a diastolic blood pressure that was 7 points higher than at the end of both 6-week phases, systolic blood pressure was 6 points higher, and heart rate was higher by 7 to 8 beats per minute.
- in contrast, the 8-week extension of the high-monounsaturated fat/lower carb [40%] led to a significant lowering of heart rate compared with the end of the initial 6-week periods. Systolic and diastolic blood pressure were 3 to 4 points lower after 14 weeks on the high-monounsaturated fat diet.

The researchers suggested that increased insulin levels on the high carb diet could be a possible explanation for the increased blood pressure and heart rate.

So where are we now?

Perhaps the answer is “confused”! But interestingly people in the UK using insulin pumps are now taught to carb count, as are those attending DAFNE educational courses. So perhaps we could conclude that there has been a change of mind and maybe the high carb/low fat diet was not the right way to treat people with diabetes but rather than admit ‘we got it wrong’, a subtle change in dietary advice is creeping in.

If pumpers are advised to carb count to obtain ‘good’ control, then surely people using injections should be receiving the same advice? In fact a good case could be argued that it is more important that people using injections should carb count because they are receiving insulin in doses rather than constant infusion by pump therapy where a little more insulin can easily be given if their blood sugars start to rise.

So much has been lost...
Most of the people diagnosed before 1986 never stopped counting carbs despite the high carb dietary advice that never quite made sense! The more carbs you eat, the more insulin you have to inject with the consequences of a higher the risk of hypos and weight increase as insulin itself can cause weight gain.

But if this knowledge has not already been lost, we are in danger of losing all this information, experience and expertise. To make matters worse, by their own admission, many dietitians do not know enough about carbohydrates. As we reported in our July 2006 Newsletter, 50% of dieticians feel that they need more training in carbohydrate estimation with a third of dietitians not feeling confident to teach people on insulin about carb counting.

Type 1 and Type 2 Diabetes - The Need to Think About Carbohydrates Differently

I can't claim to have this original thought but I do read, listen and think. Dr Mercola's website [www.mercola.com] recently described the advice of a high carbohydrate diet for people with Type 2 diabetes as a huge deception that is actually harming the very people it is supposed to help. Dr Mercola's basic message was that Type 2 diabetes is not all about blood glucose control but it is about insulin control. If we think about this it is probably right and is one of the main differences between Type 1 and Type 2 diabetes.

- Type 1 diabetes is very much about blood glucose control because the body produces no insulin and therefore the blood glucose levels have to be controlled. This is done by insulin injections to balance with carbohydrates eaten and the amount of exercise taken.
- In Type 2 diabetes the body doesn't produce enough insulin at the right time or produces insulin which the body can't use - so there is too much insulin in the body. So the treatment for Type 2 diabetes is trying to control the amount of insulin with tablets that either [i] stimulate the pancreas to produce insulin or [ii] make the body more sensitive to insulin so that it can be used properly to control the blood glucose levels.

As Dr Mercola says, the primary treatment of Type 2 diabetes is about controlling insulin levels which in turn will then help to control blood glucose levels.

So where is the deception? Dr Mercola's words not mine and perhaps this is a strong way to express the present situation. However, the dietary advice being given to people with types 1 and 2 diabetes is the same - a high carb / low fat diet - yet the two conditions really are quite different.

In many people with Type 2 diabetes and certainly at the early stages, the pancreas responds to eating carbs in the usual way and produces insulin but not all this insulin can be used properly. It follows that the more carbs eaten, the more insulin the pancreas produces and even more insulin is present in the body that cannot be used. So eating a high carb diet just makes this situation even worse. Surely logic dictates that sensible eating for people with Type 2 diabetes, and those with pre-diabetes, is a reduced carbohydrate diet with plenty of exercise to make the body work more efficiently. With this treatment, some people with Type 2 diabetes may never have to be treated with insulin or the time when insulin is needed may be delayed.

Perhaps the advice of a high carb diet for people with diabetes is misguided rather than a huge deception but with the increasing prevalence of Type 2 diabetes, this is a question that really does need answering with good quality research.

