Insulin Dependent Diabetes Trust

April 2006 Newsletter

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Good News

The good news - pork and beef insulins will continue to be available from Wockhardt UK.

The bad news - Novo Nordisk will discontinue their pork insulins by the end of 2007, leaving one supplier for the whole of the UK.

IDDT is rightly angry - people will have to change the insulin that suits them simply to increase the profits of Novo Nordisk.

"Patients' welfare will continue to be vulnerable while health policies and practice are dominated by the will of big pharma."

Professor Joe Collier, The Lancet Vol 367 Jan 14 2006

"I am still on animal insulin. I did try human insulin, but I ended up in hospital so I have stuck to the animal."

Gary Mabbutt, former England footballer. BBC News Online Feb 6 2006

"Having diabetes takes a huge commitment to personal management and I think it is vital that diabetics have a choice about which insulin works best for them, rather than the choice being made by big drug companies who want to maximise profits."

Dr Bill Lamb, Daily Mail, Feb 14 2006

To be Expected, But It Is Not Welcome!

Novo Nordisk announced the discontinuation of their pork insulins in the UK and expect stocks to last until the end of 2007. But we must remember that the good news is that animal insulins will continue to be available from Wockhardt UK [formerly CP Pharmaceuticals].

Novo Nordisk have withdrawn pork insulins in countries around the world and it has lasted longer in the UK than any other country but it was bound to happen. We are angry and have every right to be so but at the end of the day, there is no way that patients count more than profit to big pharmaceutical companies.

Here is the announcement as it appears on their website [31.1.06]:
Novo Nordisk will discontinue the sales of all its animal derived insulins. These are Porcine Actrapid® 10ml vial, Porcine Mixtard® 10ml vial and Porcine Insulatard® 10ml vial. These products will not be available after the end of December 2007.

Animal insulin is derived from the pancreas of slaughtered animals and was first produced in 1923. Since that time there has been significant improvement of insulin quality and formulation. As a consequence, demand for these old animal insulins has declined by as much 20% in the last year to a point where approximately 2% of all insulin users are currently using these products.

Novo Nordisk has supported these insulins with considerable funds despite the fact that the sale of those insulins has been stopped in many other countries. The withdrawal of these products will allow the company to rationalise its portfolio and focus additional resources into the further advancement of diabetes care.

Viggo Birch, Managing Director, Novo Nordisk Ltd, said: “Novo Nordisk is committed to providing the most advanced, safe and effective diabetes treatments in the UK and worldwide. We have been in discussions with the Department of Health, Diabetes UK and diabetes specialists across the UK. This announcement is part of our commitment to provide adequate warning of the discontinuation, so as to ensure that the few patients still on Novo Nordisk’s animal insulin in the UK are transferred to suitable alternative insulins.”

Although Novo Nordisk recognises that this discontinuation may cause inconvenience for patients still using animal insulins and additional workload for health care professionals, the company believes it is an opportunity for the users of animal insulins to have their situation reviewed and potentially to improve their treatment.

IDDT reaction:
We acknowledge that Novo Nordisk have given the notice they promised but this statement is a good PR job and like all PR jobs, the spin it puts on the reality presents a misleading picture.

- *‘Old’* doesn’t mean it is no good or that it has been replaced by something better. Pork insulin is not the *‘old’* insulin used in 1923 - it was not introduced until the late 1970s and it was the first development that provided *‘significant improvement of insulin quality and formulation’ !*
- *‘Only 2% of the diabetic population are currently using Novo Nordisk pork insulin’* - good spin again! 2% doesn’t sound much but the latest figures for people using insulin in the UK is 800,000 and 2% of 800,000 is actually 16,000 people. Novo Nordisk’s own estimate is 12,000 people but whether 12,000 or 16,000, this is still a lot of real people that are affected by their decision. It is NOT a ‘few patients’ as referred to by Viggo Birch!
- *“Novo Nordisk is committed to providing the most advanced, safe and effective diabetes treatments in the UK and worldwide.”* Yes, the new insulins may be ‘advanced’ technologically but they have not been proved to be safer or more effective than pork insulin - the high quality, long-term, independent trials have never been done.

But the last statement that ‘Novo Nordisk recognises that this discontinuation may cause inconvenience for patients’ is not

spin but a gross under estimation of the reality!
The word *'inconvenience'* is insulting and offensive to people who need pork insulin. Using pork insulin is not a matter of 'convenience' and anyone who is still using pork insulin is doing so because they have a real need and not because it is convenient!

- It's not convenient to have adverse reactions to GM human or analogues insulins.
- It's not convenient to have had to resist the regular pressure from doctors and specialist nurses to change to GM human and analogues insulins.
- It's not convenient to have to be assertive to insist on trying pork insulin when adverse reactions to GM insulins are experienced.

None of this is convenient - people have had to do it because they need animal insulins to remain healthy, have a good quality of life and have hypo warnings.

Whatever the research may or may not show is of little importance, the reality in day to day life for this group of people is that they NEED pork insulin, they know it and their families know it because it shows every day of their lives.

Novo Nordisk's statement shows they don't understand that everyone with diabetes is different and different insulins will suit different people, or if they do, do they care? But above all, it shows that as a company, they have not been listening for the last 20years, or if they have, do they care?

Another interesting quote from Winston Churchill

'Men occasionally stumble over the truth, but most of them pick themselves up and hurry off as if nothing ever happened.'

Seems particularly relevant in today's world of drug trials, especially if the results threaten perceived wisdom or vested interests!

Have We Given Up?

Most certainly not, there's a job to do!
We won't change Novo Nordisk's decision but we are not going to rollover and see people changed to analogues unless this is their informed decision. No one can deny that IDDT members are determined and persistent - it took 11 years to achieve the statement that 'the Dept of Health fully accepts that some people need animal insulin'! But we still have a job to do????..

We need guarantees - one supplier leads to vulnerability
This vulnerability has been highlighted by stock problems at Wockhardt and let us be clear, it is the job of the government to ensure that the drugs people need are available and it is guarantees from government that we shall be seeking.

We need to ensure that people receive the choice of changing to pork insulin
If history is not to be repeated and if people are not to be put at risk of adverse reactions, every last one of the thousands of people using pork insulin needs to be made aware that they can stay on pork insulin from Wockhardt UK. While responsibility for communication of this message rests with the Dept of Health and with Novo Nordisk, be assured that IDDT will be doing our best to get the message across in whatever we can.

This is not an opportunity to change people to analogues insulins
Finally, we know only too well that this may be seen as an opportunity to change people to the 'new' analogues insulins and some people will be put under pressure to change but we will be supporting people in their wish to stay on pork insulin.

Novo Nordisk pork insulin is not identical to Wockhardt pork insulin
We have members who had adverse reactions to GM insulins and although Wockhardt pork insulin removes these, they achieve better control with Novo Nordisk pork insulin, probably because it is faster

acting. Their needs have to be addressed.

No, we have not given up and nor will we!
We will continue to work to try ensure that people with diabetes have the choice of animal insulin, are not misled and are not 'forced' to change to GM insulins through lack of information and choice. Some of us have fought this battle for the last 20 years, so we are not simply going to accept the might of industry and we are not simply going to walk away now. Insulin manufacturers' strategy may well be to transfer everyone to insulin analogues but as long as their long-term safety and efficacy is unknown, alternative insulins have to remain available. We have no doubt that our members will help and support us as they have done so magnificently in the past.

Workhardt Animal Insulins Will Be Available

We are fortunate in the UK that Wockhardt UK [formerly CP Pharmaceuticals] supply pork insulin in both vials and cartridges for use with pen injection devices and many people are already using this brand. Here is a chart of the nearest pork insulins:

Novo Nordisk pork insulins to be discontinued by the end of 2007	**Wockhardt pork insulins in vials and cartridges**
Pork Actrapid [short-acting insulin]	Hypurin Porcine Neutral
Pork Insulatard [Intermediate acting]	Hypurin Porcine Isophane
Pork Mixtard 30 [pre-mix]	Hypurin Porcine 30/70 Mix

Note: Hypurin cartridges are used with a choice of Autopens made by Owen Mumford and they are available with an NHS prescription.

