Insulin Dependent Diabetes Trust

April 2008 Newsletter

Registered Charity No 1058284 - Issue No 56

Does Informed Choice Exist in Diabetes?

I apologise for the front page of this Newsletter devoting itself yet again to the message that pork insulin is still available, but IDDT's experiences over the last 3 months have shocked, surprised and dismayed us.

At the end of 2007 Novo Nordisk discontinued supplying pork insulin in the UK. We expected there to be some people who were not aware of this, some misinformation and some people to panic at the thought of changing their brand of pork insulin. In all honesty, we thought that this could be seen as an opportunity to change people to GM synthetic insulins – namely insulin analogues described by Novo Nordisk with the meaningless term of 'modern insulin'.

But we hoped that we would not see a repeat of the 1980s where people were told that all animal insulins had been discontinued so forcing them to change to GM synthetic insulin. We were wrong! Across the country, some consultants, GPs, specialist nurses and pharmacists have told their patients that animal insulins [both pork and beef] are no longer available and they will have to change to insulin analogues. IDDT has been inundated with calls from people desperate to know how to get hold of pork and even beef insulin! To be fair, we have also received calls from health professionals wanting to know how to get hold of pork insulin.

IDDT has long held the view that people with diabetes are not receiving an informed choice of treatment, not only about their insulin options but also about dietary choices. This apparent dearth of information about the availability of pork and beef insulins would suggest that this is true.

We will continue our advertising campaign through local newspapers to try to reach people with diabetes to inform them of their insulin choices. This is important for people who are not informed of the continued availability of pork and beef insulin from Wockhardt UK but also for people who experience adverse reactions to human and analogue insulins – they need to know that animal insulins are an option for them to try.

Is there a plus in all this? Yes - IDDT's membership has grown significantly!

It is only Novo Nordisk that has chosen to discontinue pork insulin. Wockhardt UK [CP Pharmaceuticals] pork insulin will continue to be available in vials and cartridges. This chart shows Wockhardt equivalent pork insulins:

Wockhardt Pork insulin	Novo Nordisk Pork insulin
Hypurin Porcine Neutral	Pork Actrapid
Hypurin Porcine Isophane	Pork Insulatard
Hypurin Porcine 30/70 Mix	Pork Mixtard

Germany Refuses to Fund Rapid-Acting Insulin Analogues for Type 1 Diabetes

In February 2008, the joint commission of healthcare insurers and physicians G-BA (Gemeinsamer Bundesausschuss), recommended that rapid-acting insulin analogues for Type 1 diabetes will not be paid for by the public health insurers if they remain more expensive than human insulin. The G-BA has made exceptions for some patients eg for those who are allergic to human insulin and those who had not achieved glycaemia control with human insulin in the past and for whom this can be achieved by rapid-acting insulin analogues. These exceptions will apply to all groups with Type 1 diabetes – children, teenagers and adults.

The insulins that are affected are: NovoRapid [aspart], Humalog [lispro] and Apidra [glulisine] which are a third more expensive than human insulin.

The recommendation is the result of a review of all the available research by the German Institute for Quality and Efficiency (IQWiG) which is equivalent to NICE in the UK. The German Ministry of Health will decide upon the recommendation. In 2006 IQWiG found similar results for the use of rapid-acting analogues for Type 2 diabetes and the German Dept of Health accepted the G-BA recommendations not to fund rapid-acting insulin analogues.
In the press release, the neutral chairman of the G-BA stated: *"Human insulin as a treatment of patients with type 1 diabetes is in every case just as suitable and just as effective as a rapid-acting insulin analogue". He sees the decision, including the exemptions, as allowing the best possible treatment to all patients with "only a price-based restriction".*

Drug company reactions!
As could be expected, they oppose the recommendation and have 60 days to make their case against it.

- Sanofi-Aventis said the recommendation is 'highly irresponsible'.
- Novo Nordisk said it 'showed that economic efficiency is more important than the quality of modern treatment' and also criticised the quality of the information upon which the G-BA based its decision saying:'The evaluation of the medicine was based on only a handful of scientific studies and differs considerably from the methods and results in comparable countries'.

Are there answers to these criticisms?

- **Irresponsible?** The evidence from research shows that rapid-acting insulin analogues are not superior to human insulin for the majority of people but they are a third more expensive, so surely the

G-BA is being very responsible in not wasting resiurces on insulins that have no additional benefits? Quote the G-BA Chairman: 'It is ensuring the long-term financial viability of essential medicinal care by the statutory healthcare insurers.'

- **Quality of modern treatment?** Again, the answer to this one is that the research has not shown treatment with insulin analogues to be superior – just being 'modern' doesn't make it superior.
- **The evaluation was only based on a handful of studies?** Novo Nordisk was singled out for criticism by the head of IQWiG, Peter Sawicki, at the G-BA presentation as he repeated accusations made in 2007, that the firm had refused to release study data for the evaluation. Referring to two long-term studies with children and teenagers which Novo Nordisk had financed, the IQWiG report said that "Novo Nordisk was not prepared - as opposed to the producers Sanofi and Lilly - to put up the necessary information to our disposal." So why did Novo Nordisk refuse to release information to IQWiG? If they have evidence that insulin analogues are superior in children and teenagers, then surely it would be in their interests to supply it to IQWiG?

Can the decision be justified?

- Yes, according to the G-BA as it stated that it had thoroughly considered whether a justification for a higher price for the recombinant insulin analogue could be supported by scientific research. "Such proof has not been supplied by the pharmaceutical industry, although analogue insulin has been on the market for over ten years".
- Yes, according to Professor Edwin Gale in his article 'Nice insulins, pity about the evidence' [Diabetologia (2007) 50:1783-1790]. Professor Edwin Gale also demonstrated that there was no evidence of benefit of treatment with insulin analogues for the majority and questioned the justification for the extra expenditure when services for people with diabetes are lacking.
- Yes, according to IDDT's report ,"30 years of synthetic insulins, are people getting the best deal?" It showed that there is insufficient evidence of benefit to warrant the extra NHS funds on insulin analogues and highighted that the long-term safety of insulin analogues has yet to be established. This money would be better spent on patient education or supplying needed blood glucose test strips. [A copy of the report is available from IDDT and we also have available a German version]

It is for these reasons that IDDT has continually lobbied for NICE to assess the use of all insulins for their clinical use, their safety and their cost effectiveness. Wasting resources on expensive insulins with no proven benefit, while at the same time arguing for better education and services for children with diabetes, lacks logic, reason and just plain common sense!

An analogy... IDDT received this analogy from someone with diabetes, it should set us all thinking!

- I do expect my government to pay for clean drinking water.
- I do not expect my government to pay for Perrier mineral water (because it is a luxury item etc).
- I do want Perrier to be available, so I can purchase it if I want.

So IF one sees analogues in a similar light,…..

- I do expect my government to pay for human non-analogues.
- I do not expect my government to pay for analogues if they are more expensive than human non-analogues
- I do want (more expensive) analogues to be available, so I can purchase them if I want.

But then I only use on average 4 units Humalog/ Novorapid a day because I follow a lower carb regime! So the costs would be very low if I had to pay full price!

And think what could be done with all the extra money being allocated to analogues, in both the developed and developing countries!

Diabetes and Coeliac Disease

Gluten consumption may be a shared cause of the development of Type 1 diabetes and Coeliac disease
This paper [Med Hypotheses Feb 2008] puts forward the idea that the increasing incidence of Type 1 diabetes and the increase in Coeliac disease could be triggered, directly or indirectly, by the increased intake of gluten in food products.

It is believed that enterovirus infections can trigger Type 1 diabetes. Gluten is the trigger for Coeliac disease. It has been shown that the duration of exposure to gluten is related to the prevalence of Type 1 diabetes and that people with Type 1 diabetes have an inflammatory reaction in the gut at diagnosis. So the Swedish authors of the paper are suggesting that gluten consumption could be a common cause for both Type 1 diabetes and Coeliac disease. They suggest that early diagnosis of Coeliac disease followed by a gluten-free diet could lead to a reduction in the incidence of Type 1 diabetes.

So what is coeliac disease?
It is a condition in which the lining of the small intestine is damaged by gluten, a protein found in rye, wheat, barley and oats. This damage causes foods to not be absorbed properly by the small intestine and so before diagnosis there is weight loss and possibly malnutrition. However, many cases remain undiagnosed, often referred to as silent celiac disease, or may be falsely diagnosed as irritable bowel syndrome. Only a third of cases are ever diagnosed as coeliac disease and treated with a gluten free diet.