And here we go again, a study that looks at controlling blood sugars in people with Type 2 diabetes rather than insulin...
An international study [Diabetes Care, Nov 2005] showed that many doctors delay prescribing drugs or insulin to people with Type 2

diabetes. The authors class this as bad on the basis of their belief that controlling blood sugars is the key to preventing complications without considering that controlling insulin levels would also control blood sugars!

In 13 countries 3,790 doctors and nurses and 2,061 patients with type 2 diabetes who were not taking insulin were surveyed about their attitudes towards insulin which were that:

- over half of physicians reported “threatening” their patients with needing insulin if they did not take a more active role in controlling their blood sugar. [So when did threatening people ever work?]
- 50% to 55% of doctors and nurses said they would delay prescribing insulin until “absolutely necessary.” [When the damage from high sugars has already started?]
- patients often said they would blame themselves if they ended up needing to take insulin [hardly surprising finding is they are ‘threatened’ by their doctors!]. But patients who ate better, exercised more and were less distressed about their diabetes were less likely to blame themselves.

The lead author said that Type 2 diabetes is progressive and while diet and exercise can help, many people eventually need medications, including insulin, to control their blood glucose levels. However, he also said that doctors are often not inclined to tell patients that they need insulin but give treatment that is less effective when they should be to concentrating on getting blood sugars down. He says that patients should be demanding medications and insulin of their doctors. Perhaps we would say that patients should be demanding better dietary advice but it is worth noting that perhaps it is no surprise that the study was funded by Novo Nordisk, the manufacturers of insulin.

Patients Can Report Adverse Drug Reactions

You can now report any suspected adverse reactions you experience, so do use this right. You only have to suspect, not prove, that adverse effects are caused by a drug. Adverse drug reactions can occur immediately or days, weeks or even years after taking a medication.

Here’s how to report any adverse reactions:

- **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.

Note: Reporting an adverse reaction to the manufacturers does not have the same effect because they have to write to a health professional to have this supported before they can report your adverse reaction to the MHRA. So if your GP does not respond to their letter, your report merely stays on file at the manufacturers unless the MHRA specially requests the information. So by all means make a report to the manufacturers but make sure that you also fill in a Yellow Card.

IDDT believes that a more effective system for monitoring suspected adverse drug will result in greater safety for patients.

Obesity - Is There Uncertainty?

There are constant warnings that obesity and overweight will shorten

our lives unless we take action and this is almost unquestioned. However research [Journal of the American Medical Association, June 2005] suggests that the obesity epidemic and its dangers may not be quite as it has been painted.

The research showed that if you are classed as overweight, you may have a lower risk of premature death than those classed as having a healthy weight and it also showed that in the long term, not dieting may be better for your health than trying to lose weight. In other words, people who had tried dieting tended to die younger than those who had not!

The researcher suggests that it is far from certain that obesity and overweight takes any measurable toll on mortality and even severe obesity failed to show up as a statistically significant mortality risk. In fact the statistic that obesity has been responsible for 400,000 extra deaths a year has been radically revised downwards and this is not what we expect!

A possible explanation is that there are more than a hundred risk factors for heart disease eg poor diet, lack of physical fitness, stress and some gene variations but most studies linking heart disease to obesity lump all these risk factors in with obesity. But this recent study separated out the various risk factors which then gave a very different picture showing that the number of deaths linked to moderate and severe obesity ranged between 22,000 more to 7,000 fewer deaths. There is obviously a wide margin of error and these results are controversial but all this implies that there is uncertainty.

Clearly if you are overweight, smoke, eat poor food and don't exercise, then you are more at risk of illness but if you are overweight, or even obese with a healthy lifestyle, then this risk becomes less certain. It remains to be seen what effect, if any, this research will have.

Yet More Uncertainty About Anti-Obsity Pills Prescribing up by 400% in Scotland

The number of NHS prescriptions for overweight people in Scotland has increased fivefold in the last 5 years - doctors gave almost 90,000 prescriptions for anti-obesity drugs last year at a cost to NHS Scotland of £4.1million. In 2001 there were just 18,000 prescriptions costing £765,732. Despite this huge increase, there are questions about whether drugs alone can combat obesity and that these drugs are given to appease people when what they really need is support to make long-term lifestyle and eating behaviour changes.