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 http://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.

You can also access information on the suspected adverse reactions

You can make a more informed choice of insulin treatment by taking a look at the suspected adverse reactions that have already been reported. Go to http://www.yellowcard.gov.uk/ and then CLICK on 'download adverse drug reaction listings'. Albeit that at the time of writing, these have not been updated since 2004, they make very interesting reading!

I have been a diabetic for 31 years. I am in very good health other than terrible hypos that I have been experiencing which have grown worse and this can be quite dangerous when a low blood sugar hits that I don't feel. I used beef and pork insulin for at least 25 years and always felt my sugar drop and never experienced any of the issues of late. For quality of life and my and my husbands piece of mind, please tell me how or where I can purchase pork insulin.

Around the World

Insulin treatment is not about choice or need any longer - treatment is being dictated by big pharma

People with Type 1 diabetes need insulin to stay alive and so do many with Type 2 diabetes and the number of people with diabetes is increasing. But amazingly the choice of insulins is decreasing to meet these increased demands! Over the years we have witnessed leading insulin manufacturers phasing out effective and less expensive insulins to replace them with newer and more expensive insulin analogues, regardless of patient choice or need. Countries have been picked off one by one so that drug companies can justify their actions by saying that global sales are down.

Clearly insulin manufacturers are blissfully ignoring the International Diabetes Federation [IDF] March 2005 Position Statement which stated that *'All insulins have slightly different properties, and patients should not be changed from one to another insulin type unless there is a clear advantage.' Not to mention perhaps the most important statement from the IDF that 'No insulin type will suit every patient, and it is important that variety is maintained in order to find the insulin that suits each patient best.'*

United States

Nowhere highlights this situation better than the United States. In 2005 Eli Lilly discontinued 4 insulins - short and intermediate-acting pork insulins effectively making the US an animal insulin free zone and 2 long-acting human insulins, Ultralente and Lente used by 66,000 people. The only long-acting options that remain are Lantus or Levemir [only recently licensed in the US]. Not only are there varying opinions on the long-term safety of analogues and their potential for carcinogenic effects but in a country where many people have to pay for their insulin, there is a huge price increase.

And which one do you chose - Lantus or Levemir? Well according to the Wall Street Journal [29.11.05], Novo Nordisk aim to increase their market share in the US to 80% by visiting 4 out of 5 doctors in the US who prescribe diabetes treatments, including smaller practices. So it looks as if Levemir may win out!

A very balanced article 'And Then There Were Some' in the February edition of Diabetes Health debates these issues which must concern all of us, patients, physicians and healthcare professionals alike. If you have access to the internet it is well worth a read, visit www.diabeteshealth.com/insulin if you don't then IDDT will be happy to send you a copy - call 01604 622837 or write to IDDT, PO Box 294, Northampton NN1 4XS

But the Canadian authorities see sense!

Although Eli Lilly also announced the discontinuation of pork insulins in Canada in April 2006, a very different situation exists in Canada. Like the UK, Health Canada [equivalent to UK Dept of Health] has accepted that some people need animal insulin because they are unable to tolerate synthetic GM insulins and so they have granted a licence to Wockhardt UK for Hypurin Regular [short-acting] and Hypurin NPH [intermediate-acting] pork insulins. Lilly is working with Wockhardt to try to ensure that users of their pork insulins are made aware that they can continue to use pork insulins and do not have to use GM insulins that cause them adverse effects.

Europe

By June this year Novo Nordisk animal insulins will have disappeared from all European countries and only in Switzerland are Wockhardt UK pork insulins licensed.

Other countries

In S Africa and Australia, Novo Nordisk discontinued pork insulins many years ago but some people have obtained them through personal importation schemes that apply in most countries. However, Novo Nordisk have now stated that they are no longer producing animal insulins and according to a letter from the company to one of our members 'patients can - very safely- be transferred to 'human' or analogue insulins'. People who have had adverse reactions know that

this is not the case! However, pork insulin can be imported through the personal importation process from Wockhardt in the UK.

Note: In Australia beef insulin is available through the usual health system.

More Comments On Meters For People With Visual Impairment

The best people to comment on blood glucose meters for people with visual impairment are the people who have to use them, so we are always grateful for any comments that I can pass and especially to David Danetree who keeps IDDT regularly informed.

He says the SensoCard Plus has been improved recently so that you just press a button on the right hand side, insert the strip in the left side and it is set up, making it easier to use. However he is very impressed with the Compact Plus. He thinks that this is the best meter that has been produced and it is good that the finger pricker is attached to the meter.

We are always happy to hear your comments on anything, well almost anything!

Remember: IDDT produces the Newsletters in large print or on tape, just let us know them in either of these versions. Give IDDT a ring on 01604 622837

Another interesting quote from Gary Mabbutt
'I still use needles and insulin. I did try a pen once. I was playing away at Manchester and when I went to inject myself the pen jammed and I had to take a taxi to Manchester Royal Infirmary to get some more insulin and needles. So after that I have always said 'If it is not broken, why fix it?'

Gary Mabbutt, former England footballer. BBC News Online Feb 6 2006

Fighting Back Through the Press

Despite the claims of the big pharma companies, the adverse effects to synthetic insulins are not just a UK problem. While patients fight back, they have to resort to the press to expose what can only be described as the uncaring, profit-motivated actions of the insulin manufacturers.

In Germany on June 30th Novo Nordisk will discontinue supply of Semilente pork insulin and replace it with an insulin analogue [Levemir] that was introduced to the German market only a year ago. For anyone allergic or unable to tolerate it, there is no alternative insulin and while it is possible to import pork insulin from either Switzerland or the UK, many health insurers are refusing to pay for it. Here are the main points from an article in a German national newspaper:

The Myth of Human Insulin, by Gisela Sonnenburg

Die Welt.de Feb 3rd 2006

- Dr Ernst von Kriegstein of the Paul-Gerhard-Trust in Wittenberg stated that there were problems during the initial studies of 'human' insulin in the USA because some patients had to discontinue the trials due to 'incompatiblity'. Despite this, Novo Nordisk and Eli Lilly went ahead and doctors who converted patients on to human insulin were paid DM100 per patient.
- Complaints from patients were not heeded. *"I was not told at the outset what I was getting"*, said Armin Schenk. Like Schenk, hundreds of patients in Germany suffered; they lost the early warning signals of an impending hypo and some people had an allergic reaction showing up as anaphylactic shock and nausea.
- But human insulin was promoted as the wonder drug: *"Incompatibility of human insulin is impossible, as its structure is identical with that found in the human body,"* stated Markus Leyck Dieken, head of Novo Nordisk in Germany. Many doctors reinforced the myth suggesting that allergies were due to the additives, like zinc. Dr Nikolas Tacke, a lobbyist in Berlin, stated that *"products made by*

gene technologies are the safest known."

- Such theories are not supported by recent findings of the Institute for Quality and Efficacy in Healthcare (IQWiG) which relate to insulin analogues. Head of IQWiG, Prof. Peter Sawicki, stated: *"Up to now we have only evaluated short-acting insulin analogues in patients with Type II diabetes. For these patients we can state, with certainty, that they bring no real advantages." Even the predicted ease of use was not confirmed. "It is a fairy story that insulin analogues offer an improvement to one's eating habits or lifestyle."*
- However, it is no fairy story that *"experiments with animals and cell cultures suggest at least the pathophysiological possibility of carcinogenicity."* In short: insulin analogues carry the risk of cancer. But this is not new; as early as 1992 all studies in patients of an analogue from Novo Nordisk were discontinued, as the result of the development of breast cancer in rats.
- Professor Chantelau warned: *"Many cancers have a long period of latency. That for breast cancer can require 15 years. The industry has conducted many patient studies with human insulin and analogues - but no long-term studies into the possibility of cancer."* That was also the warning from the IQWiG. Chantelau's main criticism of gene-modified products is that *"normally insulin is produced by specialised cells. It is a highly complex synthesis."* The biotech production is not identical to that of nature: bacteria such as Escherichia coli or certain yeasts are gene-modified so that they produce the molecules, or part molecules, of human insulin. Whether or not the folding of the amino acids is identical to that of human cells is not known - only the chemical formula is identical. How incompatibilities result for the patient has not been researched.
- Referring to the refusal of many insurance companies to pay for imported pork insulin, Prof. Konrad Wink from the Pharmaceuticals Commission of the German Medical Association (AKdA) said *"But that can be no reason to force a patient to switch to a product that may not be tolerated. It should never have come to this".* The AKdA will recommend to the insurers that they should meet the costs of porcine insulin.