There is a growing belief that all children and adults with Type 1 diabetes should be screened to detect coeliac disease as:

Research in Finland has shown that:

- only 24% of 300 people with coeliac disease had classic symptoms,
- 36% had minor symptoms,
- 27% were diagnosed with associated diseases and 13% by chance.
- 51% had another autoimmune disease with 16% of this group having diabetes.

[Coeliac Disease and Type 1 diabetes – the case for screening. Diab Med 2001;19]

Research in Oxford in 67 children and young people with diabetes who had antibody tests for coeliac disease showed that 11 were antibody positive. Of this 11:

- only 1 had coeliac disease symptoms,
- 4 had a history of gastro-intestinal problems but not severe enough to seek medical advice.
- 6 showed no symptoms at all.
- 9 of this group of 11 agreed to a biopsy and 8 of them had typical coeliac features of the small bowel. All were treated with a gluten-free diet and were symptom free up to 2 years later.

This study showed that a high percentage of these youngsters with diabetes had coeliac disease but the majority of them did not show the classic symptoms. [Coeliac Disease in Children and Adolescents with IDDM. D.B.Dunger et al. Diab Med, Vol 15: 38-44]

Research published in Diabetolgia also showed that in 491 people with Type 1 diabetes there was a high presence of undiagnosed coeliac disease [5.9%] and it was also higher than normal in their first degree relatives [1.9%]. The study also looked at 4000 healthy people and their rate of undiagnosed coeliac disease was only 0.25% adding weight to the view that adults and children with Type 1 diabetes should be routinely screened for coeliac disease. [Diabetolgia 2001;44:151-155]

Good News for people with coeliac disease and lactose intolerance
Some people with coeliac disease also develop lactose intolerance which occurs when there is a shortage of lactase. Lactase is an

enzyme needed to break down lactose [a sugar found naturally in milk] into more digestible sugars which are easily absorbed into the bloodstream.

It is widely believed that people with lactose intolerance cannot eat cheese because cheese is made from milk. But traditionally-made British hard cheeses such as Cheshire, Cheddar, Wensleydale, Lancashire and Red Leicester, are safe to eat because nearly all the lactose naturally found in milk is removed in the whey during the cheese making process.

Dietary control of lactose intolerance is individual and depends on people learning through trial and error how much lactose they can tolerate. If you have been avoiding cheese due to lactose intolerance and want to try eating the hard cheeses, then try little bits first. Cheese is a good source of calcium, needed for healthy bones, and also contains protein, vitamins and other minerals but it does contain fat. If you would like further information about British cheeses visit www.cheeseboard.co.uk

NOTE: If you would further information about Coeliac disease, contact IDDT for a free leaflet 'Coeliac Disease and Diabetes' on 01604 622837 or e-mail enquiries@iddtinternational.org

Counting the Clicks - Has Anyone got an Answer?

We were recently contacted on behalf of someone with diabetes who is partially sighted who uses an insulin pen but cannot see the figures so has to use the clicking device on the pen to dial up his dose. His clinic have supplied him with a I unit pen. However, he has over 60 units per dose and sometimes has difficulty remembering how many clicks he has counted. And as many of us older folk know, the more you think about how many you've counted, the less sure you become. Naturally this gentleman is worried that he is either going to over or under dose.

Other than holding the pen under a desk magnifier or drawing up with a syringe and magnifier, we can't find anything available to help. So we wondered if our readers had any ideas in how to solve this problem. If you can be of any help, please contact Jenny, telephone 01604 622837 0r e-mail enquiries@iddtinternational.org

Why smaller Shots of Insulin get Absorbed Faster, Peak Sooner and are out of Your System Quicker

By Scott King, Editor-in-Chief, Diabetes Health

I want to share an important lesson I learned about twenty years ago from Peggy Wong at the UCSF Diabetes Teaching Center. It concerns how long insulin lasts after you push down that plunger and create a "depot" of insulin under your skin.

We know a shot of insulin does not make a perfect sphere when injected, but it does create a pool of insulin in the subcutaneous tissue that approximates a ball or sphere. After the insulin is injected, it starts to be absorbed by the tissue it actually contacts. As you will see from the formulas and examples below, the larger the shot, the more time it takes to be absorbed by your body.

In the chart below, we have calculated the volume and surface area for seven differented sized injections. You might remember from a past math class that the radius of a sphere is the distance from the center to the surface of the sphere. The chart shows that as the radius grows, the amount of surface area in relation to the volume gets smaller and smaller.

For example, lets say you test your blood sugar and it is 12mmols/l

[220mg/dl in the US]. You decide you need 4 units of insulin to bring it back to 5.5mmols/l [100mg/dl]. Let's look at the chart to see the difference between taking one shot of 4 units versus taking four shots of 1 unit. Both provide equal amounts of insulin.

With the 4-unit shot, there is only approximately 0.6mm of surface area available for the insulin to 'escape' into the surrounding tissue. With 4 shots of 1unit each, there is actually 0.96mm surface area – about 50% more!

So which one do you think is going to hit the blood faster? Yes, the one with the most surface area. In fact, I have had healthcare pros recommend splitting up a dose like this to get a high blood sugar down. And one of the syringe makers once explored the possibility of making a 'sprinkler' syringe in which the insulin would come out of holes up and down the shaft of the needle, creating many small depots and therefore, faster absorption.

Units of insulin [1 unit of insulin is .01ml]	Surface area in mm squared
1	0.24
2	0.38
4	0.60
8	0.95
16	1.52
32	2.41
64	3.82

Looking at the chart, you can see that as the shot gets larger, there is less and less surface area as compared to the volume of the shot. This forces the insulin to wait longer to be absorbed, because the insulin molecules in the middle of the injected ball won't come into contact with the tissue until the insulin molecules surrounding them get absorbed first.

Another problem with the large shots is variability in absorption. The larger the injected ball of insulin, the longer it will be there, and, therefore, the more unpredictable it becomes. Absorption is affected by body movement, which can hasten absorption, and by changing temperatures, both within the body and in the environment outside the body. Hot tubs, for instance, speed up absorption. If you get into a hot tub after taking a large shot, more insulin is mobilized by the heat than would be after a small shot.

I feel that all insulin users should try to understand as much as they can about this powerful, wonderful, lifesaving drug. So it is crucial to understand the mechanics of how insulin is absorbed. I hope this little math lesson helps.

About Scott: *Scott has had Type 1 diabetes for many years, follows a low carbohydrate diet and has edited a magazine called 'Diabetes Health' for many years. Scott started the magazine as 'Diabetes Interview' for much the same reasons as the IDDT Newsletter – much of the information around at the time did not take into account the experiences of people who actually live with diabetes and was written by doctors in medical language. Scott has given IDDT permission to publish his article from the November 2007 edition of Diabetes Health.*

A couple more reminders about injections...
Injecting in your arms
A picture in an American publication showed the insulin injection being into the front of the arm and following edition pointed out that this is incorrect. The bicep muscle is in the front of the arm and insulin must not be injected into muscle. So if you inject in your arms, it must be given into the skin at the back of the arm.

Mixing up your insulins
Occasionally mistakes happen and people give, or are given, short/rapid-acting insulin instead of long-acting insulin or vice versa. With animal and human insulins the short-acting insulin is clear and long-acting insulin is milky but both rapid-acting and long-acting insulin analogues are clear making mistakes more likely. IDDT joins with

Diabetes Health in the US in calling on the three insulin companies to make changes to the vials or cartridges so that the difference between short/rapid-acting and long-acting insulins is more obvious – a bright red label or red metal cap. If people mix up their statin with their blood pressure pills the odd time, it is not life threatening but giving the wrong dose of the wrong insulin is dangerous and can be life threatening. There must be a better way for insulin manufacturers to keep people safe.

Tight Glucose Control of Type 2 Diabetes - Study Stopped Early

The US National Heart, Lung and Blood Institute has stopped the intensive glucose lowering part of a large, major clinical trial of people with Type 2 diabetes and cardiovascular disease after more patients died than in the standard treatment group. The ACCORD study [Action to Control Cardiovascular Risk in Diabetes] was designed to find out whether intensively lowering blood sugars would reduce the risk of heart attack, stroke or death in people with Type 2 diabetes who had two or more additional risk factors for heart disease or who already had heart disease.