All the drugs have some side-effects, as listed below, and people who have come off the drugs after losing weight have found that the weight quickly goes back on.

The Scottish Executive has said that these drugs should only be used as part of a weight management programme and should only be given to people who have made serious attempts to lose weight by diet, exercise and other changes in behaviour. Dr Andrew Walker of Glasgow University, is quoted as saying that while these drugs play an important role in treating obesity, they are fairly drastic and were really designed for people who are very obese. Are the drugs successful - Dr Walker says that the main problem with the weight issue is that will power does not come in a capsule.

The anti-obesity drugs are:

Xenical - costs the NHS around £40 a month and blocks the enzyme that digests fat so stopping a third of the fat eaten from being digested. It can cause flatulence and frequent bowel movements and if a high fat meal is eaten while on the pills it can lead to incontinence.

Reductil - costs around £50 a month and works by boosting serotonin levels so making slimmers feel satisfied with less food. Side effects can include raised blood pressure and heart rate, headaches, dry

mouth, constipation and sleeplessness.

Accomplia - the most recent drug, costs about £55 a month. It targets the endocannabinoid system which governs the body's appetite. It taps into the same brain system as cannabis and critics say that it may alter moods. A recently published Cochrane Review of Accomplia found that after one year it produces modest weight loss of about 5% of body weight and only the higher dose of 20milligrams produced significant weight loss - 1.5 inches on the waistline - and slightly reduced blood pressure. However the higher dose brought on more, and more serious, side effects than both the lower dose and a placebo. The side effects included nausea, dizziness, headache, joint pain and diarrhoea but more serious side effects included psychiatric and nervous system disorders. All the studies were funded by the manufacturers, Sanofi-Aventis, so this is possibly the drug in its best light!

Just a note, Accomplia went on sale in July 2006 in Europe and in the UK was approved for use in the NHS. Health insurers in Germany have dismissed Accomplia as a 'lifestyle' drug and are refusing to fund it and in Denmark, cost reimbursement is only in overweight patients with life-threatening obesity-related conditions.

By the way there is a new pill to allow normal eating - scientists are developing a drug to be taken before each meal which could allow people with diabetes or those with coeliac disease to eat many of the foods that are 'off limits'. The pill would allow their bodies to cope with a wider variety of foods by decreasing the permeability of the intestines. It has been designed in the form of a control release capsule to be taken 20minutes before a meal. The active ingredient, AT 1001, released into the gut inhibits the action of the protein Zonulin which regulates the permeability of the intestine. Animal studies have shown that blocking Zonulin can prevent the development of diabetes. The researchers believe that taking AT 1001 should restore the barrier function of the intestine wall in people with coeliac disease and diabetes. Human trials in both groups of people were expected to start in 2006

Just to Remind You About Body Mass Index [BMI]

With the rise in obesity and overweight, we are always hearing about BMI - body mass index. While getting on the bathroom scales tells you your weight and importantly, whether it is going up or down, it does not tell you your BMI, a measurement used in all the guidelines about weight and obesity.

BMI is weight in kilograms divided by height in meters:

- underweight: BMI <20
- acceptable: BMI 20-25
- overweight: BMI 25-30
- obese: BMI >30

From Our Own Correspondents

Agreeing with the group discussions
The Report on IDDT's Conference 2006 was interesting. I have had Type 1 diabetes for nearly 30 years and I agree with all the comments made in the group discussions on insulins and food values. All the aspects of the problems of insulin are not explained properly by either the doctors or diabetic nurses and I find that the values of food are not explained properly.

Mr R. W.
By e-mail

Having diabetes in Zimbabwe
Dear Jenny,
I I would say Hello...! I lead the diabetes voluntary support group of the Senior Citizens Club in Zimbabwe and I thought you might like to know

about life with diabetes here. You may know from news reports that life here is very strained, with official inflation rates at 1,200%p.a.