"Threat to diabetes as drug giant goes over to GM insulin."

UK Daily Mail, Feb 14th 2006

An excellent article in the Daily Mail recounted the history 'human'/ animal insulin saga pointing out the vulnerability of being left with one supplier of pork insulin after 2007. There was support for patients from Dr Bill Lamb, consultant paediatric diabetes specialist from Bishop Auckland [that was like music to my ears - Jenny]. He said: "There are many different insulins available and what is indisputable is that some combinations work better for some people than others. The scientific evidence says one thing and the personal experience another. I have treated people who have said that human insulin did not suit them. However, it has to be said that some people in the past had problems with animal insulins.

"Having diabetes takes a huge commitment to personal management and I think it is vital that diabetics have a choice about which insulin works best for them, rather than the choice being made by big drug companies who want to maximise profits".

The article also included IDDT's Bev Freeman's adverse experiences with 'human' insulin with the title of 'Injections turned me into a zombie'. IDDT received a lot of calls and interestingly the majority were from people who recognised themselves as having similar symptoms to Bev and wanted to know how they could change to pork insulin, but then this happens every time there is press coverage of the adverse effects of GM insulins.

Uncaring and unacceptable

These two articles alone show the big pharma companies that remove animal insulins that people need and knowingly leave them with alternatives that cause adverse effects, as in Germany and other countries, can only be described as uncaring and unacceptable. Big pharma may have no conscience, many within the medical profession may be prepared to ignore the needs of their patients who have to use pork insulin and governments may use the classic escape that they cannot interfere with commercial decisions. But responsibility and

accountability for the health and lives of people with diabetes who need animal insulin must rest somewhere - perhaps with all three.

The insulin that is causing me stomach problems is Novolog analogue insulin and Novolin N human insulin are causing me stomach problems. Many thanks again for all your help in locating a source for animal insulin for me, you have been a real lifesaver for me. [USA]

Pharmacutical Industry News

Novo Nordisk receives subpoena in the US
December 20th 2005: the US Attorney for the Eastern District of New York has served a subpoena on Novo Nordisk calling for the production of documents relating to the company's US marketing and promotional practices. The company believes that the investigation is limited to its insulin products. The subpoena suggests that the documents are necessary for the investigation of potential criminal offences relating to healthcare benefit programmes. Novo Nordisk state that they intend to co-operate in this investigation but they cannot predict how long the investigation will take or when it will be able to provide additional information.

Novo Nordisk gets subpoena in United Nations investigation [20.2.06] - insulin manufacturer Novo Nordisk received a subpoena from the U.S. Securities and Exchange Commission ordering it to provide documents relating to the United Nations [UN] oil-for-food program in Iraq. Novo Nordisk have stated that they will comply with the subpoena and fully cooperate with the investigation. The company was among more than 2,000 companies and individuals accused in a UN report in October of paying kickbacks to Iraqi officials to secure contracts under the oil-for-food program during Saddam Hussein's regime. The company has denied any wrongdoing. The oil-for-food program was set up in 1996 to help Iraqis cope with UN sanctions imposed after Saddam's invasion of Kuwait and allowed Saddam's regime to sell oil provided the proceeds went to humanitarian goods. Allegedly Saddam curried favour by giving vouchers for Iraqi oil that could then be resold at a profit. Novo Nordisk said its sales of pharmaceutical products, mainly insulin, to Iraq under the program amounted to approximately $48 million.

Eli Lilly reprimanded by UK Regulatory Authority for leaflet carrying only Diabetes UK logo [Financial Times, 14.2.06]. Lilly, the manufacturer of many drugs including insulin produced a leaflet about its schizophrenia drug Zyprexa that did not mention the potential side effect of the risk of hyperglycaemia and diabetes. Zyprexa generated £2.4bn in sales last year.

The Medicines and Healthcare products Regulatory Agency [MHRA] forced Eli Lilly to withdraw a leaflet providing advice to doctors that it wrote and sponsored on behalf of the charity Diabetes UK. Eli Lilly was accused of misleading patients by not showing that it had written and paid for the leaflet, which carried only the Diabetes UK logo. Only after inquiries by the Financial Times did Lilly agree to issue a corrective statement on its website and that of Diabetes UK.

This action by the MHRA is the first ruling against drug company - patient organisation links but it took a long time! The leaflet was first circulated in September 2003 and not until May 2005 did the MHRA contact Lilly to withdraw the leaflet - nearly two years for people to be misled! And these findings were not made public until February 2006!

On the grounds that this was a 'grey area' of legislation, the MHRA admitted that it had been slow to follow up and insist on the correction as well as the withdrawal of the leaflet, but would in future be quicker to ensure remedial action was taken. Diabetes UK said the leaflet, produced by Lilly UK with its input, 'could be mistaken for a Diabetes UK publication' in contravention of its working practices for engaging with pharmaceutical companies.

Abbott Laboratories suspended from ABPI membership over breach of code, 10.2.06 - Abbott Laboratories has been suspended

from membership of the ABPI for a minimum of six months due to serious breaches of the ABPI Code of Practice. The breaches were likely to bring discredit on, or reduce confidence in, the pharma industry and according to the press these included Abbott sales representatives paying for lap dances, dog track entertainment, Wimbledon tickets, and other favours for health professionals. This will have little practical effect, but it draws attention to ethics violations and that voluntary policing of the drugs industry is not very effective.

The interesting thought here is that the company is penalised but not the healthcare professionals who accepted the 'inappropriate hospitality'!

Avandia, Avandamet and Actos

Link to macular oedema to be investigated by European Medicines Agency
On December 16th 2005 the European Medicines Evaluation Agency [EMEA] announced that its scientific committee [CHMP] will investigate a possible link between Avandia, Avandamet and Actos, the class of drugs known as glitazones, and macular oedema.

Macular oedema is fluid in the macular region of the eye, the macular being the area of the eye that is responsible for fine vision such as reading. Macular oedema causes blurry or distorted vision and is said to be the most common cause of loss of vision in people with diabetes.

The EMEA have stated that since 2000, they have been alerted to 35 cases of macular oedema in people taking Actos [pioglitazone] and 28 cases in people taking Avandia/Avandamet [rosiglitazone]. However, they were not able to say how these figures compared with people not taking gltazones. The EMEA spokeswoman is quoted as saying, *"We do not know if it (the oedema) is caused by the diabetes or the drug - or neither. In some cases patients got better when they stopped taking the drug and in some cases they got better when the drug was still being taken".*

GlaxoSmithKline manufacturers of Avandia/Avandamet will be sending out a 'Dear Doctor' letter to inform doctors of the situation. However, they stressed that this is extremely rare - less than one in 10,000 cases. Fine, but not if you are the one person out of 10,000!

Later News 5th Jan 2006: the Food and Drug Administration and manufacturer of Avanda and Avandamet, GlaxoSmithKline, have stated that patients using these two diabetes drugs have reported blurry vision and swelling of the legs and feet. The company also said it has received "very rare" reports of new or worsening diabetic macular oedema. A letter has been sent to doctors in the US informing them of this and also states that in some cases, stopping treatment or reducing the dose eliminated or improved the condition.

If you are taking these drugs and are concerned, then you should discuss your options with your doctor.