The trial found that intensively lowering blood glucose levels to below the recommended level [HbA1cs of less than 6%] increased the risk of death compared to standard, less intensive treatment of HbA1cs of 7 to7.9%. There were 10,251 participants and over an average of 4 years, 257 in the intensive treatment group died compared with 203 in the standard treatment group. The findings also showed that 10% less heart attacks and strokes occurred but when they did, they were more likely to be fatal.

Most of the participants in the intensive treatment group were treated with combinations of approved diabetes medications including insulin.

The Data and Safety Monitoring Board, the independent group monitoring the trial, recommended that it was stopped when it found that more deaths occurred in the intensive treatment group. The study participants receiving intensive blood glucose lowering treatment will now receive less intensive treatment.

The researchers were surprised by the higher number of deaths. They don't know the reasons so far but say it could be due to the adverse effects of lowering blood sugars too far in older people with heart disease or the adverse effects of a particular drug or drug combination.

Interim results from another study [ADVANCE] comparing intensive glucose lowering treatment with less intensive treatment in more than 11,000 people with Type 2 diabetes and a high risk of heart disease, show no increased mortality in the intensively treated group. Nevertheless, Professor Holman at the University of Oxford said that the results of the ACCORD study have to be taken seriously.

Standard targets for blood glucose control are still important
There have been misleading press reports about the stopping of this study. It is important to recognise that the study participants were included in the ACCORD trial because they were at especially high risk of heart disease – greater risk than is associated with diabetes alone.

Nevertheless, the study showed that aiming for 'normal' blood glucose levels of 6% or less in people with Type 2 diabetes at high risk of cardiovascular disease increased the risk of death. It OweveHow

remains unclear whether the ACCORD findings apply to people recently diagnosed or those whose cardiovascular risk is lower than those people studied in ACCORD so the presently higher recommended HbA1c target levels for Type 2 diabetes should continue to apply and should not be lowered.

Pharmaceutical Industry Under Investigations

Pharma companies investigated over suspected illegal bribes to Iraq

At the beginning of January this year many pharmaceutical companies hit the headlines as part of the UK Serious Fraud Office [SFO] investigation into alleged illegal bribes paid to Saddam Hussein's Iraq regime. The SFO have confirmed that the number of pharmaceutical companies being investigated runs into 'double figures' three of which have confirmed that they have received 'Section 2' notices with requests to supply documents relating to their participation in the United Nation's Oil for Food programme.

The UN's Oil for Food programme was established in 1996 so that Iraq could sell its oil while ensuring that the proceeds went only to providing humanitarian goods and services such as food and medicine. In 2000 the Iraqi government began to require payments from companies in exchange for contracts to sell humanitarian goods –often referred to as 'after sales services fees'. When the scheme closed in 2003 the Iraqi government had received almost $2billion from over 2,000 companies. While some companies have already admitted paying illegal fees, others such as AstraZenica and Novo Nordisk are strongly denying any wrongdoing although the report lists them as having paid $1.5million in so-called 'after sales services fees'.

Major probe into the pharmaceutical industry by the European Commission

Hot on the heels of the UK's Serious Fraud Office's investigation, the pharmaceutical industry is facing another blow to its image. The European Commission launched an investigation into the entire European pharmaceutical industry with unannounced inspections over a two day period of a number of leading drug companies to try to find evidence of incriminating documents showing hampering new medicines reaching the market. The aim of the EC is to expose any evidence of anti-competitive behaviour - the first time it has carried out completely unexpected and unannounced raids on pharma companies.

So what's it all about?

There has been a significant drop in the number of 'novel' new medicines reaching the European market over recent years. From 1995 to 1999 an average of 40 novel new drugs were launched each year but between 2000 and 2004 this dropped to an average of only 28. A similar situation has applied to generic medicines.

The EC is suspicious that companies have made agreements, settlements or contracts with each other to slow down new drugs and cheaper generic medicines reaching the market so maintaining prices and increasing profits. Distortion of the market by anti-competitive arrangements infringes EC regulations. A final report is due in 2009.

Adverse Drug Reactions - Surprising Facts

Just three drugs alone account for a third of all adverse reaction reports in the US

Just three drugs accounted for 59,000 of the 177,000 reported adverse drug reaction reports among older patients across the US - warfarin, insulin and digoxin. Scientists think that even small changes to prescriptions and the way the drugs are monitored would reduce the numbers of people suffering these adverse effects. [Ann Intern Med,2007;147]

Hypoglycaemia, resulting in seizures or loss of consciousness, was the most common reaction to insulin. This reminds us that good control is the avoidance of hypoglycaemia as well as avoidance of hyperglycaemia but newer insulins and different regimes do not appear to have improved this situation.

Recreational drugs are killing far less people than prescribed drugs

A separate report from the US pointed out that recreational drugs, including cocaine and heroine, are responsible for 10,000 – 20,000

deaths per year in the US but:

- an estimated 106,000 hospitalised patients die each year from drugs which are properly prescribed and administered according to medical standards and more than 2 million suffer serious adverse effects [JAMA 1998;279:1200]. Adverse reactions to correctly prescribed drugs are the fourth leading cause of death in the US. [Newsweek, April 27, 1998]
- From 1998 to 2005 reported serious adverse drug events increased 2.6 fold and fatal adverse drug events increased 2.7 fold. [Archives of Internal Medicine 2007;167:1752-1759]
- 86% of adverse drug reactions for which people were admitted to intensive care units were preventable. [American Journal of Health-System pharmacy 2007;64(17):1840-1843]

While there are some major differences between the US and the UK health systems and more drugs are prescribed in the US probably influenced by direct-to-consumer-advertising of prescription drugs being allowed, these figures act as a stark reminder that all drugs have side effects that can affect some people.

Headlines in the UK – drug reactions 'kill thousands'
UK official figures from the 'Yellow Card Scheme' run by the Medicines and Healthcare products Regulatory Authority [MHRA], show that almost 3,000 people have died in the past three years after suffering serious adverse effects or allergies to their medicines and over 13,000 had an adverse drug reaction but survived with hospital treatment.

A study published last year suggested that 6.5% of all patients admitted to hospital had experienced a reaction, and that in 4 out of 5 cases medicines they were taking were to blame. This adds up to as many as 250,000 cases a year with an annual cost to the NHS of £466 million. The Liberal Democrats are calling for a 'full investigation' into this issue.

The Dept of Health [MHRA] has launched a campaign to encourage patients and pharmacists to report adverse drug reactions as follows:

If you have access to the internet go to www.yellowcard.gov.uk and CLICK on submit a Yellow Card report. Paper Yellow Card can be obtained from your GP, Pharmacist, by telephoning the MHRA on 0207 084 2000 or e-mail patientreporting@mhra.gsi.gov.uk

What the Papers Say

Evening Chronicle, Newcastle, 14.12.07
Alison Blackburn, who registered blind 8 years ago was awarded a four figure sum at Newcastle Crown Court after it found that Diabetes UK was in breach of the Disability Discrimination Act [DDA]. Alison took action under the DDA after the charity could not supply her with information in braille or large print.

Alison is a former nurse, Chairwoman of Newcastle Disability Forum and a member of the Dept of Health retinal screening advisory committee. She told reporters that she has been a staunch supporter of Diabetes UK and this was not about money but about the principle: *"I've made legal history with this case and the best thing that has happened is that Diabetes UK have said that they will get better – that's all I've ever wanted."*

Swiss Newspaper, Der Bund, headlines, 14.1.08
"A professor incriminates human insulin. Human insulin may cause traffic accidents; the Bernese diabetes expert, Professor Arthur Teuscher, fights for animal insulin."
This was the headlines after a court case following a driving accident involving a man with diabetes who went hypo at the wheel. Here's what Professor Teuscher had to say:

"Diabetic drivers increasingly inform me about unexpected complete lack of hypoglycaemic symptoms on synthetic "human" insulin or

analogues. That may lead to severe traffic accidents. My advice is: get beef / porcine insulin which is still available.

On 4th December 2007 the superior judge at trial in Interlaken came to the conclusion the driver is not guilty: He was not aware of any hypoglycaemic symptoms while speeding at 80 kilometers through the tunnel zig-zagging and crashing into an oncoming car, leaving an invalid couple."

Note: Don't forget that Professor Teuscher's book Insulin 'Insulin – A Voice for Choice' can be purchased from IDDT at £13.50 incl p&p. For your copy, contact IDDT, PO Box 294, Northampton NN1 4XS, Tel 01604 622837 or e-mail enquiries@iddtinternational.org

Medical Shop - New Look Catalogue and Website

Owen Mumford's Medical Shop has launched a new catalogue and website. Medical Shop's new catalogue shows products designed to make life easier for people with diabetes. Medical Shop's website is www.medicalshop.co.uk and the online ordering system promises that goods are received within three working days. The new FREE catalogue can be obtained by calling 0800 731 6959.

