# Insulin Dependent Diabetes Trust

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## Happy New Year!
## Something to celebrate In 2005!

The Trustees of IDDT send good wishes to all our members for 2005 and a big thank you for all your help and support during the last 12 months. The New Year is a time for reflection - looking back over the last year and looking forward to the next. For IDDT and our members, last year was one of hard work and I am happy to say some real achievements. Thanks to your determined support and hard work and the support, enthusiasm and commitment of many MPs and MEPs, we have good reason to celebrate the New Year.

**An Adjournment Debate on Diabetes, House of Commons on 16th November 2004 and led by David Amess MP.**

He presented an excellent case for the need for continued availability of animal insulin and he asked the Minister for reassurances that he would do everything possible to ensure that the choice of animal insulin will continue to be available.

**Her Majesty's Government unambiguous response was made by The Parliamentary Under-Secretary of State for Health, Dr Stephen Ladyman:**

*" The hon. Gentleman asked about the availability of both types of insulin, and I can give him the assurance that he sought; to the best of our knowledge, there are no plans to discontinue the production of the two types of insulin. Were we to become aware of such plans, we would, of course, express a view, and our clear view is that which type of insulin a patient receives should be a clinical decision. That decision certainly should not be controlled by commercial considerations or*

*issues of availability. I hope that that reassures him."*

[Hansard 16 November 2004, 1331]

Wonderful, and in case you can't believe it, I repeat the Government view:

***"?. our clear view is that which type of insulin a patient receives should be a clinical decision. That decision certainly should not be controlled by commercial considerations or issues of availability."***

This is a huge step forward. The Dept of Health has always maintained that it cannot interfere with commercial decisions and while this may well be true, Her Majesty's Government has now stated that insulin treatment should be dictated by clinical decisions, that is by patients' needs, and not by pharmaceutical company decisions or by availability.

We must congratulate the Parliamentary Under-Secretary for so clearly expressing this principle. We admire his perception in ensuring that the principle applies to everyone with insulin requiring diabetes with no suggestion from him that it only applies to some people. This is especially important as there are still totally unsubstantiated claims that the adverse effects of GM insulin only apply to people who have previously used animal insulin. While this is not the case, and IDDT has evidence to demonstrate this, we have to ensure that animal insulins will continue to be available as an option for everyone and not just those presently using it.

We also have to be careful that the words 'clinical decisions' are not misinterpreted to mean decisions made by doctors alone. We are involved in those decisions - one of the very basic rights of patients in the NHS since 1948 has always been to an informed choice of treatment. And let's not forget too that this government is very much pro-choice, certainly in terms of health.

It introduced the NHS Plan putting patients at the centre of care and making them equal partners in decisions about their treatment. While many people with diabetes are not given an informed choice, they are not, or should not be, exceptions to this. This government has provided all the support we need to ensure that we, the patients, can make choices about our treatment and the type of insulin we want to use, whether this is animal, human or analogue.

**So we have to put aside our fears or timidity of our doctors and nurses and behave as equal partners in decisions about treatment and exercise our rights to informed choices. If you are worried about doing this, you have plenty of support to give you confidence. Here they are some examples!**

- **NICE Guideline on the treatment of Type 1 diabetes [Press Release, July 2004]:**

*"The new guideline makes clear that care should be patient centred and the views and preferences of individuals with type 1 diabetes should be integrated into their healthcare. Diabetes services should be organised, and staff trained, to allow and encourage this."*

Thanks to a Parliamentary Question from Tim Loughton MP on Sept 7th 2004, the Minister of Health did confirm that patient preference should form part of the choice of insulin type and regimen.