Visual Field Loss, Driving and the DVLA

What is visual field loss?
Visual field loss can occur for several reasons, such as glaucoma, but in people with the diabetes a very common cause is laser treatment for retinopathy. Laser treatment is used to seal leaking blood vessels so preventing further deterioration. Many people have had laser treatment until the leaking blood vessels are stopped and then there is no further trouble for years and years.

However, laser treatment has the disadvantage of damaging the retina in the area where the laser is used and this can leave blind spots - the size being dependent on the amount of laser treatment.

Measuring visual fields
There are various ways of measuring visual fields and the commonly used one is where you are asked to look at a central light spot on a screen and then lights are flashed about the screen and you will be asked which ones you can see. Any of the lights that are not seen indicate a blind spot. In real life we may well never notice blind spots for three reasons:

1. we have two eyes and what is missed with one eye is often covered by the other
2. we are normally moving our eyes around all the time and not looking at a fixed spot, especially when driving
3. we adapt to situations. For instance, people with the use of only one eye [who are legally allowed to drive a car] learn to automatically move their head more.

So clearly the tests for visual field loss do not resemble the real life situation and they were never designed as a definitive test to give a black and white answer to whether or not people should drive. These instruments were designed as a test to detect any field loss warranting further investigation. There are no instruments that will give this definite answer but DVLA rely on such tests to make decisions about whether driving licences are issued or denied.

Driving and visual field loss
People with diabetes receive a medically restricted driving licence which means that a maximum of every three years they have to reapply for a licence and they are asked to give permission for the DVLA to contact their doctor for a report. If there have been changes in the eye or laser treatment has taken place, then the DVLA ask people to visit a local optician for a visual field check. It is worth noting that you can go to your ophthalmologist for this test and report.

The DVLA will then either renew the licence or remove it but bear in mind, that this decision is made on the results of instruments that were never designed for this purpose. So it is not unreasonable to question such decisions and in fact you can appeal.

No change for 20 years but the DVLA are removing licences???.
Many people have had laser treatment in the past which has successfully halted the progression of retinopathy with no further treatment for 20 to 30 years. Their driving licences have been renewed regularly every three years and then suddenly they have found that their licence has been removed. There is only two ways of looking at this:

- the ophthalmologists' decisions to pass people as suitable to renew their licence was wrong in the first place and the DVLA is therefore criticising their professional skills
- the DVLA have tightened up the regulations for driving without telling anyone and dare I say, without evidence from research to show that the methods they are using to make their judgements are appropriate.

IDDT member, Stephen Chadwick lost his licence 3 years ago - his laser treatment was then 10 years ago with none since. He immediately saw his ophthalmologist who sent a report to the DVLA confirming that Stephen's licence should be renewed and theDVLA renewed it. But 3 years later, in 2005, they did exactly the same thing again but so did Stephen and the DVLA reinstated his licence, again!

Jackie Banks has waged an almost one woman campaign against the DVLA for 7 years because this happened to her. She had laser treatment 28 years ago and it has remained the same for all this time, yet suddenly her licence was removed. She appealed against the decision and her licence was reinstated but, 3 years later it happened again. So the battle went on, Jackie is still driving and has successfully helped others to appeal against DVLA decisions. Jackie has pressed the case with the DVLA and attended a meeting to try to explain the patients' perspective. We have to express gratitude to Jackie for her painstaking investigations and hours of work for people with diabetes.

What can conclusions can we draw?
Jackie and Stephen's cases highlight a flawed system that can result in people with diabetes losing their driving licence, possibly their job

as a result and certainly a lowering of their quality of life.

- Why should someone whose eyes have not changed for 20 plus years have their licence removed when previously an ophthalmologist has stated that they are fit to drive?
- If the tests were correct and reliable the first time they were carried out, why has the DVLA reversed their decision on appeal? Clearly, the first decision did not stand up to scrutiny!
- So how many people have had their licences removed unnecessarily because they accepted the DVLA decision without question?

Stephen and Jackie, and many others, fit into a special category. They had laser treatment which stopped their retinopathy progressing and the DVLA has approved them as fit to drive for years but for no valid reason, suddenly removes their driving licence - then decides that they are fit to drive after all!

No one would advocate that people should drive unless they are safe to do so, but clearly there are grey areas, largely because there is no definite test to measure what people actually see in real life when they have two eyes open and move them around. Sadly, the DVLA don't seem to understand this or that retinopathy is not always progressive.

If you have lost your licence, this article may help you. If you would like to chat about this, call Jenny on 01604 622837 or e-mail jenny@iddtinternational.org

As I have informed you in the past; for the past 22 years; I have been taking Lilly pork insulin (NPH and Regular) because when I tried the human insulins; I did not feel well on them. I was lucky at that time because my original endocrinologist sort of believed me and told me that it was ok to remain on the pork insulin.

"I Walked Out of Hospital in my Slippers!"

Many people call IDDT about their experiences of being an inpatient in hospital in the hope other people will learn from their experiences and IDDT member, Jean, is no exception to this. Jean is a qualified nurse who has had Type 1 diabetes for many years. She has an overactive thyroid and needed an operation. She followed all the correct procedure and informed the hospital of medications including the need for Hypurin Porcine Neutral.

Once in the ward, she checked several times that they had got the correct insulin and she was assured that they had. The next morning just before going into theatre she could see doctors putting insulin into the drip they were about to give her but the insulin was cloudy and not clear as Neutral insulin should be - in other words they were about to use long-acting insulin in her drip!

To cut a long story short, she questioned the type of insulin they were using but the medical staff said that she had got what she asked for, pork insulin. To make matters a whole lot worse, they refused to believe her when she told them that they should use short-acting insulin in the drip. Extremely upset and without more ado, she walked out of the ward in her slippers stating that if they thought she was going to allow them to cut her throat when they didn't even know what insulin they should be using and wouldn't listen, they had another think coming.

Angry and extremely upset at what could have happened, Jean sat outside the PALS office [patient's complaints] until they opened and exploded! From there she was given two options - to make a formal complaint or to go represent patients on an advisory committee about patient care and policy. Jean chose the latter on the basis that she feels she can perhaps have a greater influence than going through a lengthy complaints procedure where ranks may well close. She's due to go in for her operation next week but is receiving tip-top care this time. But as she rightly points out, she is at what is classed as a 'good' hospital, this should never have happened but perhaps the

biggest insult was that the staff showed no respect for her knowledge of her diabetes.

Jean's message to readers: it is vital to check everything and keep control of your diabetes while in hospital. What would have happened if I had been a more timid person who simply put my trust in the professionals? It doesn't bear thinking about.

Problems in hospitals have existed as long as some of us can remember but they ought to be improving - are they?

An interesting piece of research answers this question for us. The medical case records of all patients occupying in-patent beds in a busy urban hospital were audited on a single weekday in 2003 and this was repeated 3months later. The information was then compared with an identical audit carried out 12 years earlier in 1991. The results showed:

- the number of bed available had reduced by 25%
- diabetes management was considered inappropriate in 29% of patients compared with 20% in 1991
- Almost half the discharge summaries in 2003 did not mention diabetes.

So diabetes management in 2003 was less than satisfactory in more patients than in 1991. Where is it going wrong?

Other common problems in hospitals

An in-patient stay is treated as an opportunity to change your insulin!
IDDT regularly receives calls from people who have either had their type of insulin changed when they have been admitted to hospital or have had to be pretty forceful to remain on their usual insulin. Clearly this is mainly from people using animal insulins but we have also had reports of people being changed from 'human insulin to Lantus in this way. The British National Formulary [BNF] 2004 advises that people with Type 1 diabetes having surgery should be put on an infusion drip and says: "Give an injection of the patient's usual insulin on the night before the operation". So if you are placed under pressure to change to a different insulin while you are an inpatient, remind the staff of this BNF!

Your pens are taken off you!
Another frequent problem that people experience is that when in hospital their insulin pens are taken off them by the staff. One of our members checked this with NHS Direct and was informed that the pens are your property and should not be removed from you. Whether or not NHS Direct advice is followed is another matter but NHS Direct supports your right to hang on to your pens!