Government to Fund Islet Cell Transplants

The NHS is to make islet cell transplantations available to people with Type 1 diabetes who have lost their warning symptoms of hypoglycaemia. The government is allocating £2.34 million in islet transplant services in the first year, increasing to a maximum of £7.32. It is expected that about 20 transplants will take place building up to about 80 people in 6 centres across the UK.

To date 12 islet cell transplants have taken place in the UK as part of a research programme in which islet cells from the pancreas of a dead donor are injected into the liver of the person with diabetes. Developed in Canada, about 50 transplants have taken place and while many of the people have not remained insulin free over time, they have required less insulin with fewer and less severe hypos. Islet cell transplantation means taking immunosuppressant drugs for life but equally hypoglycaemia without warnings can ruin people's quality of life.

Apparently hypoglycaemia now costs the NHS £15 million a year in hospitalisations and ambulances, so perhaps it is time that the overall problem of hypoglycaemia is addressed more fully as modern treatments do not seem to have reduced this problem.

Islet transplantation is not as new as we thought
In the 1960s Paul E Lacey began research into islet transplantation and published the primary method of processing islets from the pancreas of small animals. In the 1970s, he began working with rodent models to show how transplanted islets could eliminate diabetes and did the first successful transplant in 1972. During the following years, he applied the same principles to dogs and monkeys and also tried to develop a way of eliminating the need for life long immunosuppression drugs. In 1989 Lacey and his colleague carried out the first islet transplant that enabled the patient to stop insulin injections.

Pig islet cell transplants
One of the problems with transplanting human islet cells is the shortage of donor organs so the possibility of using pig islet cells is exciting. Transplantation of organs or cells from animals to humans [xenotransplantation] is not allowed in the UK for ethical reasons.

A 41year old man had the pig cells injected into his abdomen in 1996 and his insulin requirements were reduced by 34% for a year. [Xenotransplantation, March 29, 2007] In 2006 tests, only recently available, showed that the insulin in the man's blood was pig insulin,

not human insulin. The company hopes to conduct small scale clinical trials in the coming months.

Rejection – a major concern is the rejection of the pig cells by the human immune system but a recent development seems to make this a step nearer - alginate, an ingredient in seaweed, has been used to envelope the pig cells so that the immune system does not destroy them.

Other researchers at Minnesota University who have successfully transplanted islet cells from pigs into diabetic monkeys, have developed a special combination of drugs. This would have severe side effects in human beings, so still needs to be refined. Trials in humans are expected to start in 2010. [Nature Medicine, Feb 2006] 'Biosecure' pigs are being raised by a non-profit organisation, the Spring Point Project, in ultra clean conditions at a cost of $36,000 per pig for two years. The pigs are given special food, drink purified water and breathe filtered air. The Project is asking for donations under its Sponsor a Pig Programme! More information available at www.springpointproject.org

IDDT News

IDDT Annual Meeting
Sorry I got the date wrong in the January Newsletter! IDDT's Annual Meeting will take place on Saturday, October 11th 2008 at the Paragon Hotel in Birmingham. And just to keep you guessing the title of the meeting is 'Half full or half empty?'

IDDT has produced two new Information leaflets:
Osteoporosis – is there a link with diabetes?
Sexual dysfunction in men and women

If you would like copies of these new leaflets, publication list or any of our other leaflets, please contact IDDT, PO Box 294, Northampton NN1 4XS, Telephone 01604 622837, or e-mail enquiries@iddtinternational.org

Apologies for the error

Sorry about the error in the January 2008 Newsletter about IDDT membership cards. Of course it should have read that the back of the card says:

"I have diabetes. If I am disorientated or unconscious, please call an ambulance on 999". I assure you that this is what the card actually says!

Delay in the report about insulin analogues and their carcinogenic risks.
In the January meeting we promised the report on this meeting in Germany but it is delayed until its publication in a medical journal.

Confused messages!
IDDT had a stand at the Education show for teachers manned by Bev Freeman. All stands have 'give aways' to attract people, in our case IDDT stick on 'fluffy bugs'. On the next stand Diabetes UK were giving away packs of jelly beans. Not only was Bev confused about the message this gives out and why they would do such a thing, but so were some of the teachers!

For our American Members

Several of our American members who import pork or beef insulin from Wockhardt UK have contacted IDDT about a new, more stringent form which Wockhardt require to be signed by their doctors. This new demand from Wockhardt is more than the FDA require. The forms, which only apply to America, will make personal importation almost

impossible for some people, especially those who already have difficulty in finding doctors who will issue prescriptions for UK animal insulin.

IDDT has written to Wockhardt asking them to explain and re-think this new policy. People who are unable to tolerate GM human and analogue insulins will suffer without the animal insulin they need. We await a response and will post it on our website when it arrives.

Should I Take Statins?

IDDT receives many queries from people with diabetes about statins. The first question is whether to take or not to take statins, especially when cholesterol levels are normal. The second is about the side effects – tiredness, muscle pains and generally feeling unwell are the most common ones reported to IDDT. The third and worrying reports are from people with normal cholesterol and blood pressure levels who feel their doctors pressurise them to take statins by threats of all sorts of complications if they don't.

Dept of Health meets targets
In February 2008, the Dept of Health announced that they had met the targets 5 years early for reducing deaths from cardiovascular disease [CVD] by 40% in people under the age of 75. This was put down to:

- improvements in speed of treating thrombosis after calls for help – in 2001 24% of people received treatment within an hour and this has now increased to 70% and
- to the doubling of prescriptions for statins.

Undoubtedly there is evidence that statins reduce cholesterol levels and the risk of heart disease and stroke in the general population – the reason the government made one of the low dose statins available to the public as a non-prescription drug. But this policy was controversial as some doctors' organisations held the view that cholesterol levels can be just as effectively reduced in many people with a healthy diet and plenty of exercise. They were also concerned about their possible side effects but despite this, statin therapy for people in their mid-life has almost become 'the norm'.

It also became the norm for people with diabetes but only one study [CARDS] looked specifically at statin use in people with diabetes.

It cannot be assumed from one study that people with diabetes will react to statins in the same way as the non-diabetic population. Equally, it can't be assumed that statins will have the same effects in people with Type and Type 2 diabetes or that they are beneficial in people with diabetes without vascular or heart problems.

So researchers in the UK and Australia carried a meta-analysis of 18,686 people with diabetes [1,466 Type 1 and 17,220 Type 2] and 71,370 people without diabetes and tracked any lowering of mortality rates that could be attributed to a reduction in LDL [bad] cholesterol levels for 4.3 years. [Lancet, Jan 12, Vol.371, p.117-125]

The results showed:
- an overall 20% reduction in their risk of stroke or heart disease. This translates into 42 fewer deaths per 1000 of people with diabetes treated with statins compared to those who were not. Another way of putting this is that for every 1000 people with diabetes treated with statins for 5 years, there will be 42 less major vascular events.
- Statins had a beneficial effect on all people with diabetes no matter what cholesterol levels, their age, sex or previous history of cardiovascular disease.
- The effects of statins were the same in people with Type 1 and Type 2 diabetes. However, the researchers note that there were so few people with Type 1 in the study, this was 'at the limit of significance' which means that the evidence is not very robust and with larger numbers of people with Type 1, the results could have been different.

- Each reduction of 1 mmol/l of LDL-cholesterol was associated with a reduction of 9% in all cause mortality and of 21% in major vascular events eg heart attacks and strokes. There was no lower limit below which there would be no benefit.

Researchers' recommendations:

- Statins should be offered to most people with diabetes regardless of their age, sex or cardiovascular health and history with the exception those at low risk such as of children with Type 1 diabetes and certain contraindications for the use of statins eg pregnancy.
- Significantly, this study shows that it is the size of the reduction in LDL cholesterol levels that is important in preventing hearts disease and stroke, whereas the present object of statin treatment is to reach a specific target level of cholesterol, so the
- researchers recommend that the guidelines for statin use may need to be reviewed.

Presumably this means the NHS may have to change its targets for GPs as they presently treat to targets of total cholesterol equal to or less than 4.0mmols/l, LDL [bad cholesterol] 2.0, HDL [good cholesterol] equal to or greater than one 1.0 or an LDL reduction of 30%.

Does this study still leave unanswered questions?

Yes, I am afraid that it does, especially for people with Type 1 diabetes.