- **NICE Clinical Guidelines on Glycaemia Control in Type 2 diabetes [April 2003]**

*"Despite the lack of an evidence-base to support current practice, the group recognised that usual insulin therapy both for people with diabetes starting and continuing insulin now utilised human species insulin rather than beef or pork. However the purified forms of these latter species of insulin are appropriate options for clinical and patient choice."*

- **National Service Framework for Diabetes**

*This centres on encouraging patients to be equal partners in their care: "??.[PCTs] should ensure that systematic treatment regimens are in place? at the heart of these will be regular reviews, which will be based on a diabetes record and a care plan developed and agreed jointly between the person with diabetes and a member of the diabetes team".*

- **The General Medical Services Contract**

This requires delivery of services to meet laid down standards, one of which is: "treatment plans that include patient preferences".

- **Commission for Patient and Public Involvement in Health [CPPIH]**

This body has been set up by government with the remit to *"put patients and members of the public at the centre of all decisions that affect their health".*

- **Ask About Medicines campaign 2004**

The booklet for the 2004 campaign produced for patients prepared by a partnership representing health professionals, patient organisations, the NHS, Government and the pharmaceutical industry gives three key messages:

1. Everyone is entitled to be involved in deciding whether a medicine is right for them.

2. Everyone should be able to get good information to make decisions about medicines, from the source they choose.

3. Health care professionals need to help people make choices, and we support them in that.

## News From The Pharmaceutical Industry

- **Novo Nordisk's insulin analogue sales** are now approaching 30% of the world insulin market and make up 20% of their sales of all insulin products. Their latest analogue, Levemir has been launched in 10 countries including the UK and Germany.
- **The City of New York has filed a lawsuit** against 43 pharmaceutical companies for overcharging its Medicaid programme for drugs for the last 12 years, Novo Nordisk is one of the companies.
- **Aventis - two new types of OptiPen Pro called the OptiPen Pro 1 in the UK.** One has a metal insulin cartridge holder and takes only Ypsomed Penfine Universal Click needles and the other has a clear plastic holder which takes Ypsomed Penfine Universal Click needles and BD Micro-Fine needles. The correct needles must be used for each pen otherwise there may be insulin leakage leading to the wrong dose being given. Further information can be obtained from Aventis on 0845 6066 887. In the US Aventis has gained marketing approval for a re-useable injection pen, OptiClik.
- **4.10.04 A new fast acting insulin analogue from Aventis, Apidra** has received marketing approval by the European Commission for the use in ADULTS WITH Type 1 and Type 2 diabetes. It was approved in the US in April 2004.

## And In The Pipeline

**Inhaled insulin**

- **Kos Pharmaceuticals** have said that their experimental form of inhaled insulin in a mid-stage trial has proved as effective as Lantus [glargine] at controlling blood glucose levels in people with Type 2 diabetes.
- **Aventis/Pfizer inhaled insulin**, Exubera, has been refused approval by the EU licensing authority stating that 'it is not licensable at this time'. Although the inhaled powder has appeared

to be effective in clinical trials, there have been reports of small decreases in lung function and a build up of antibodies that potentially affect the drug absorption.

- **Novo Nordisk inhaled insulin** trial for Type 1 diabetes has been stopped abruptly before completion based on the results of phase lll trials. The results showed that the treatment "did not work optimally for patients with Type 1 diabetes" producing higher glucose levels after meals and lower levels during the night. Phase ll trials in Type 2 diabetes did not show these effects.

**Insulin patches** - lottery funding of £140,000 has been given to Starbridge Systems, Swansea to help them develop an insulin patch. The patch looks like a cross between a credit card and a first-aid plaster and it has tiny pumps which respond to high-density light bursts. The system involves wax in the pumps melting and pushing the drugs through tiny needles. It is thought that the patches will contain 3 days supply of insulin and will be easy to remove and stick to various parts of the body. It is hoped that the prototype will be developed by the end of 2004.

## Insulin Pump Therapy - bit and pieces

- **Research shows that pump therapy in young children is no better than injections and the number of hypos is greater**

Research at Indiana University studied 42 pre-school children who were treated in two groups one multi-daily injections and the other with an insulin pump for 6 months. They found that blood glucose levels did not differ between the two groups and the number of hypos, abnormally low blood sugars, was higher in the children using pumps than those on injections but both groups had one instance of seizure due to a severe hypo. Parents were happy with pump therapy and 95% of the children continued on pump therapy after the end of the study.