So How Should diabetes Be Managed In Hospital?

The Physician's Weekly [November 7th 2005], an American journal, suggests the development of a programme for the management of diabetes when someone is in hospital and such programmes should:

- Give consideration should be given to permit self-use of equipment and drugs already in the patient's possession.
- There should not be an additional burden on dietary or nursing staff.
- Hospitals should recognise that fear of causing the patient harm and deficiencies of knowledge and skills may underlie staff resistance to patients managing their own diabetes.
- Self-management is appropriate for competent adults with stable levels of consciousness and who have demonstrated that they know their daily insulin needs. When this is the case, the patient and the doctor should consult with the hospital nursing staff to agree that self-management is appropriate and that the patient will share with the nursing staff insulin doses and blood glucose test results for record keeping.

This all seems pretty reasonable and should be achievable in all hospitals, so if you have to go into hospital for a planned stay, why not discuss setting up this programme with your doctor BEFORE you go in.

Planned discharge from hospital
The article also says that there should be discharge planning that is appropriate, achievable and agreeable to the patient and their family.

Hospital staff usually explain what is required verbally and may also give written, or even video-taped, information. A Cochrane Review [Cochrane Library, Issue 3, 2004] of hospital discharge information on how to manage care effectively at home only found studies looking at parents caring for their children. The review showed that parents had a better understanding of the care needed when given both written and verbal instructions, rather than verbal instructions alone. So it may well be worth asking for the information about your care after discharge to be in writing - none of us can remember everything!

Try Harder Doesn't Work!

Received by e-mail from Mr T.D.
People who do not have to live with diabetes just think you take the necessary jabs and every thing else will be fine. What few people realise is that the determination of insulin dose is not a simple calculation and the problems in determining the dose must be infinitesimal so when some well-meaning professional says, "Try harder" I don't think they truly understand the complexity of their job! Lets take a look at some problems that immediately spring to my mind:

- Variety of choice in animal insulin types and variety of choice in "human" insulin types
- Body mass
- General lifestyle and eating habits. Is today a work-day or a rest day? Weather conditions (extremes of temperature either hot or cold)
- Exercise taken (or lack of it)
- Humour (good or bad), emotional state at the time, stress
- Was it a good jab?
- The state of the immune system - is it under attack from a virus or infection?
- Medications themselves

Last week my sugar levels shot up but I didn't have a cold or any obvious signs of infection other than stiffness. I tested frequently and increased my fast-acting insulin but with little effect and I felt awful. I crawled to the doctor and it seemed that I had a chest infection that large doses of antibiotics cleared up and my blood sugars started dropping. My point is that I don't think I made any wrong decisions along the way but there was simply nothing to say what was causing the high readings and 'trying harder' is not the answer.

At the end off 2005 Lente and Ultralente will be done away with. I cannot afford to pay $80.00 a vial for Lantus insulin. NPH never agreed with me. I cannot get help with the costs of this new insulin. What do I do? I've been on insulin nearly all my life for 60 years. Now I'm at the end of what might of been a few more years.

More Experience of the Disability Living Allowance [DLA]

I was pleased to see the letter by the writer who explained the difficulties experienced when claiming DLA.

After 24 years of good health, despite type 1 diabetes, my situation changed in 1984 shortly after being transferred to human insulin: I became very tired, lost warning signs of hypoglycaemia beginning and my diabetic control became very erratic. As the situation worsened

over time, I applied for DLA in 1995. My claim was rejected and I had to appeal. The reasons given by the DWP were bizarre, e.g. I could 'prevent a nocturnal hypo by setting an alarm clock'. I understand this information was given by a medical advisor to the DWP.

With the help of a Social Worker, an expert in Benefits, I won the appeal and have received DLA (care and mobility components) since that time. On the last award, the care component was actually increased.

My health certainly has not improved and if anything has worsened with very serious problems with cognitive functions. However, in February 2006, the DWP decided to reject my DLA renewal claim and once again gave reasons that betray a complete lack of understanding of the subject of diabetes. I can only assume that once again, this was 'advised' to the DWP by someone whose lack of understanding of the subject is obvious. As someone who has been a type 1 diabetic for nearly 50 years, and had to cope with all its complications, and the life- threatening problems caused by human insulin, I am surely in a better position to interpret my own situation.

Now I have the stress of waiting for a re-consideration of my claim by another DWP adjudicator which will take several months, and if it is refused again (and I cannot see one DWP officer counteracting another), I will have to attend an appeal, which will take another 6 months or more to arrange, and require me to travel much further than I feel safe doing.

My anger is fuelled by the fact that my health troubles are not of my own making (despite the DWP's offensive suggestion that they are) but directly attributable to a drug that was unnecessary, costly, had no benefits over existing insulin, and the manufacturer knew beforehand would result in hypoglycaemias occurring more quickly (1) and was therefore dangerous.

On making enquiries, I now discover that due to cost-cutting, the Social Services cannot help me with advice or representation, so I am literally 'on my own'. Occasions like this help me to understand why people feel the only way to vent their frustration and anger is by direct action.

(1)Science News, 27 June 1981, vol. 199, p.199.

David Nicholls (Dr.), Dip.RS, B.A.(Hons.), MPhil, PhD. Herne Bay, Kent.

Novo Nordisk Have Over Half of the Total Insulin Market Worldwide

A Stock Exchange Announcement by Novo Nordisk in January 2006 showed that the company's total market share worldwide of insulin sales measured by volume is 51%, up from 50% in 2004. Sales of analogues increased by 61% with their worldwide share of insulin analogue market being 34%, up from 28% in 2004.

It has to be said that the easy way to increase the sales of their newer and significantly more expensive [and more profitable] insulins is to simply prevent people from using the cheaper ones. How? Discontinue them! Their discontinuation of some of their human insulin products in 2005 'forced' people to change to analogues and no doubt, they hope that the discontinuation of pork insulin will do the same.

A reality check of the effects of such decisions: on the very day of writing this article, IDDT received a call from the son of a 75year old man with diabetes who is very distressed and upset. After 10years of successfully using Human Mixtard in pen cartridges twice daily, Novo Nordisk withdraw it and his doctor has changed him to the more complex regime of analogues with 3 injections before meals and an injection of long-acting insulin at night, using two different pens. He is confused by the new regime and frightened of using the wrong pen at the wrong time. This regime may not be complex to a 25year old or a 55 year old, but to a 75year old living on their own, it is. His quality of

life has gone down and his stress levels have gone up. Whether or not Novo Nordisk believe that analogues result in better diabetic control is immaterial to this man and many like him, because his quality of life is so much worse. He, and many people like him, are paying the price of shareholder profits.

IDDT suggested that his son discusses with the doctor changing his father to Hypurin Porcine 30/70 Mix, the nearest equivalent to Human Mixtard 30 and a way that his father can stay with two injections a day in the same pen.

Importion of Animal Insulins for Personal Use

There have been requests from people in various countries that the Newsletter provides information about how to import either beef or pork insulin from Wockhardt UK [formerly CP Pharmaceuticals] but as there are variations in the systems for different countries, shortage of space prevents this. There are some common factors that apply:

- Most countries have some system for importation of drugs for personal use.
- The systems only apply to drugs that are not available in the patient's own country.
- The systems require a letter of support and prescription from a doctor - proving to be a problem in the US.

Details of how to import can be obtained from Wockhardt UK

website http://www.wockhardt.co.uk/ +44 1978 661261 or their postal address is Wockhardt UK, Wockhardt UK Ltd, Ash Road North, Wrexham Industrial Estate, Wrexham LL13 9UF, UK

What's New?

Lilly launched a new pen
In October 2005 Lilly launched a new pen for use with their Humalog range of insulins. It is called the HumaPen Luxura and has a clear cartridge holder so that users can see when the insulin is loaded and the dosage can be moved forward, or backwards if over dialled, with no loss of insulin.