- The evidence from this study for the use of statins in Type 1 diabetes is not overwhelming, so should statins be used routinely in people with Type 1 diabetes or not, especially if cholesterol levels are normal? If so, at what age should statins be prescribed?
- The study says statins should not be used in children with Type 1 diabetes because they are low risk but at what age do they become high risk to take statins?
- Are statins any more effective at reducing cholesterol than strict diet and plenty of exercise for Type 1 and /or Type 2 diabetes?
- All drugs have side effects in some people, do we know how many people have side effects that affect their quality of life?
- GPs are treating cholesterol to target levels according to NHS guidelines, will this change as a result of this large, long-term study?

So what's the answer to the original question of 'Should I take statins?'

The researchers recommend that virtually everyone with diabetes should be offered statins. This means that you have a choice. As it is the size of reduction in cholesterol levels that is important, not your actual cholesterol level, you may prefer to try lifestyle changes before trying statins - health eating, regular exercise and stopping smoking.

A new study offers an explanation for the adverse effects of statins

Statins can result in muscle weakness and pain and rarely debilitating and life-threatening muscle damage. A new study suggests that a gene, known as atrogin –1 plays a key role in statin related muscle toxicity. Statins lower cholesterol by inhibiting a key enzyme used in cholesterol synthesis [HMG-CoA reductase] but statins may also activate the gene atrogen-1 which plays a key part in muscle atrophy. Three separate tests showed that even at low concentrations statins led to muscle damage caused by atrogin-1 and as the statin strength was increased, the muscle damage increased. [The Journal of Clinical Investigation December 2007; 117(12):3940-51]

By the way, claims that statins prevent Alzheimer's are dubious

Apart from their role in treating cholesterol levels, it has been claimed that statins may prevent Alzheimer's disease and so it is not surprising that people with a family history are tempted to take daily statins.

However, research [Neurology Jan 16, 2008] concludes that statins offer no protection against Alzheimer's disease. 929 people with an average age of 75 agreed to have their brains autopsied after death. At the beginning of the study they were free of Alzheimer's and were given cognitive tests for up to 12 years before they died. Brain biopsies were performed on 262 individuals - 47 statin users and 215 nonusers. The scientists found that statin use at any time during the

study had no influence on which person had developed markers of Alzheimer's disease.

Foods That May Help Your Cholesterol Levels

Nuts are good for you

We all know that people with diabetes should protect their hearts by exercising, avoiding refined carbohydrates, reducing intake of foods high in saturated fats and increasing other types of healthy foods and this includes nuts. Years ago I remember my mother telling me that nuts were not good because they are high in fats and in calories and yes they are, but good fats - monounsaturated and polyunsaturated fats.

There is research that shows nuts can significantly reduce total and LDL [bad] cholesterol levels when eaten as part of a healthy diet. This includes almonds which contain a type of Vitamin E, peanuts, pistachios, pecans, and walnuts. The latest news seems to be about walnuts because they contain alpha-linolenic acid (ALA), a plant-based omega-3 fatty acid, which may protect the heart by reducing cholesterol and also reduce inflammation which is the cause of the build up of plaque in the arteries.

Nuts have little effect on blood glucose levels because they are low in carbohydrates, high in fibre, fat and protein and can suppress the appetite by increasing the feeling of fullness. So in moderation, they are good snacks for people with diabetes.

Oats for breakfast

The saying that breakfast is the most important meal of the day appears to be true and recent research suggests that a bowl of oatmeal porridge is the way to start the day. Oats are far less refined than wheat, are always eaten as whole grain and contain a fibre called beta-glucan which can lower the rise in blood glucose after a meal and delay emptying of the stomach [J Am Nutrition, 2007;26].

A Cochrane Review found that eating oats and oatmeal nearly halved total and LDL blood cholesterol levels while having no effects on HDL [good] cholesterol. [Cochrane Database Sys Rev, 2007:CD005051] The reviewers did have some concerns about the trials as they were small and of short duration but they estimated that eating oats and oatmeal results in a 5-15% overall reduction in the risk of coronary heart disease.

Other studies have shown:

- oats may help to normalise blood pressure,
- increase sensitivity to insulin so helping to reduce the risk of Type 2 diabetes,
- as a low glycaemic index food oats may help to stabilise weight
- oats may help with weight loss because they provide a feeling of fullness.

There is more research to be done into oats but till then, porridge for breakfast seems a good idea.

Re-thinking the "Dark Ages" for Treatment of Type 1 diabetes

By Scott Strumello

This was first published on Scott's blog [15.1.08] and he received immediate responses from people recognising his experiences as being so similar to their own. Scott lives in America and I live in the UK but it could be our family's experiences after my daughter was diagnosed in 1975.

The story only starts to diverge when Scott says that doctors in the US did not change patients to 'human' insulin if they were doing well

on animal insulin. Sadly not so in the UK, as many of us remember – there was a wholesale change of 84% of the diabetic population regardless of their control or their wishes and often even without their knowledge as the new 'human' insulin was merely substituted for their usual animal insulin!

When I was diagnosed with type 1 diabetes as a 7 year-old kid on July 24, 1976, not much had really changed since the discovery of insulin. I began this trip using Clinitest urine testing and that lasted for over a decade. I made slight adjustments to my short-acting insulin if my test results were on the high-end of the scale. Blood glucose monitors were introduced in the mid-1980's, and I recall my family was one of the first to get a meter (since there were two of us who had it, I guess the price was justified); but the other kids I knew used colour-coded strips and they told stories of how they could slice the strips in half and double the number of tests they got from a single vial. I remember thinking that was pretty cool.

When I was quite young, I did experience some problems with nocturnal hypoglycaemia, and I would wake up in the middle of the night screaming with the most horrible nightmares. I was taken to the hospital as they tried different insulin regimens and finally settled on a combination that worked quite well until the manufacturer stopped making one of the insulin varieties I relied upon for glycaemic control. This was my first, rude introduction to the business of diabetes. I struggled to find a comparable insulin with the same kinetics, but I was told, that's the way things were.

Aside from insulin, treatment consisted of adherence to a diet of largely whole foods with strict limits on refined carbohydrates (bread, crackers, rice, potatoes, etc.), and a mandate to ride my bicycle, play ball outside with other kids or do whatever else we could to amuse ourselves (my mother didn't want the kids inside, glued to the TV and pestering her while she prepared dinner anyway). In the summer, we got to spend time swimming in the pool to keep cool. For snacks, we were given things like carrot and celery sticks or peanuts that we shelled ourselves, and we drank water from the hose in the backyard when we were thirsty. Occasionally, we would get unsweetened Kool-Aid that my mother sweetened with Sweet & Low.

For much of my early life, I was treated with that supposedly allergenic animal insulin that I have been told repeatedly by promoters was "unpure" and was supposed to cause all kinds of allergic reactions (although I didn't have any) and I did not have the wild gyrations in my blood glucose levels that kids with diabetes seem to have today. My older sister, who was diagnosed with type 1 in 1969, did have some visible examples of lipodystrophy, but over time, that all but disappeared, probably due to greater purity of the insulin starting in the early 1970's. In fact, I could make a fairly convincing argument that our lifestyle was actually far superior to the way many kids live today.

Interestingly enough, I have actually had parents of newly-diagnosed children make the bold claim that I grew up in the so-called "dark ages" of diabetes care, but I beg to differ with that assessment. Although I can't know for certain because we didn't have an accurate method for monitoring, I believe my blood sugar levels were within a reasonable range. In fact, when I had my first haemoglobin A1C test done (remember, I lived for quite a while before that test was created), my doctor told my parents to keep doing whatever they were doing. Because I have yet to have any real complications so far, I would dare say that I was pretty well cared for in spite of suggestions to the contrary.

In 1982, Eli Lilly and Company received FDA approval for Humulin, which was supposedly human insulin - just like the body makes (in reality, it is synthetic, a good comparison is the difference between artificial vanilla and natural vanilla - it tastes similar, but not exactly). I recall that company advertised the heck out of that insulin in magazines like the ADA's Diabetes Forecast and elsewhere, but almost no one I knew with diabetes switched because doctors were reluctant to switch patients who were already doing well with a prescribed treatment plan. Also, the new synthetic human insulin was more expensive and offered no apparent benefit. It wasn't until the company announced

plans to discontinue those insulins when patients switched to Humulin en masse.