However, the authors commented that it remains to be seen whether the benefits of pump therapy in terms of flexibility and convenience justifies the extra cost. They also recommended that studies are necessary to see the effects of long-term pump therapy in children of very young ages.

Journal of Pediatrics, Sept 2004

- **Insulin analogues result in modest improvement in glycaemic control compared with soluble insulin in pump therapy**

A systematic review of trials of at least 10weeks which compared rapid-acting insulin analogues with soluble insulin in pumps showed a reduction in HbA1cs of only 0.26% with analogue insulin and some studies reported fewer numbers of hypos, depending on the definition of hypoglycaemia. There were no differences in weight or insulin dosage. Only two studies reported on patient preference and in both cases analogue insulin was preferred.

Diab Med 2003, 20:863-866

- **Animal insulin can be used in a pump**

**IDDT continues to receive quite a few queries about whether or not pork insulin can be used in a pump and the answer is: yes it can and IDDT has members who do!**

**NICE Guidelines for pump therapy**
Readers may remember there was a letter from Mrs E.J. in the April edition of IDDT's Newsletter in which she said that after many years of Type 1 diabetes, her blood sugars had huge swings and she had constant joint pains. Basically she was fed up and applied to go on the pump.

In February 2003 the National Institute for Clinical Excellence [NICE]

issued guidelines for pump therapy recommending that *"insulin pump therapy is considered as a treatment option for people with Type 1 diabetes for whom multiple dose insulin therapy has failed and who have commitment and competence to use CSII therapy effectively."*

They also state that injection regimes using 24hour-acting Lantus must be tried before pump therapy can be funded by the NHS perhaps a surprising recommendation when Lantus had only been on the market a few months and therefore the evidence of benefit or otherwise on the wider population was unknown.

So Mrs E.J. tried Lantus [with Humalog] but this did not help and so while she was waiting for her pump costs to be approved, she thought she would try pork insulin. The results were that her blood sugars became stable and predictable, her joint pains completely disappeared and she lost a stone in weight.

Mrs E.J. raised the question with IDDT about why the NICE Guidelines do not recommend that people should also try animal insulins as well as Lantus, as this would be an even cheaper option. IDDT did put this forward in the public consultation for the NICE Guidelines but not unsurprisingly, our views were not heard - yet again!

The use of pump therapy has increased and in young children, especially in the US and IDDT receives increasing numbers of enquiries from people who are being advised to consider pump therapy because of their erratic blood sugars. We have yet to hear from anyone being advised to try animal insulin to see if this improves their control. So perhaps it is a good idea to look at the evidence that resulted in the NICE guidelines:

**Objectives of pump therapy** - better control and improved flexibility of lifestyle

**Research comparing pump therapy and multi-daily injections [MDI] showed:**

- On average only 0.6 percentage points lower HbA1cs were obtained with pumps compared to multi-daily injections, so the overall effect was to lower HbA1cs to below pre-pump levels. Some studies showed an improvement in HbA1cs at 4 months but not at 6 months.
- Insulin usage went down at 4 months but not over a longer time.
- There was no difference in body weight.
- Patient preference slightly favoured pump therapy [many were using older pumps and so this may be biased] but only one study looked at quality of life
- Only observational studies and not randomised controlled trials found a significant reduction in hypos. [Randomised controlled trials [RCTs] provide the best form of evidence]
- In pregnancy, there was no significant difference in HbA1cs or baby's birth weight between pump therapy and injections
- In adolescents there was generally no differences found, although in one study of 25 adolescents with poor control there was a reduction of 40% in the rates of hypoglycaemic episodes with pump therapy compared to injections
- In children, no randomised controlled trials have been carried out to compare pumps and injections, so there is no good evidence either way.
- In people with Type 2 diabetes - no research.