We have a national medical strike in the public sector, of doctors, pharmacists and nurses and you can imagine how this impinges on the population. When Government pharmacists are working they don't have much to do because there are very few medicines on their shelves.

Insulin is very expensive and scarce and although the Ministry of Health has subsidised the cost for low-income workers, often there is none to be had. Most people with diabetes here cannot afford to buy test strips as one pack of 50 costs more than an average workers' take-home pay for a month and there are too many other, more important claims on the money - such as for food and family.

It is a sad situation, but we 'soldier on' and do what we can. We hold meetings twice monthly. We had a donation of syringes so are able to supply members with an occasional syringe and they make it last a long time. I use a cartridge pen for the Humalog which I purchase for myself outside Zimbabwe, and I have used the same needle for 8 months past - and contrary to the adverts, it is not yet blunt and with a thrice daily usage, has served me hundreds of times....!

I thought you may be interested in hearing about another country. I must close by saying that in our circumstances, the desirability of animal and human insulins is not a consideration here. You will appreciate that for a diabetic, getting insulin of any kind - even date expired, is better

than having no insulin at all.

By e-mail
Name withheld

Tips from experience
Dear Jenny

I would like to comment on the articles by Dr Katherine Morrison in Issues 50 and 51 of the Newsletter. Having been diagnosed as a Type 1 diabetic in 1960, I was introduced to a low carb (130 grams per day) diet of red and black "portions". I am appalled that today's dieticians don't even discuss the correlation between control, insulin and hypos. Over the years I have increased my carb intake somewhat, but having tried the high carb diets more than once I found I just put on weight, I have stuck with what works for me, despite many changes in insulin regimes over the years.

Dr Morrison's wish to keep her son's sugar levels so precise indicates a level of perfectionism which might back-fire if he rebels as soon as he leaves home. The idea of using more that 2 types of insulin in any one day and extra injections is also dangerous for most people as it allows more room for mistakes.

My own formula is to either increase insulin by one unit or reduce carbs 10gms for every full point above 6.00 in my blood sugar readings before meals. It is important to remember that a normal dose and normal meal at breakfast after a low reading is likely to repeat itself throughout the day, similarly with a high reading.

Another tip I have followed since I went on to quick acting insulins is NOT to take an injection before a meal if the blood sugar is lower than 4.00 or when in a restaurant and I have no idea when the meal will be served. With a high protein, high fat or low carb starter or meal, the insulin can get into the blood stream before the sugar from the food: I actually had a hypo even whilst eating!!

Snacks were a very important part of my regime when I was on medium to long lasting insulins, as a top-up of sugars was needed to balance the slowly released insulin. Even on fast-acting insulin this is still true to a degree to counter tail-off effect of the insulin up to 4 hours later, not forgetting the presence of basal insulin. It is a matter of trial and error; some days I need one, others I don't.

I fully agree with the article about tight control being stressful, and told my Consultant that I refuse to be over-medicated any more.

By e-mail
Ms A.

Response from Dr Katharine Morrison
Dear Jenny,

Alison has many valid points to make about the management of diabetes and patient choice. I am very pleased that Alison has found a way of eating and insulin administration that has served her so well over 30 years of type 1 diabetes. It also sounds a bit less complicated than the method that I am using with Steven. Perhaps other people with diabetes would benefit from her advice. I feel it is a terrible shame that many other people diagnosed at the same time as she was were not informed about the value of sticking to 130g carbohydrate or less in their diets.

One of Albert Einstein's quotes was, "The solution to the problem should be simple, but no simpler." This is true for physics and also for diabetes. I think that instead of the NHS sausage factory it is essential that every person with diabetes finds their own solution that works best for them. Alison has stood up to her consultant and also noticed some things in my articles that are quite different from her understanding of the situation. I hope to clarify some of these points here.