Insulin For Developing Countries

We would like to say a huge thank you to everyone who has sent us supplies of unwanted, in-date insulin, syringes etc to help people in developing countries. During 2007, IDDT collected a massive 27,430 mls of insulin in cartridges, pre-filled pens and vials, 5,360 blood glucose test strips and thousands of syringes and lancets. The supplies have gone to clinics in India and Africa. With your help, the lives of people unable to afford insulin are being saved, so thank you and please keep the supplies coming! Send them in a box or jiffy bag to: IDDT, PO Box 294, Northampton NN1 4XS.

The World Health Organisation is becoming more involved in non-communicable diseases in developing countries. IDDT Co-Chairman, Jenny Hirst, was invited to attend a meeting in Geneva to discuss the availability and costs of oral medications and insulin for people with diabetes.

NHS News

GP / patient relationships under threat
Researchers at Leicester University are calling on the government not to jeopardise the GP and patient relationships in their primary care reforms. They are concerned at the shift away from the traditional role of the personal GP who knows the family to teams of health professionals, NHS Direct and walk-in centres. They interviewed 279 GP patients and 12 GPs in their area and what they found was perhaps obvious to us, as patients:

- Patients welcome an ongoing relationship with their GP.
- Patients were more likely to trust GPs that they had had positive experiences with in the past.
- Seeing the same GP repeatedly reduced uncertainty and built a secure form of trust.
- GPs felt that ongoing relationships helped to achieve cooperative outcomes and made it easier for them to deal with difficult patients and sensitive issues.

Promised benefits of GP contracts have not materialized.
The National Audit Office [NAO] has reported that the new GP contact is costing £1.76billion [9.4%] more than the government expected and that the promised benefits for patients have not materialized. GPs have seen a rise in their salaries but those of us that remember the negotiations of the new contract, will remember that GP representatives repeatedly told the government that they would exceed the targets the government set them. This has proved to be the case.

GP surgeries to open longer hours
Changes to GPs opening hours will come into force in April 2008 and could mean that the average practice will open an extra 3 hours a week. Ministers want extra opening in the evenings and weekends but GPs are concerned that this would damage daytime services. The British Medical Association says the plan is unsafe for doctors because they will have to work alone at night and patients will not be able to access the full range of surgery services. However GPs were forced to accept the new hours otherwise the government would have allowed Primary Care Trusts to purchase services from other providers and this would have taken money away from GP practices.

GPs concerned over database security
A BMA News poll has indicated that 9 out of 10 doctors said they did not feel confident that the government proposal of a centralised NHS database would provide adequate safeguards about patient information. Only 6% said they had confidence in the government's ability to protect patient information on the NHS database while 93% per cent indicated a lack of confidence.

Public Accounts Committee Report and generic drugs
In January 2008, the government's Public Accounts Committee reported that there was an unnecessary expenditure of £200 million on drugs in the UK. Some of this was on unnecessary prescribing and waste on unused drugs but the Committee reported that GPs are prescribing too many branded medicines when the generic equivalents are available. The British Medical Association agreed that more generic drugs should be prescribed, providing that they are monitored carefully.

NHS working with the pharmaceutical industry
The Dept of Health has issued new guidance to encourage the NHS to work with the pharmaceutical industry to improve patient care. The guidance states:

"Joint working between the pharmaceutical industry and the NHS must be for the benefit of patients or the NHS and preserve patient care. Any joint working between the NHS and the pharmaceutical industry should be conducted in an open and transparent manner. All such activities, if properly managed, should be of mutual benefit, with the principal beneficiary being the patient."

While it is good that patients will benefit, some people may feel uncomfortable and be concerned about conflicts of interest with industry being involved in the NHS. Is it simply another source of funding to provide the care that should come directly from the NHS and what is the gain for the pharmaceutical industry? If it is selling more medicines, will our choice be eroded?

Recent Research Towards A 'Cure'

Stem cells in the pancreas of mice...
Researchers have discovered stem cells in the pancreas of mice that can produce new insulin-producing beta cells. Until now research has shown that new beta cells form under certain conditions but they were thought to be from pre-existing beta cells that could sometimes be persuaded to divide rather than from stem cells. This raises the possibility that adult pancreatic stem cells could be found in humans. Although this hit headlines in newspapers, a lot more work has to be done before the discovery can benefit humans.

And diabetic mice cured with cocktail of drugs
Scientists at Havard University managed to stop the destruction of the islet cells of mice with Type 1 diabetes with a mixture of three drugs but were not been able to regenerate them. But in a new study they found that by adding another drug to the original mixture, the cells regenerated and the mice started producing their own insulin. [New Scientist, 28.2.08] The extra ingredient is an enzyme called alpha 1 anti-trypsin and it is thought that this may reduce the inflammation of the pancreas which is involved in Type 1 diabetes. Trials in humans are being planned. As we know the focus for a 'cure' has been on islet transplantation but this latest method with drugs is less complicated as there are no problems with finding donors or the problems of rejection.

Pharmaceutical Industry News

AVANDIA - Europe announces new warnings
After all the controversy about the Type 2 drug Avandia [rosiglitazone] and its increased risk of heart attacks, in January the European Medicines Evaluation Agency [EMEA] announced that the Type 2 drug Avandia and Avandmet should carry new heart warnings as well as being contraindicated [not suitable] for some patients. At the same time European and American diabetes associations [ADA and EASD] stated that doctors should "consider more carefully whether to use this class of drugs versus insulin or sulphonylureas" as the second line of treatment. So if you are worried about using Avandia or any of this class of drugs, you should discuss alternatives with your doctor.

New drug for Type 2 diabetes approved in Europe but not the US
In February, Novartis announced EU approval to market low dose Galvus [vildagliptin] for Type 2 diabetes. It is not recommended for people with liver impairment, moderate to severe renal impairment or congestive heart failure. Approval was only given after Novartis agreed to label changes recommending liver monitoring at the start of treatment, every 3 months for the first year and periodically after that. Approval was also given for Eucreas, a combination of Galvus and metformin but only for people Type 2 diabetes unable to achieve glycaemic control at the maximum dose of metformin alone or who are already treated with Galvus and metformin as separate tablets. Galvus works by targeting islet dysfunction to restore the body's natural ability to increase insulin and decrease glucagon and metformin works mainly by decreasing the production of sugar by the liver and increasing insulin sensitivity. According to Novartis, there is no overall weight gain with Eucreas and a low incidence of hypoglycaemia.

However, it is worth noting that Galvus has not approved in the US and the FDA has asked for a large new clinical trial and there are suggestions that it may never be approved in the US. Perhaps this raises some questions about the EU approval?

Novo Nordisk discontinue their inhaled insullin development
Within weeks of the announcement of the discontinuation of inhaled insulin Exubera, Novo Nordisk announced that they are halting development of their inhaled insulin, AERx. It is currently in Phase III trials and patients will be switched to alternative insulin recommended by their doctor. The decision will cost the company 175 million Euros.

Novo Nordisk maintain that there were no safety concerns over their inhaled insulin but that it was unlikely to produce significant clinical or convenience benefits over insulin injections with pens. Will the other two players in the inhaled insulin market, Lilly and MannKind, continue with their inhaled insulins or has the market been tarnished to an extent that all inhaled insulins will be tarred with the same brush?

By the way...Exubera will be available for longer to existing users
On October 18th 2007, Pfizer announced that inhaled insulin, Exubera, was to stop and it would only be available until 16 January 2008. Pfizer has subsequently announced that it will make supplies of Exubera available for a year to people already using it who meet the NICE criteria depending on existing stocks and expiry dates.

Safer Drugs - The European Drug Approval System Needs an Overhaul

An article in the British Medical Journal [BMJ Vol 335, 803-5 19.10.07] experts argue that the European drug regulations need changing to ensure that they meet the needs of patients and doctors. Licensing of new drugs in Europe is controlled by the European Medicines Agency [EMEA] but new drugs only have to show that they are equivalent to current treatments rather than show any superiority.

Independent research
The authors believe that not having to show superiority favours the drug companies and that new drugs should be required to offer some advantages over current treatments or to be cheaper. They suggest that one way to ensure this would be to introduce some element of independent research by a non-profit organisation before a drug is licensed. At present it is the manufacturers who prepare the reports for drug approval and independent research only takes place afterwards.

Transparency
The EMEA keeps all its information secret, unlike the FDA in the US and they see no reason to keep toxicology and clinical information secret as it is essential to see why a new drug has been approved or a new indication for use granted.

The experts also believe that other information should be made

public – the size of the majority that approved a drug, the reasons the minority opposed approval, conflicts of interest and post-marketing commitments.