**Costs**

At the time of the guidelines, the additional costs of pump therapy over 'normal' insulin therapy was between £1100 to £1400 per year. Primary Care Organisations and NHS Trusts were supposed to have funding arrangements in place for implementation of these Guidelines by February 2004 but many areas have still not done this resulting in many people still self-funding their pump therapy and others who qualify for it being unable to get funding through the NHS.

**For members in the US**

**Medtronic recalls insulin infusion kits**

Medtronic manufacturers of pumps have recalled its Quick-set Plus Infusion sets because of problems that can interrupt insulin flow and cause serious consequences. The FDA defines this as Class 1 recall - there is reasonably probability that the use of the product will cause serious health consequences or death.

## IDDT Goes To Westminster

**Report from Jenny Hirst**
Of course, the major news is Dr Stephen Ladyman's statement discussed in the front page article and with this encouragement, we must press on. Your MPs and MEPs have been actively pursuing this whole business and we are grateful for all their help but the battle is far from over!

**Update:**

- **IDDT gives evidence to the Health Select Committee**

The Health Select Committee is holding an Inquiry into the influence of the pharmaceutical industry on health. On behalf of IDDT I gave written evidence to the Inquiry in August and was invited to give oral evidence in November. I hope I did OK! The written evidence is available on our website www.iddtinternational.org but if anyone without internet access would like a copy just call IDDT on 01604 622837.

**Meeting with the Minister of Health**
Thanks to the help of David Hinchliffe MP, Chairman of the Health Select Committee, the Minister of Health, Rosie Winterton has agreed to a meeting with him and IDDT in December. [After the deadline for this Newsletter, so we will keep you posted.]

- **CP Pharmaceuticals**

As many of our members will be aware, CP have had a supply problem with 5 of their animal insulin products. IDDT first became aware of this in September when members reported having difficulties obtaining their particular animal insulin. CP later sent a notice to healthcare professionals to say that they expected stocks to be back to normal by mid November.

Lord Warner's standard responses to your MPs have been that CP can meet any increased demand if Novo Nordisk discontinue supplies. This present out of stock situation hardly gave us confidence that this would be the case. So for the first time, I wrote to Lord Warner directly to say so! He sent me one of his standard responses that did not cover this issue! So I wrote to say so and still have not received a direct response! However, one of the MPs did receive the following reply:

*"Ms Hirst has raised her concerns on a number of occasions. I can only reiterate that I have reassurances from CP Pharmaceuticals that they would be able to cope with any additional demand for animal insulin should Novo Nordisk cease production.*

*Given that Novo Nordisk has committed to giving the Department at least 18months notice before discontinuing any supply, and further that they will not make a decisions until summer 2005, Ms Hirst can be reassured that there will continue to be more than one supplier of animal insulin until the end of 2006 at the very earliest."*

This is not the answer we want to hear! I would have been a great deal happier if he had said that the Dept of Health is looking into the stock problems at CP to ensure that they will very much NOT happen if/when CP are the sole supplier of animal insulin. Does he not realise that if this happens after 2006, neither the Dept of Health nor patients will just be able to lay their hands on another source of animal insulin??? We will be following this up.??.

- **Novo Nordisk**

Your MEPs have been in correspondence with Novo Nordisk and you will remember that the company has said: “The company is aware that there are people with diabetes who are only able to tolerate animal insulins.” They also said that they would set up an Expert Panel to look into the issues. This has now changed - no longer an Expert Panel but on October 25th their MD stated that “We will consult Health Care Professionals, the Dept of Health as well as Diabetes UK which represents people with diabetes in the UK.” Great!!! The group set up to represent people who experience adverse effects with GM insulins, IDDT, is not going to be consulted! I wonder why not????

It gets better when he says:

*“I would also like to comment on the number of people using animal insulins. Whether we are talking about 15,000 or 20,000 people I am confident that only a fraction of this number does have problems with human insulins. This is the information I get from doctors and nurses all over the country. Of this fraction of people that have a real problem when using human insulin, I suggest that they should try the new insulin analogues which conceptually are structured in the same way as animal insulins.”*

In another response to an MEP, Novo Nordisk state that the problems with GM insulins only exist in the UK. Tell that to all our members in countries across the world, to those who are importing animal insulins from the UK at very high costs to themselves and to those in the US who have bought second fridges to stock pile their animal insulins, in case they are discontinued.