New rapid-acting analogue insulin
Sanofi-Aventis, manufacturers of the long-acting analogue, Lantus [glargine], has introduced a new rapid-acting analogue insulin Apidra [glulisine]. It is in the same group of insulins as Humalog and NovoRapid. Approval is for use in ADULTS. The documents about the use of Apidra state:

In children and adolescents - there is on its use in these groups [means trials have not been carried out].

Use in pregnant women - again no adequate clinical information and there is a warning that 'caution should be exercised when prescribing for pregnant women.

Use in nursing mothers - it is unknown whether Apidra is excreted in the millk.

The clinical studies for approval showed:

- When compared to Humalog in people with Type 1 diabetes, blood glucose values were the same [26 week study]
- In terms of efficacy, immediate post-meal injection was comparable to pre-meal injection and to short-acting 'human' insulin injected 30-45 minutes before meals. [12 week study].
- In people with Type 2 diabetes, a 26-week clinical study followed by a 26-week extension safety study showed that Apidra was comparable to short-acting 'human' insulin in terms of HbA1cs.

So Apidra does not appear to have any advantages in control over existing insulins.

Note Jenny found interesting: when it became known that Apidra was likely to reach the market, I went to the Compendium of Medicines to look it up. At this stage it was classed as a 'virtual product' which apparently means that although not yet licensed, it has been prescribed 3 times in the last 12months. There was very little information about it but a list of yes/no answers to a few questions - sugar free? NO, gluten free? NO. Fascinating!

Inhaled insulin has been approved!
Inhaled insulin has been approved for use in adults with both Type 1 and Type 2 diabetes in Europe and the US. Reports suggest that it will not be available in the UK until May 2006 but there could be a further delay as NICE has to review it and issue guidance about its use within the NHS, expected date for this is September 2006.

The inhaled insulin, Exubera, made by Pfizer and is designed to offer adults with diabetes an alternative to insulin injections before meals. Long-acting insulins will still have to be injected once or twice daily. There are still some concerns about possible lung damage with long-term use.

In the US, the FDA panel expressed concern about the bulkiness of the dispenser and that some patients experienced coughing or a slight decrease in lung capacity when using inhaled insulin. Pfizer are to study the long-term effects on the lungs and the safety and efficacy in people with lung disease. Costs may also be an issue as it is expected that inhaled insulin would cost $4 to $4.5 a day compared to about $1 a day for injected insulin.

Taking a look at the evidence????
A Cochrane Review of inhaled insulin to compare the efficacy, adverse effects and patient acceptability of inhaled versus injected insulin.

The reviewers found only 6 randomised controlled trials with an overall number of participants of 1191. Three trials included patients with type 1 diabetes and three with type 2 diabetes. Three trials had a duration of 24 weeks, and three of 12 weeks. Few studies were published in full and so the quality of the studies could not be assessed and only two studies appeared to use the same basal insulin in the inhaled and injected groups, so the reviewers describe the quality of the evidence as 'not great'.

The Review shows:

- HbA1cs were similar for all the trials so control was about the same with inhaled insulin as with completely injected insulin regime.
- Overall the numbers of hypos were similar but one trial showed a statistically significant increase in severe hypos in the inhaled group.
- All trials reported significantly better patient satisfaction and better quality of life with inhaled insulin. However, patient satisfaction is based on five trials, of which only two have been published in full; also the three trials containing quality of life data are all only published in abstract form at present.
- No adverse effects on the lungs were observed but longer follow-up trials are needed.
- More insulin has to be given by inhaled than by injection to achieve the same effect, and the cost-effectiveness still has to be assessed.

Published in the Cochrane Database of Systematic Reviews 2006 Issue 1, http://www.thecochranelibrary.com/ or go to www.cochrane.org/reviews/en/ab003890.html

Comments from other sources - Diabetes UK said that it will be welcomed by some people but a spokeman for the American Diabetes Association, said that injected insulin will still allow people to better control their dosage.

Just a note: if inhaled insulin costs more, will people pay for it?
A study in Canada looked at patients' willingness to pay more

for inhaled insulin than the usual cost of insulin for injections. [Pharmacoeconomics 2005:23(12)] The average age of the patients was 51years with 75 having Type 2 diabetes and 19 Type 1. The results indicated that people would prefer inhaled insulin to insulin injections and would be willing to pay a substantial amount per month to use it, this particularly applied to those not presently using insulin. Significantly more people with Type 2 diabetes using oral drugs preferred inhaled insulin than those with type 1 diabetes using insulin (98.5% vs 69%) suggesting that people who have never injected are prepared to pay extra to avoid them. No doubt this research will help the manufacturers to know their target audience for marketing inhaled insulin!

I live in the US and I do not have a doctor who approves my use of animal insulin, Is there any place I can purchase this without a doctor's letter, I would rather use nothing than use their poison. I surely hope you can offer some advice.

From our own Correspondents

The issue of the recommended amount of dietary carbohydrate is of pivotal significance to diabetes outcomes.
Dear Jenny,

I would like to support Dr Morrison's excellent article in the January edition of the IDDT newsletter.

One area of pivotal significance to diabetes outcomes is the issue of the recommended amount of dietary carbohydrate that people with diabetes consume.

I'm writing in a personal capacity as a person who has had type1 diabetes for the last 48 years since the age of 6.

Dr Morrison makes the points well about the advantages of the lower carbohydrate approach. The article has profound and often unrecognised implications.

Much dietary advice for diabetes continues to recommend, for example, 50 - 55% of daily calories coming from carbohydrate. For an average male on 2000 calories a day this amounts to around 270 grams of carbohydrate daily as the recommended intake. This is a very large carbohydrate load for a body that has major problems with carbohydrate metabolism!

As Dr Morrison indicates, this requires much more insulin, guestimates about the amount of carbohydrates actually being consumed, and if one is trying to get good control, is much more likely to produce severe hypos in addition to worsening of gastroparesis (delayed stomach emptying) which many people with diabetes experience.

So why was high carbohydrate recommended for diabetes? One partial explanation is that there was increasing rates of heart disease, which in the 1950's was put down to fat in the diet. So the logic was that we should reduce the fat, so what will people eat??.carbohydrate. But we now are aware of the healthy and unhealthy fats.

In summary, lower amounts of carbohydrate require lower amounts of insulin, and this results in more predicable blood glucose outcomes with less hypoglycaemia, among many other benefits.

Ron Raab
Vice-President, International Diabetes Federation http://www.idf.org/
President, Insulin for Life Inc http://www.insulinforlife.org/

Surely this is the proof
Dear Jenny,

Some years ago I rang you up because I felt so awful, I was having hypos and didn't know it and my behaviour was quite different from my normal self. I was taking 'human' insulin and after reading information

from IDDT, I decided to go back to pork insulin. I was so much better within days.

Then a few months ago my doctor changed me to Lantus and for the first few weeks it seemed OK but then I started having problems again. So my doctor changed me to Levemir but my blood sugars were all over the place and then it seemed to stop working altogether and had no effect on my blood glucose levels. I have now changed back to pork insulin and I feel fine and my blood glucose levels are back under control.

Over the years I have tried GM insulins twice and returned to pork insulin twice and it is obvious pork insulin is the only one that really suits me. I think that I have proved that some of us cannot use the GM insulins and this is why it is so important that IDDT continues to fight for us to have the animal insulin we need. Thank you for all you do for us.

Robert Cassells
N Ireland

I applaud IDDT but??.
Dear Jenny,

I applaud the actions of IDDT in getting recognition of the need for animal insulins to be available for us.

I have one problem with this concept, as far as I am aware, manufacturers have a free reign to make and market what they want without any regard for their customers and can, if they wish, disregard any Ministerial advice or opinion. There is no contract between the manufacturers of insulin and the Government. I feel that there ought to be as in this country, the purchaser of insulin is the NHS and I feel that as the consumer the Government ought to be able to override commercial decisions that are against the patients' best interests.