Alison is quite right about teenage rebellion being a possibility. I am indeed a perfectionist regarding Steven's blood sugar control but because I am a bit obsessive- compulsive by nature it's no effort at all for me to wade through textbooks, articles and the internet in search of the best way to prevent the devastating consequences of diabetes that I know only so well from my medical practice. I can only hope that in the future Steven will remember what worked when his control was excellent should he decide after any wild years to resume good control. In the first five years after a type 1 diagnosis glucagon is still released by the pancreas in response to hypoglycaemia. The DCCT studies showed that when the intensive treatments of the study group were discontinued their blood sugars gradually became went up to the same as the control group. Even after many years of what we would now consider poor control the original intensive group showed much reduced complications such as retinopathy, kidney and heart disease. This phenomenon has been called the persistence of "Metabolic memory."

Therefore there is a well-known window of about five years after diagnosis when the pursuit of normal blood sugars is relatively risk free. Why is this not emphasised in NHS diabetes clinics?

Instead parents are told that HbA1cs of below 7 are very risky indeed. Since the complications of diabetes take a long time to develop, they should concentrate on helping their kids get used to the injections and blood testing and not worry too much about blood sugars. HbA1c of 7.0- 7.5 s is absolutely excellent they say and the important thing is to limit fat in the diet especially saturated fat such as in butter, cream and red meat because this causes heart disease. Oh really?

Instead of following the deluded path of the high carb/low fat enthusiasts I have emphasised a low carb/high fat approach. I have had to increase carbs due to Steven's growth spurt and teach him techniques to deal with not only high fat and protein meals but also higher carb meals.

I agree that the more insulins a person has to juggle with the more potential for error there is. The alternative is pump therapy but this did not work for Steven. To get as good control on multiple daily injections as on a pump takes a bit of experimentation and we only give 7 units of insulin per injection to maximise absorption predictability.

Like Alison I have certainly found that getting the mornings sorted out are more than half the battle. We have chased high blood sugars throughout the day because we did not get that rogue dawn phenomenon or viral induced high blood sugar under control.

I could cry at the silly letters I get back from diabetology consultants and their junior staff who are parotting the same rubbish about high carb diets being good and fat consumption as being bad. I am sick of doctors making decisions about the acceptabilty of various standards of diabetes control and what efforts should be made to achieve this. These decisions are for the patient or carer to make. The decisions

need to be properly informed but they are not for the health professional to make. They are yours.

Alison has taken a stand about what she will and will not accept. Well done Alison!

Katharine Morrison

Thailand Bulletin No 1 From Jack Haves

Part One The Journey – Coping with time change. Transporting medical supplies safely and securely.
You may be wondering who I am. My name is Jack Haves, a student, aged 18, and I'd like to relay some experiences and give some tips for fellow diabetics who may be travelling to new destinations, be it alone or with family. These are drawn from my own experiences as an English teaching volunteer working in rural Thailand.

So, how did I come to be in rural Thailand? I'm currently taking a gap year after finishing my A levels in the UK, and intend taking up a place at Aston University, Birmingham in Autumn 2007 (if they still want me of course!). I decided to volunteer for the charity Project Trust (www.projecttrust.org.uk) who offered what I wanted from a gap year - a full year long project where I would have the opportunity to become fully immersed in a different culture whilst, hopefully, making a contribution to the local community.
What am I planning to write about? Basically my experiences in South East Asia and how, as a diabetic, I've had to adjust, or not, as the case may be.

Planning
Initially, given my diabetes, I had to do some extra planning in preparation for a full year living abroad. I had to try and see if it was possible to secure enough diabetic supplies to last as long as possible. Even if your prescribed supplies are available in the country you're going to, and this is something you will need to research, they are almost certainly going to be more expensive to obtain. I then had to deal with the increased airport security measures that were introduced in August 2006 which severely restricted the supplies you could carry on a plane as hand-luggage.

I should explain, at this stage, my own insulin regime. I inject 4 times in a typical day with two different types of insulin. I use NovoRapid - very short acting insulin - at each meal (3 times a day) and a long-acting insulin, 'Levemir', which I refer to as my night-time injection.