**What can I say - we appear to be back to square one!** Apparently, there’s only a tiny fraction of us and only a tiny fraction of a tiny fraction who have real problems with human insulin, so the rest of us are making it up because doctors and nurses say so!!!!! Doctors and nurses ‘saying so’ is really scientific stuff! But the actual numbers are not too important as no one should suffer unnecessarily because of a lack of insulin to suit their needs.

And analogues are ‘conceptually’ structured in the same way as animal insulin. Dear me! He actually means that the molecules of analogues are different from the molecules of insulin the body produces, just as the molecules of pork and beef insulins are different. However, ‘human’ insulin which was ‘sold’ on the basis that the molecule was identical to the body’s insulin molecule. So was the case in favour for ‘human’ insulin wrong in the first place? Why did they go down the very expensive route of researching ‘human’ insulin, then analogue insulins to then tell us that analogues might be better because they are more like animal insulins. He’s almost arguing the case for everyone being on animal insulin!

**But we must ask ourselves why there is something of U-turn**
Perhaps because we are not going away, we are not giving up, we are not all succumbing to the pressure to change to analogues and we are receiving some answers in our favour. We all know that we are right - there’s no evidence that GM insulins are better and the recent Cochrane Review on short-acting analogues has warned us that there is no long-term safety information, not to mention the potential analogues have for carcinogenic effects that animal insulins don’t have. There are significant numbers of people who can only tolerate animal insulins and if they are happy and healthy on animal insulins, there is no clinical to change their insulin - to quote Stephen Ladyman!

There may be another reason for this renewed rather defensive attitude from Novo Nordisk. Drug companies have been coming in for some stick recently as have the drug regulatory authorities, the MHRA in the UK and the FDA in the US. The Seroxat scandal and the immediate discontinuation of the arthritic drug, Vioxx, because of serious side effects, including deaths, must influence the attitude of all drug companies. In both cases the side effects were known but ‘overlooked’ by regulatory authorities but not until many people suffered did proper investigations take place. So the UK government has decided to overhaul the MHRA, the body that licenses medicines,

recommending that members should not hold any interests in the pharmaceutical industry and 2 lay members should be included.

It does strike me that there is a similarity because we know that at the very least, loss of hypo warnings and the joint and muscle pains were known to be side effects of GM 'human' insulin before they were licensed in 1982 - but they were ignored too!

**The campaign's not over!**

I am delighted that 2004 has ended on such a positive note with Dr Ladyman's statement in the House but our campaign is not over?.

- we have to actually ensure that there will be a continuous supply of animal insulin and that we are not left with one single supplier for the whole of the UK.
- we have to ensure that all people with diabetes actually do receive the truly informed choice to which they are entitled including the risks and benefits of animal, human and analogue insulins.
- we have to ensure that diabetes education programmes encourage choice and include independent information based on high quality evidence about ALL insulins.

Above all, we have to continue to seek recognition and acknowledgement that adverse effects to synthetic GM insulins do occur for some people. They are very real and can have very damaging effects on their lives and those of their families. We owe this to everyone with insulin requiring diabetes and to future generations to ensure that they do not suffer unnecessarily as many of us have done.

**So the message for 2005 is keep up the good work. Our next steps will depend on the meeting with the Minister and we will keep you posted!**

## American Diabetes Association Links With Nestle

In what the American Diabetes Association [ADA] describe as 'sponsorship agreements' rather than endorsements of products, they have struck a deal with the food giant Nestle. Nestle is reducing the sugar content of some of its products and inventing new versions of others and promoting them in adverts in diabetes related publications.

For an undisclosed fee the ADA will include a Nestle-produced magazine in the packs of information it sends to people with diabetes plus a letter from Nestle in membership letters to new members. Through this push, Nestle expect to reach 250,000 people.