If a manufacturer decided to stop producing animal insulin there is no authority or contract to stop this happening. I have had the recent experience of Novo Nordisk withdrawing Human Actrapid in cartridge form. The withdrawal has gone ahead leaving many diabetics without the insulin that they have become accustomed to. Novo have 'conveniently' bought out a replacement insulin which is more expensive and has a different action to that it replaces.

Howard Glansfield
East Midlands

Independent nurse prescribing
Dear Jenny

I read with great interest your article on the above in the January 2005 newsletter as I have an interest in this development from a number of perspectives. Professionally I am a pharmacist within a specialist Mental Health Trust and one that is taking the extended prescribing role in a positive way by providing a degree level medicines management and therapeutics course for all nurse prescribers before they go in to local practice. One thing I have learned from this is that nurses work very much within a competency framework and will before embarking on any intervention ask, am I competent to do this. Before we developed the non-medical prescribing agenda we consulted our patients and there was an overwhelmingly positive response to the nurse being able to provide medication. Prescribing should be understood as more than just a pen to paper exercise and many patients said they prefer nurses because they 'speak my language'.

In the field of diabetes where I am a patient I find a highly specialist nurse to have more understanding of realities of living with diabetes than a junior doctor who is 'fully trained' and on rotation. I cannot let the term fully trained pass without comment as conceptually in the model of lifelong learning no one is ever 'fully trained' and it is and has been for many years that an experienced practitioner (nurse or pharmacist) often guides a junior prescribing doctor on therapeutic matters.

Herein lies another important aspect of prescribing - the relationship and confidence in the prescriber. In many ways modern and good prescribing is best done not in isolation. Supplementary prescribing formerly records through a clinical management plan the shared responsibility; most importantly the patient is an equal player in this agreement.

A few points to address more directly. The hippocratic oath has no standing in law. Any professional is accountable for their practice and liable if they get it wrong. Nurses assess to the point of diagnosis but formal diagnosis remains with the medical profession.

A final thought...if current arrangements with only doctors prescribing were that good how come we have so many adverse drug events related to medical prescribing.

I suspect that most people when choosing whether to be cared for by medical or nursing staff will base that decision on relationship and less so on training and professional standing. Perhaps others might like to comment on this issue.

Alan Pollard
Worcester

Canadian Expert Drug Advisory Committee Recommends That Lantus Is Not Funded

In Sept 2005, the Canadian Expert Drug Advisory Committee [CEDAC], an organisation similar to NICE in the UK, recommended that Lantus [glargine] is NOT listed for funding. This means that although Lantus has been granted a licence, the cost will not be covered by the health system.

The summary of CEDAC's reasons is that the submission by the manufacturer was based on the assumption that patients treated with Lantus achieved lower HbA1cs without increasing the numbers of hypos when compared to intermediate-acting insulin [NPH]. However, this assumption was not supported by the results of the randomised controlled trials.

The cost of Lantus in Canada is $5.50 per 100units and the cost of NPH is only $1.60 and CEDAC felt that the reported differences in clinically important outcomes of Lantus over NPH justified the threefold difference in cost.

It does make you wonder why the UK NHS is paying for it, especially as it is public money!!!

I've been reading about the availability of pork insulin being non-existent in the USA...Do you know of any company that makes pork insulin so I can obtain it? I was on 'human' insulins for a year and had serious hypos twice a week. After a year, I'd had enough and went to pork insulin. I can't believe that pork insulin may not be available to me...can you help??

IDDT Supports Research into Insulin Analogues

As regular readers will be aware, IDDT has always been concerned about the lack of information about the long-term safety of insulin analogues and in particular their potential for carcinogenic effects. IDDT has awarded a grant for research that investigates some of our concerns and here is an abstract of the research that is being carried out.

Do insulin analogues have mitogenic activity? Analysis of the interactions of insulin analogues with the IGF-IR signalling system
Haim Werner, Ph.D. and Zvi Laron, M.D.

The use of insulin analogues in the treatment of diabetes has enormously expanded in recent years. Insulin analogues are artificial derivatives of human insulin that are designed to display better activity profiles. Short-acting insulin analogues include, among others, insulin lispro (Humalog) and aspart (NovoRapid) whereas long-acting analogues include insulin glargine (Lantus) and determir (Levermir). While the clinical benefit of insulin analogues in terms of glycemic control has been extensively studied, the long-term effects of most analogues, including a potential carcinogenic activity, have not been systematically evaluated. It is becoming increasingly clear, however, that one potential safety risk of insulin analogues stems from the fact that the structural modifications introduced into the native molecule, in addition to altering its absorption kinetics, may enhance their affinity for the insulin-like growth factor-I receptor (IGF-IR). The IGF-IR is a potent cell survival-promoting receptor that mediates the proliferative effects of the insulin-like growth factors, IGF-I and IGF-II. The question whether insulin is capable of inducing mitogenic effects through its cognate receptor or via the IGF-IR has been extremely controversial for many years. In fact, recent studies revealed that some of the newly developed insulin analogues exhibit an increased affinity for the IGF-IR and display atypical activities, such as inhibition of apoptosis (programmed cell death) in tumor cells and abnormal post-receptor signalling compared to native insulin.

The essence of the present grant application is to investigate the potential oncogenic properties of insulin analogues, in comparison to native insulin and IGF-I. Specifically, analogues will be evaluated for their ability to induce and sustain cellular proliferation, invasiveness, and protection from apoptosis. Further information on the biological activities of insulin analogues will be provided by studying the nuclear proteins (e.g., transcription factors) that might be differentially induced by insulin analogues and that are responsible for transducing their mitogenic activities. To this end, a proteomic approach will be employed. The ultimate goal of proteomics should be to identify and characterize the entire collection of proteins that are induced by particular stimuli, and that constitute the molecular basis to the cell's biological response. Taken together, the proposed research may shed light on the biological and possible pathological events elicited by insulin analogues. The information generated may be important when evaluating the potential benefit of analogue-based therapy in diabetes treatment.

For copies of IDDT's Supplement: ***'The Safety of Insulin Analogues - should patients be concerned?'***, please contact IDDT on 01604 622837 or go to the Home page of our website www.iddtinternational.org

IDDT News

Calling all parents!

- IDDT now produces Information Packs for Parents and also Packs for Teachers to help them to understand the needs of children with diabetes in their class. If you would like either or both of these Packs, contact Bev Freeman on 01604 622837, e-mail bev@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS
- The number of parents of children with diabetes who are joining IDDT is increasing and as parents have special interests we are going to publish a short 'Parents Bulletin' between the quarterly Newsletters. If you would like to receive the 'Parents Bulletin', please contact Bev through the above contact details.

Calling all members!

IDDT's Annual Meeting, 'Make Your Voice Count', will be held on Saturday, October 14th 2006 at the Paragon Hotel in Birmingham, so please put the date in your diary. Last year's meeting was a great success and we hope that even more of you will join us this year - it's your opportunity to meet other people with diabetes, to have your say and to learn more about more about diabetes. The programme and booking forms will be sent to you in due course.

Stories From the Past

A new website showcases life stories of people with diabetes providing a collection of audio recordings of life-stories of people with diabetes diagnosed with the condition between 1927 and 1997. Not only is it important to not forget how diabetes treatment has changed over the years but it is also important to remember that there are valuable lessons to be learned from people who have lived long lives with diabetes. http://www.diabetes-stories.co.uk/

Just an interesting quote in the European Pharmaceutical Executive, Jan/Feb 2006 from Lise Kingo, Executive Vice President, Novo Nordisk:

'Everything you do in the company has to balance being economically viable, socially responsible and environmentally sound.'

What is socially responsible about removing pork insulin?

Clues To The Cause Of Ongoing Pain

There are many conditions that result in on going pain and neuropathy in people with diabetes is one of them. Neuropathy is a complication of diabetes caused by damage to nerve fibres - neuropathy affecting the feet and legs being the most commonly form. Ongoing pain from nerve damage is a burning or sharp stabbing/shooting pain that can occur spontaneously and it is difficult to live with because there is no currently available treatment that works for everyone.