Time differences
Like most destinations outside Europe, Thailand has a large time difference (currently GMT+7 hours) with the UK. I dealt with this with advice given by the diabetes nurse at my NHS clinic. I was recommended to 'bridge the gap' by doing half of my night-time insulin half way through the flight and then the other half once reaching night-time at my destination. This seemed to work fine for me. However, as I use short-acting insulin each time I eat a meal I ended up doing more than my usual 3 injections as I ate for an extra 7 hours of the added day in Thailand. I actually left Britain in the early afternoon and arrived early morning with a full day to follow so it was an extremely long day of eating! This initial transition was difficult but after this I resumed my usual 4 injections a day regime.

Transporting insulin
A bigger problem was transporting a large amount of insulin and other diabetes supplies when restrictions, due to the threat of terrorist activity, had been placed on what liquids you could take as hand luggage. Despite my best endeavours to become intimate with the security staff at Heathrow Terminal 3, there was no other practical alternative than to put the bulk of my supplies in my luggage in the aircraft hold! Although not recommended by the manufacturers because of the low temperatures there, it was that or throw away valuable prescribed drugs. To try to ensure that my insulin did not freeze in the plane's hold I packed my diabetic supplies into a large cool bag and wrapped this with bubble wrap. I wrote a note on the outside to explain what they were to minimise the chances of the package being unwrapped in the

event of Customs officials deciding to check my roller bag. I wrapped the package in a towel and finally some clothes for insulation and protection. Fortunately my bag was never searched. When I landed in Bangkok I immediately checked my insulin bottles to check for bubbles (sign of freezing) or any damage to the bottles and transferred everything into a fridge as soon as possible . Fortunately everything went smoothly and I am still using those supplies over 4 months later without a problem!

In this report I've felt it appropriate to dwell on the practical aspects of travelling long distances as a diabetic. It's not an exciting subject but a necessary one and something I'd found it difficult getting practical information on. In my next bulletin I hope to report on something a little more exciting – the transition into rural Thai life.

IDDT Goes to Westminster...

The Trustees would like to thank you, our members, for contacting your MPs to ask them to sign Early Day Motion 535 [EDM]. Your response has been fantastic and we are very grateful for your help and continued support. Already over 80 MPs have signed the EDM and many more have written to say that they have written to Minister of Health. We are also very grateful to all the MPs who are helping us.
The Early Day Motion expresses concern for the threat to the supply of animal and human insulins by Novo Nordisk and the subsequent reduction in patient choice. It also expresses concern that many patients are being transferred to insulin analogues before the potential for carcinogenic effects of these insulins has been investigated. It calls for the National Institute of Health and Clinical Excellence (NICE) to assess the safety, clinical and cost effectiveness of all insulins to provide patients and clinicians with the necessary information so that both doctors and patients are able to make informed choices.

The Minister has informed IDDT that he has asked his officials to a draft request to NICE that they review all insulins. As we have not received further information, Adrian Sanders MP is asking a Parliamentary Question about the progress of this. It is also interesting that in one response, the Minister also refers to the Dept of Health's 'insulin strategy' - something we have been requesting for a long time. We are also following this up to find out what the strategy is and if it can be placed in the Commons Library as a public document.

We'll keep you posted but if you haven't yet written to your MP about signing the EDM, please do so, it certainly is not too late. We are happy to supply further copies of the original details, just call Jenny on 01604 622837 or if you use e-mail this will be easier for you, just contact Jenny at enquiries@iddtinternational.org

Pharmaceutical Industry Developments

Measuring blood glucose levels with a ring - OrSense Ltd, an Israeli company, is developing a ring that can measure blood sugars by tightening the skin around the finger, partly by blocking off blood flow in a similar way to blood pressure monitors. The build up of blood allows a computer chip inside the device to analyse blood glucose levels. This measurement is then transmitted to a watch-like device worn on the wrist which displays the result. Researchers have tested the ring on 27 people with diabetes and it was as accurate as conventional finger-pricking blood glucose tests.