Bias and suspicion
They also believe that the present system is subject to bias and suspicion and argue for a European pharmacovigilance system to be set up [monitoring of adverse effects of drugs]. At present this takes place in each country and yet a drug is licensed by the European Agency.

Making drugs safer
The experts acknowledge that their suggestions may prolong the time it takes to approve a new drug but this would be in exchange for safer, better and more trustworthy drugs. Drug companies could be compensated for the longer time it takes for drugs to reach the market by extending the length of patents.

Is there any relevance to diabetes medications?
Yes, take a look at the last Newsletter which pointed out that 'human' insulin is not superior to animal insulin and that insulin analogues are not superior to 'human' insulin for the majority of people. So if the suggestions of the experts had been in place, would these insulins have reached the market? They may have done, but not so quickly and more importantly, the marketing of them would have had to be truthful because:

1. The system would not have been secret.
2. Any superiority would have to be proved by research for them to receive a marketing licence.
3. There would have had to be independent research not just manufacturers' research which can be biased.
4. In the marketing blurb, the false information about the supposed advantages of synthetic insulin could not have been given because we would have been able to check it out!

We have to look to the future and the need to avoid the misdeeds of the past, so IDDT can do no other than support the proposals in the BMJ article.

And by the way, did you know that medicines are regulated but what goes in them is not!
As we are aware drugs, including insulins, have preservatives and other substances in them, as well as the active drug – you only need to look at the information about your insulin or tablets to know this. These additional substances are called excipients. What is quite amazing is that the drugs themselves are highly regulated for safety and quality but, with certain exceptions, the excipients are completely unregulated and uncontrolled. This can leave the quality and safety of pharmaceutical products in doubt.

The European Commission put out an industry-wide consultation document in March 2007 proposing formal regulations to improve standards and recently this has been supported by the European Fine Chemicals Group [EFCG]. Their past Chairman pointed out that about 90% of a tablet can be an excipient and 10% the active ingredient [the drug] so it does not make sense to have 10% regulated but 90% unregulated!

There is a mixed response from the excipient manufacturers who fear legislation will increase prices which will have an impact on the drug companies using their products. However, it looks likely that the proposals will be accepted by the EC and there will be legislation to bring the excipients up to a more consistent level of quality to improve patient safety.

And there is new legislation in Europe will improve the regulation of drugs for children
An article in the BMJ [Dec 12. 07] says that new legislation in Europe will improve drug regulation for children and make drugs safer.

Many drugs used in children in European countries are unlicensed or off-label drugs and have not been specifically scientifically evaluated and licensed for use in children. In December 2006 the European

parliament passed legislation to ensure that drugs for children are subject to high quality research. It will also ensure that there is information on the benefits and harms of drugs used in infants and children without subjecting children to unnecessary clinical trials and without slowing down the availability of new drugs for adults. A European register of clinical trials in children will be established and the results submitted to the regulatory agency will be made public.

There will be financial incentives for drug companies to study drugs in children although the article points out that the experience in the US is that drug companies are more likely to study drugs that are prescribed extensively in adults because they provide the most profit.

From Our Own Correspondents

Bogus paramedics!
Dear Jenny,

I recently went to a talk about the work of paramedics and was fascinated by the bogus paramedics operating on the M25 and M11 - quite amazing! They turn up and claim to be registered paramedics but are not. So we were warned that we should always check the badge of the ambulance crew / paramedic if they turn up in a car with just a blue light. Anybody can purchase a blue light to put on the roof of a car and claim to be a paramedic!!

Mr B.D.
Herts

What do they think it is?
Dear Jenny,

Just thought I had to tell you that I asked my clinic about going on to an insulin pump but was told that because I am on beef insulin this is not possible. The reason given was: *"Not sure but probably because it is too thick to go through the tubing."*

I can't believe that there is such ignorance from health professionals.

Ms A.S.
E-mail

Note: IDDT knows of several members successfully using pork insulin in their insulin pump and at least one member using beef insulin. It is also worth remembering that the first insulin pumps were in the time before synthetic human and analogue insulins were even on the market.

I am alive today due to 50 years on beef insulin
Dear Jenny,

I was recently presented with a Nabarro Medal for having Type 1 diabetes 50 years and I told the newspaper reporter most emphatically that I am only alive today due to using beef insulin all the time I have had diabetes. I have always been careful about what I eat and drink. At the presentation my consultant said that I was living proof that as long as it is well managed, diabetes should be no bar to living a long and productive life.

Many thanks indeed to your goodself and the team at IDDT for all the marvellous fight you have shown on our behalf.

Mr William Woodward
Lancs

Government Plans for Prevention of ill Health

New Health and Wellbeing Committee
Gordon Brown has created a new cabinet committee on health and well-being to prevent ill health. This is an increased emphasis on preventative medicine - keeping people healthy to improve quality of life and reduce NHS costs. He also proposed an NHS constitution to set out the responsibility of individuals for their own in health in return for the right to treatment. This is bound to be a hot potato and consultations will take place later this year.

Screening the population to prevent diseases
He plans to offer people screening for early signs of heart disease, diabetes, stroke and kidney disease as part of his plan for a more 'personalised' NHS, initially for 'the most vulnerable'. Money for this has been has been set aside in the health budget for 2008-2011. However, Mr Brown said he did not yet know how many people will want to take up being screened, so it doesn't sound like a very evidence-based decision! Mr Brown does not seem to be taking the advice of the government's own advisory committee, the National Screening Committee which has not recommended population-wide screening for any of these conditions but a narrower programme of vascular risk assessment 'that could include measurement of risk factors such as blood pressure, cholesterol and glucose'.

The Prime Minister was accused of 'inconsistency' by doctors because of recent cuts to the funding of these very same conditions. The BMA said that while congratulations were deserved to try to prevent diseases, the plans had not been thought through as there is already a shortage of staff for diagnostic screening. For the new screening programmes to go ahead there would have to be an increase in staff, equipment and hospitals changes to cope with increased numbers of patients.

IDDT's comments to the media on diabetes screening:
"While we have to agree with the principle screening for early diagnosis, will the screening be affordable and equally available across the country? Screening the population will mean an increase in the numbers of people diagnosed with diabetes who will need treatment and an increase in those with 'pre-diabetes' who will need education and regular monitoring if screening is to succeed in preventing Type 2 diabetes.

Diabetes services are already suffering from lack of funding – restrictions of blood glucose test strips, lack of education programmes and the services for children with diabetes are suboptimal. So before greeting such screening programmes with open arms, we need to be assured that the necessary additional funding is in place for the screening itself to provide treatment, services and education for people the screening detects. We also need to be assured that the existing services for people already diagnosed do not suffer even further."

An easy place to start!

A researcher at Warwick University has developed software which could potentially identify 600,000 people who have undiagnosed or are at increased risk Type 2 diabetes. It can highlight people on GP databases whose higher than normal blood glucose tests have not been followed up. For instance, when people have had tests for other conditions, tests for glucose levels are often carried out but not followed up because the other condition is more important at the time. Out of a sample of 3.6 million anonymous records, 33,000 had 'borderline' results that would normally require a re-test and 3,700 had results that strongly suggest they had Type 2 diabetes. [British Journal of General Practice, 22.2.08] Perhaps Mr Brown should start here!

PTA = Parent & Teachers Association? "Oh, no it isn't!!!"

Submitted by IDDT member, Alan Campbell
To many of us, if we heard the initials PTA we would automatically presume it was in relation to a Parent & Teachers Associations at our child's school, but to Alan Campbell who resides in Gorton, Manchester it meant something completely different.

Alan has been on the Transplant waiting list for a Pancreas Transplant Alone (PTA) since January 2007 after suffering with Type 1 diabetes rather severely for 15 years, he ended up suffering with many of the complications related to the disease. On the 6th December 2007 at 00.05am Alan received a telephone call, which would change his life forever, but would be the best Christmas present he could have ever dreamed of.

The call was from the Transplant Laboratory at the Manchester Royal Infirmary (MRI). They had found him a matching pancreas and were requesting he came in for further tissue typing tests.

Alan was at the MRI within the hour and gave blood for the tests that needed to be done. He then had to speak to a Doctor who went through his complete medical history and then he met his Consultant Transplant Surgeon, Mr Ravi Paraarjasingam. At 06.30am the pancreas was finally confirmed as a match and his journey began for preparation for theatre. By 07.30am Alan was on his way to theatre as the 4th patient at the MRI to undergo this relatively new procedure.