What causes ongoing pain and why it occurs spontaneously has not been fully understood with research focussing on the damaged nerve fibres. Now new research at Bristol University [Neuroscience, Jan 2006] has found that it is the undamaged nerve fibres, not those that are injured, that may cause the long-term pain.

The researchers discovered that the key was nerve cells called nocireceptors, each of which has a very long fine nerve fibre emerging from it. These fibres run inside the nerves and connect to the skin or other tissues in the spinal cord. They are activated by damage from injury or conditions like diabetes and fire electrical impulses that travel from the damaged area to the spinal cord and then the brain. The faster the fibres fire, the stronger the pain becomes. The firing seems to be triggered by the inflammation of the damaged nerve fibres.

The researchers say that although more work is needed in pain associated with various diseases, this understanding may help to find more effective pain killers.

Aspartame - Special Debate In Parliament

In IDDT's October 2005 Newsletter we reported the Italian study showing that the artificial sweetener aspartame was fed to rats and many female rats developed lymphomas or leukaemias. In December 2005 in a special debate in Westminster Hall, leading scientists joined forces with MPs to urge the Government to ban all food products containing aspartame just as they did with Sudan 1, a much less common product. Lib Dem MP, Roger Williams said that when he began looking into aspartame, he was unconvinced by the internet conspiracy theories but as a man of science a number of eminent academics have persuaded him beyond doubt that aspartame represents a serious health problem.

In a 20 minute speech he covered the 30year long and controversial history surrounding aspartame:

- the science supporting its approval being biased, inconclusive and incompetent
- crucial questions over its safety being repressed since the early 80s with journalists trying to tackle these questions being threatened

with intimidating letters from the industry's lawyers

- That industry defends aspartame as safe by claiming that 500 studies have shown it to be so. But he points out that a product can be tested 4,000 times but if the tests are badly conducted and tested in such a way as to produce the desired results, its safety will always be questionable.
- the FDA website lists more than 900 aspartame-related health conditions.

Roger Williams recalled the speed with which products containing Sudan 1 dye were removed from the shops in February 2005 although humans would have to consume 3 tonnes of Worcester sauce everyday for 2 years for potentially harmful effects to occur from the tiny doses of Sudan 1 in foods. Yet despite this minimal risk, it was removed immediately. He asked the Minister to explain why the treatment of aspartame, still in 6,000 food products in supermarkets today, has been so different from that of Sudan 1.

He went on to say that he believed that aspartame should never have been licensed for use as a low-calorie sweetener and that there is compelling and reliable evidence for this carcinogenic substance to be banned from the UK food and drinks market. He called on the Government to ban the use and sale of aspartame.

Meanwhile, Roger Williams' advice for adults and their children - check the labels and make up your own mind.

Minister of Health, Caroline Flint said that the Italian researchers have been asked to make all the data available to the European Food Standards Agency for assessment and when their advice has been received, the UK Foods Standard Agency and its independent scientific advisory committees will study it. Then they will consider whether it needs to revise the advice on consuming aspartame.

Varying the use of artificial sweeteners: for people who do not want to use aspartame [Nutrasweet] or who want to reduce their daily intake, sucralose [Splenda] or saccharine are alternatives.

Hypoglycaemia - Traffic Wardens Need Education!

The Manchester Evening News [5.1.06] reported the case of a wife of a pensioner with diabetes who had collapsed while out shopping, who was booked by a traffic warden after she parked in the mayor's empty parking space.

Apparently her husband had a hypo in the shopping centre and although he had his glucose tables, he was feeling 'wobbly' so she dashed off to get bring the car nearer to pick him up. In her haste and concern she parked in the mayor's space while she went into the shops to fetch her husband. When she got back, a traffic warden was sticking a parking ticket on the car, which has a disabled sticker on it too. When asking for understanding for the emergency, no compassion was shown!

A similar incident was reported by one of our members. He was driving and felt his blood sugar dropping so he did all the right things - stopped the car, got into the passenger seat, ate glucose tablets. His wife then dashed just down the road for some long-acting carbohydrate and he was approached by a traffic warden who showed no sympathy and made him move the car before his blood sugar was back to normal.

Not for the for the first time, the message here is beware of traffic wardens!

It is truly amazing that a major, multi-billion dollar corporation would sacrifice so many people's lives all in the name of profit. Do you have any information about the availability of pork insulin. We need to do something or my wife will likely die before too long. It's a hard thing to say and to think about, but it is a hard cold fact. We are willing to go to Canada, UK or wherever necessary. If you have any advice you can share I would like to hear it. Thanks for being there in our need.

NHS News

Yet another new role in healthcare!
We have seen the government's intentions of allowing nurses to diagnose and prescribe drugs after going on a short course, now they are proposing yet another new role for the NHS in England. These new healthcare professionals are to be called Medical Care Practitioners [MCPs] who would work in hospitals and in primary care. They would be able to diagnose and prescribe drugs without needing to be medically qualified. The proposed training course is similar to that of a doctor's training but much shorter. The British Medical Association has warned that this will confuse patients and could affect the quality of care and is asking for further consultation and public debate to ensure that there is a genuine need for these posts and that they can be shown to truly benefit patient care.

Review ordered into NHS phone charges
Calling a patient in a UK hospital can be twice as expensive as calling Australia, according to an Ofcom inquiry [Jan. 2006] - calling a bedside telephone can cost up to 49p a minute. After complaints from patients, friends and families, Ofcom investigated the charges last July. In recent years, hospitals have installed entertainment consoles by patients' beds, providing access to television, telephones and the internet but regulations state that these systems must be self-financing and private contractors have claimed they have no choice other than to increase the price of incoming calls. The Dept of Health is to now form a review group to examine some of the issues raised!

NHS cuts
Health Secretary Patricia Hewitt ordered a winter round of NHS cuts to eliminate the deficit of up to £700m being forecast this year by hospitals and NHS trusts across England. A Dept of Health spokesman said Hewitt's the policy was an attempt to break a pervasive attitude among doctors and managers that the government will always bail out Trusts and that Trusts had to experience pain locally. Amazing comment! Who will really experience the pain? Ultimately patients!

Snippets..

Good idea for women over 50 to have a drink - but in moderation!

Research in Holland studied over 16,000 women over 50 and found that those who who had up to three alcoholic drinks a week were far less likely to develop Type 2 diabetes than those who did not drink at all. However, once women started to drink too much the benefit was lost.

Inequalities still exist in health care - the Office of National Statistics [Feb 2006]
This report showed that the north-south divide still exists in terms of health with the Scots having the lowest life expectancy, three years less than England but it has the highest rate of exercise. Wales has the largest proportion of disabled people, women in Northern Ireland have the most babies and England has the fewest NHS hospital beds per head of population.

£1 million spent by the NHS on art.
It was revealed in November 2005 that the NHS awarded substantial grants totalling £1 million to hospitals, clinics and GP surgeries for works of art. Answering a Parliamentary Question, Minister of Health, Jane Kennedy, said the money had been given to improve the environment in which patients are treated but not specifically to buy works of art. Critics claim that the money could have paid for 53 newly qualified nurses.

Love is a drug
A study examined 17 people who had fallen madly in love and been in love for an average of seven months. They were placed in an MRI machine and asked to look at photographs of their sweethearts. The part of the brain most strongly activated was part of the brain stem that is activated when you want something or seek any kind of reward whether this is money, food or even drugs. This "reward" part of your brain sends signals of exhilaration when it feels that it is receiving the reciprocal love it desires. This implies that early-stage romantic love

is a drive and in good relationships, this early, obsessive romantic love eventually transfers to a different level, called “attachment.” [CNN Feb 14th 2006]

Just A Thought???

If you are a cat with diabetes in the USA you can have beef/pork insulin. If you are a human being with diabetes, you can’t. How fair is that?

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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Name: ——————————————————————————

Address: ——————————————————————————

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Postcode: ——————————————————————————

Tel No: ——————————————————————————

From Your Editor – Jenny Hirst

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