Byetta [Exanatide] - is a new injectable drug treatment for Type 2 diabetes derived from lizard saliva of the Gila monster. It has become very popular in the US because it causes weight loss in many patients instead of the weight gain caused by many of the existing oral drugs for Type 2 diabetes. Approval in the US is for people with Type 2 diabetes who have not responded to other treatments and it has to be used twice a day along with other medications, not on its own. Byetta has now been approved in Europe but it is not expected to be available until sometime during 2007. Eli Lilly co-developed Byetta with Amylin and the companies are trying to develop a version of Byetta that can

be injected only once a week. The most common side-effect is nausea. It belongs to a class of drugs known as incretin mimetics which mimic hormones released in the gut in response to food that help to regulate blood glucose levels.

Insulin pump worn on skin - a tiny insulin pump device has been developed which can be discreetly worn on the skin. The tiny insulin pump, called the Starlet uses laser-heated wax to drive minute pumps and valves to supply the insulin.

Two lawsuits filed by Novo Nordisk - the first against Sanofi-Aventis alleging that Sanofi-Aventis' OptiClik pen has infringed patent protection covering Novo Nordisk's Flexpen and that this was a 'wilful and deliberate patent infringement'. The case should go to court during 2007. In the second case against Pfizer, Novo Nordisk claimed that inhaled insulin, Exubera, infringes patents owned by them and that Novo's future sales of their version of inhaled insulin, not expected to reach the market until 2011, will be severely hurt. However, the judge at a Manhattan court denied a request by Novo Nordisk to halt sales of Exubera on the basis that their claims were sepculative and it was not in the public interest.

EU approval for rapid acting insulin, NovoRapid, for use in pregnancy. NovoRapid has been approved for use in pregnancy in the EU. Business reports state that it is the first 'modern' to be approved for use in pregnancy - presumably means analogue insulins.

New combination drug launched in the UK for Type 2 diabetes, Oct 2006 - Competact combines into one pill two widely used drugs, metformin and pioglitazone, for the treatment of Type 2 diabetes. Competact combines the two and therefore reduces the number of pills people have to take by 700 a year. It will also reduce the cost to the NHS by £4.53 per month per patient.

Let us Create Friendly Schools for our Children with Diabetes

This is an aim of Dr.Almoutaz Alkhier Ahmed who cares for many adults and children with diabetes at his clinic in Gurayat General Hospital, Saudi Arabia. The culture and the care of children with diabetes may be different in Saudi Arabia, but Dr Ahmed's aims surely apply wherever there are children with diabetes. Here are Dr Ahmed's words:

The theme which I hope that all of us will work to apply throughout the coming year is: ***"Hand in hand we can create friendly schools for our diabetic children".***

School aged children spend around one fourth of their day time in their schools. School is not only a place for study but it is also place where the children can learn and grow.

What do we mean by friendly school?

- It is a school where the diabetic children can study and grow safely.
- It is a school where the rights of the diabetic children are completely preserved without any sense of discrimination based on their illness.

How can this objective be achieved?

- Provide social, psychological and economic support for the diabetic children at their schools.
- Provide medical support inside schools.
- Provide free access for diabetes information in these schools and work hard to raise the level of knowledge about diabetes in schools.
- Provide training classes for teachers looking after diabetic children.
- Supply diabetic children with free blood glucose monitoring devices if they have no ability to have one.

- Provide simple workshops to train diabetic children on how they can deal properly with their diabetes.
- Promote adherence to treatment through involving diabetic children in suitable entertainment events.
- Ensure that diabetic children participate normally with other non-diabetic children in all aspects of their daily life. This goal can be assessed by arranging combined campaigns between diabetic and non-diabetic children and observe diabetic children and their responses to other children.

How can diabetic children benefit from such project?
They can live safely in the friendly schools and be trained sufficiently look after themselves and be independent.

Unistik 3 Delivers Near Pain Free Blood Sampling

Owen Mumford's near pain-free Unistik 3 finger pricker became available on prescription from March 1st 2007. The Unistik 3 finger pricker is said to make the task of taking regular blood samples for testing blood glucose levels, easier and virtually pain free.

It is a single use disposable lancet that features Comfort Zone Technology which is a series of eight raised dots that when pressed against the skin on the finger sends a message of comfort to the brain masking the feeling of pain caused by the penetrating lancet. It is also very simple to use with the lancet pre-loaded and hidden from view at all times. The lancet automatically retracts when fired eliminating any risk of accidental needle stick injuries. A fresh Unistik 3 is used for each new test.