After spending 14 days in hospital he was discharged from Ward 10 of the MRI. He has been free of Insulin Injections since the operation, he now has to take a course of Immunosuppressant drugs for the remainder of his life. Leaving him Injection free for as long as his new pancreas works.

Alan Co-Foundered & Chaired The City of Manchester's Diabetes Support Group with a friend who has Type 2 Diabetes, Mrs Shirley Lee, Group Secretary. On the 19th November 2007 Alan received a Patient & Public Involvement & Volunteer Service recognition award from Mr Peter Mount, Chairman, Central Manchester and Manchester Children's University Hospitals NHS Trust.

For the next few months Alan will be resting up, getting used to his new lifetime regime of Immunosuppresant drugs and remaining Insulin Injection free for as long as possible.

American Diabetes Association [ADA] Now Supports Low-Carb Diets

As predicted, the American Diabetes Association [ADA] has recommended low carb diets for weight loss, something they and other diabetes organisations have resisted.

The ADA 2008 Clinical Practice Recommendations state:

- there is increasing evidence that low carb diets are as effective in leading to weight loss as diets that concentrate on lowering fat in take ie the presently recommended high carb/low fat diets.
- There is now evidence that the most important factor in weight loss is not a diet's composition but whether or not people stick to the diet. Some people will prefer a low carb diet while others a low fat diet and so people should be able to choose the diet that suits them best.
- The ADA recommends that people on low-carb diets should monitor their cholesterol and triglyceride levels regularly. [This applies to everyone with diabetes no matter what diet they are using but it looks as though the ADA believe that low carb diets automatically mean that people will eat higher amounts of fats – they may but they can eat 'good ' fats!]

This is a start but does it go far enough?
As we have said many times before, why eat a high carb diet if you have diabetes when the one thing that the body can't do properly is handle carbohydrates! Many believe that the ADA has not gone far enough. But actually it is a huge break through. The ADA has had the courage to stand alone and recognise that there is a place for low-carb diets unlike other diabetes and medical associations around the world. So let us praise the ADA and hope this is the start of common sense prevailing.

ADA are representing the best interests of people with diabetes
A letter in Diabetes UK magazine, Balance [March 2008], was critical

of Diabetes UK advocating the '5 a day fruit and veg and 30 minutes walking' policy when these are minimum standards and well below those of many other countries. Diabetes UK's response was that they are obliged to follow government guidelines. Clearly the ADA disagrees and rightly sees its primary responsibility to be to people with diabetes not to adhering to government policy which they consider to be inappropriate on the basis of the latest evidence.

So congratulations to them on this too – the role of patient organisations has little to do with government policy but much more to do with representing the best interests of their client group. Indeed, this could mean fighting government policies in order to ensure that their members receive correct treatment, as IDDT knows only too well!

Eggs - Not as Bad as we Have Been Lead to Believe!

Some years ago we were all told that eggs were bad for the heart because of their cholesterol content and we should only eat one a week. But since then research [Med Sci Monit 2007; 13(1):CR1-8] has shown that there is no link between dietary cholesterol found in eggs and blood cholesterol levels that are linked to heart disease in people who ate more than 6 eggs a week compared to those who ate only one or two. However, the research did show that in a sub-group of people with diabetes there maybe an increased risk of heart disease in those eating more than 6 eggs a week and so further investigation is recommended.

Perhaps even more surprising is that research published in the Journal of the American College of Nutrition [Vol. 19, No. 90005, 556S-562S (2000)] found that people who ate more than 4 eggs a week had lower blood cholesterol levels and lower blood pressure than those who ate less than one egg a week.

So what's in a large egg?

- 75 calories and 6 grams of protein
- Vitamins A, B6, B12, D and E [Eggs are one of the very few foods that contain Vitamin D]
- Riboflavin, folate, choline, iron, calcium, phosphorous and zinc.

So eggs are full of nutrients, most of them being in the yolk although most of the protein is in the white.

Eggs for breakfast can reduce hunger pangs before lunch and may be good for blood sugars

A study carried out in 2004 compared the feeling of being full [satiety] and hunger levels in overweight people after a breakfast of eggs or bagels. Both breakfasts had the same number of calories but those who had eggs for breakfast reported greater feelings of satiety before lunch and ate less calories during the rest of the day than those who had bagels.

Previous IDDT newsletters have also discussed the effect of protein in a meal as protein blunts the post-meal rise in blood glucose levels, so it is thought that eggs for breakfast may also lower post-meal rises in blood sugars.

New Technology for Cataract Operations

Cataracts are a clouding of the normally transparent lens inside the eye. They are common in people over 65 and more common in people with diabetes. New devices have significantly reduced the length of the incisions needed to be made for cataract operations. The cuts only have to be 1.8mm on either side of the eye [the size of a full stop] compared with a cut of up to 2.7mm usually made. The clouded lens is then broken up by using ultrasound and sucked out and a new folded lens is injected into the space and unfurled. Experts say that

these devices make the operation safer because the eye remains steady and the surgeon has greater control. The operation is quick, painless and no stitches are needed. The smaller cuts mean less focusing difficulties after the operation and less after-care is needed as there is little danger of infection. These devices are being sold to the NHS. The only drawback at the moment is that many of the lenses on the market are not yet small enough to fit through the tiny incision but this technology will catch up.

Weight Snippets

Prescription medicines may be the cause of large weight gain
Research at Glasgow University has found that some patients are putting on up to 22 pounds a year due to an unexpected side effect of prescription medicines and this could be contributing to the obesity epidemic. The patients studied were on medications for conditions such as Type 2 diabetes, epilepsy, depression and high blood pressure. With many drugs weight gain was significant and rapid but how they lead to weight gain varies eg corticosteroids increase appetite while beta-adrenoceptor blockers reduce metabolic rate. Insulin for Type 2 diabetes was found to increase weight by up to 13.2 pounds and some drugs for depression by 8 pounds. Around half of patients prescribed drugs for chronic conditions do not take medicines as they are advised and the researchers suggest that this unexpected weight gain may be a reason why people stop taking prescribed medicines. They recommend that doctors should fully discuss the risks of weight gain with patients before treatment is started.

More than 1million prescriptions are made for obesity drugs a year
This figure of 1million prescriptions for obesity drugs a year is eight times the number dispensed seven years ago. The majority of these were for two drugs - sibutramine and orlistat. Just 127,000 obesity pills were prescribed in England in 1999, but that rose to 1.06m in 2006, according to the NHS Information Centre. It comes as figures show that obesity is rising. Nearly a quarter of adults are obese, up 50% in the last 10 years and one in six children between the ages of 2 to 15 are classed as obese, up from one in ten.

There's a 'fat gene'
Research in the UK has found that there is a 'fat gene' called the FTO. This gene plays a large part in controlling feelings of hunger and fullness which affect our appetite and how much we eat. It is hoped that a drug can be developed to alter the FTO gene and therefore reduce obesity and Type 2 diabetes. Half the UK population carries a single copy of the 'fat gene' and these people are usually 1.6 kilograms heavier than those who don't. 16% of the population have two copies of the FTO gene and can be up to 3 kilograms heavier.

This research draws attention to the fact that there is a hereditary factor involved in overweight and obesity and it is also worth remembering that there is a hereditary factor involved in some people with Type 2 diabetes – it is not all self-induced as much of the publicity would have us believe.

Full blown coke should have a government health warning!
No wonder that Coke is good to treat a hypo! According to the US Nutrition Research Centre, here's what happens to people without diabetes when they drink a Coke:

- Within 10 minutes, 10 teaspoons of sugar have hit the system.
- Within 20 minutes, blood sugars spike, insulin is released to deal with it and the liver responds by turning the massive amount of sugar into fat.
- Within 40 minutes, caffeine absorption is complete, pupils dilate, blood pressure rises and the liver dumps even more sugar into the bloodstream.
- Within 45 minutes, the body increases dopamine production which stimulates the pleasure centres in the brain [an identical response to that of heroin].
- After 60 minutes, you'll have a sugar crash.

Hospitals throughout the UK using faulty weighing scales

After discovering that some hospitals had faulty scales, or even no scales at all, for weighing patients, a 12 month ‘National Medical Weighing Project’ is being introduced from April 2008. Trading standards officers are to check that scales are accurate, legal and fit for purpose, especially in cancer and children’s departments and that staff are trained to use them. In addition to the obvious, accurate weight measurement is especially important for cancer patients to ensure they receive the correct amount of treatment for their weight. Children metabolise drugs differently from adults so it is also vital that height and weight are correctly calculated for working out drug doses.

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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