To take a blood sample you twist off a protective cap, place the Comfort Zone platform against the finger and press the release button. The needle automatically retracts making for safe disposal. Unistik 3 is very small. The protective cap keeps the lancet sterile and the lancet remains hidden inside the body of the device until used, retracting automatically when fired.

Unistik 3 Comfort Zone Technology works on the Gate Theory proposed by doctors Melzack and Wall in their book The challenge of pain (Penguin, Harmondsworth 1982). Stimuli to the brain are controlled through gates in the dorsal horn of the spinal cord. When non-painful stimuli are sent to the brain a gate is opened to allow them through. As one gate is opened, another is closed thus preventing painful stimuli being experienced.

Owen Mumford offers three variants of Unistik 3 on prescription Comfort, Normal and Extra suitable for all skin types and tests. Unistik 3 can also be purchased directly from Owen Mumford.
For more information visit www.owenmumford.com or www.unistik3.com

Apologies

Alertacall
Apologies for the omitting two digits from the phone number of Alertacall, the telephone alarm service for people who live alone. The correct telephone number for enquiries and application forms is 0808 156 5777 or you can phone IDDT on 01604 622837. Remember there is a discount if joining through IDDT - just quote 'diabetes 1' or 'iddt 1'.

And Another Apology!
We are really sorry that page 3 of the report on IDDT's Annual Meeting was repeated on page 4. This was due to circumstances beyond IDDT's control. A 'proper' copy is included for UK members and further copies are available by calling IDDT on 01604 622837 or e-mail enquires@iddtinternational.org

Snippets...

Debt-hit NHS removes light bulbs
About 40 light bulbs have been taken down in hospital corridors at Epsom and St Helier hospitals to help the debt-ridden NHS trust save money. It needs to save £24m over 18 months. It said some bulbs had been removed from corridors and communal areas and no clinical areas were affected. The trust's annual electric bill is £3m. Tom Brake MP said the "crazy" move would be funny were it not so serious. He said: "If our hospitals are scrimping money on light bulbs, how can they afford the latest drugs and high quality patient care?"

Implants act as airbags
A car crash victim in Bulgaria was saved by her 40DD breast implants which acted as an airbag to absorb the impact of a head on collision!

More money is spent on makeup than on health
The President of the British Osteopathic Association [BOA] launching National Back Care Week in 2006 said that people are spending more time and money on looking good than on tackling a back or joint problem. The results of a BOA survey showed that 31% of respondents would act more quickly to put right a bad hair cut or broken nail compared with 10% who said that a muscular or joint problem take priority.

Healthy Coke - can you believe it?
According to a US report [Beverage Digest, Dec 8 2006] Coca Cola plans to launch a new version of Diet Coke that is fortified with vitamins and minerals. Diet Coke Plus will be the first 'nutrient-enhanced' carbonated soda to be offered by a major brand. In the first nine months of 2006, Diet Coke's sales, excluding Wal-Mart, dropped 3 percent, in spite of increased spending on adverts. So what do they do? Add apparently healthy ingredients to a drink that is laden with artificial sweeteners! The report also stated that Pepsi plans on introducing a new line of enhanced carbonated drinks called "Tava."

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

IDDT
PO Box 294
Northampton
NN1 4XS

Name: _____

Address: _____

_____

Postcode: _____

Tel No: _____

From Your Editor – Jenny Hirst

IDDT welcomes the submission of letters and editorial articles for consideration of publication in future issues of the IDDT Newsletter. The editor and trustees do not necessarily endorse any opinions or content expressed by contributors and reserve the right to refuse, alter or edit any submission before publication. No part of this publication may be reproduced in any form without the prior written permission of the editor.

Insulin Dependent Diabetes Trust
PO Box 294
Northampton
NN1 4XS

tel: 01604 622837
fax: 01604 622838
e-mail: support@iddtinternational.org
website: www.iddtinternational.org