One of the new Nestle products, the Carb Select, is slightly smaller than the regular Crunch bar, has no sugar and one gram less saturated fat than the full-size bar. It has 12% fewer carbohydrates per ounce and a third less total calories but it has a massive 42% more sodium! 99% of the sodium we eat comes from salt and we eat on average twice as much salt as we should, so just how healthy are these bars?

The ADA also has an agreement with Kraft Foods but says that it does not endorse Kraft or Nestle products but has 'sponsorship agreements'. This is a fine line and however the ADA wish to define it, people's perceptions will be that the ADA is promoting these products and they are OK foods. As a result, some people may be encouraged to eat more of them despite possible higher fat and sodium content.

During the 2003 financial year Kraft donated more than $250,000 to the ADA and Nestle over $100,000, which no doubt will rise considerably following this new deal! It is ironic that the ADA is doing deals with the very companies that have made the foods that have contributed towards the obesity epidemic and therefore Type 2 diabetes!

## Useful Information

**If you have access to the internet??..**

- **www.specialistinfo.com** - a new medical consultant and GP database has been launched that holds details on consultants and GPs and has a fully searchable facility. The site works on a subscription basis but there is a discount for charities. The database is of particular use for identifying a consultant with particular special interests or quickly finding the contact details of a consultant. For information on how to subscribe, please contact: Emma Cox, Subscriptions Manager, Healthcare Knowledge Ltd, 31 East Parade, Harrogate, HG1 5DA, tel 01423 505024/562003, e-mail to: enquiries@healthcareknowledge.co.uk
- **www.diabeticshop.co.uk** - This site is designed to help people living with diabetes obtain products and services that can assist in living a more natural daily life.
- **www.diabeticgoumet.com** although a US based site, it has some interesting nutritional and medical information and news updates about research.

**Useful information for those with coeliac disease**

Gluten free foods can be obtained from:

- Lifestyle Healthcare Ltd, Centenary Business Park, Henley on Thames, Oxon RG9 1DS, Tel 01491 570 000 or order online at www.gfdiet.com
- Gluten Free Foods Ltd, Unit 270 Centennial Park, Elstree, Herts WD6 3SS Tel 020 8953 4444 or visit www.glutenfree-foods.co.uk

## Novo Nordisk To Discontinue Some 'Human' Insulins

The need for people with diabetes to have INFORMED CHOICE of insulin treatment has always been at the centre of IDDT's beliefs and activities. We have never believed that treatment should be dictated by commercial decisions of the pharmaceutical companies but should be based on the needs and preferences of patients - something Parliamentary Under Secretary of State for Health also believes. But here we go again - choice is being dictated by industry! In October 2004, following in the footsteps of Eli Lilly, Novo Nordisk have given 18months notice of discontinuation of some GM 'human' insulin products. They admit in a statement to healthcare professionals that this will have significant impact on the lives of people using these insulins and the workload of professionals caring for them.

The first person to complain to IDDT about this decision was a healthcare professional, so perhaps this time our stance on the importance of choice will be more widely supported by doctors and healthcare professionals. Having a choice of insulins is not, and never has been, only an animal insulin issue because people with diabetes are all different and a wide choice of insulins is necessary to suit all the varying needs.

While we hate to say 'I told you so', IDDT predicted in a previous Newsletter that having introduced insulin analogues, the choice of some of their 'human' insulins would be removed! Yet again we have witnessed the introduction of new, more expensive insulin, the analogues which are being widely prescribed without the caution that any new drug deserves. This is particularly important for insulin analogues as there are concerns about their potential for carcinogenic effects, something that was not denied in our discussions with the Dept of Health in May 2004.

It is for readers to decide whether or not Novo Nordisk's discontinuation of these GM 'human' insulins is a deliberate policy designed to

'encourage' people to change to their newer more expensive insulin analogues, NovoRapid and Levemir. But for people who can remember the 1980s, it is reminiscent of their policy to not provide pork insulin in cartridges for pens, knowing that many people would choose to use a pen rather than a syringe, so 'forcing' them to change to GM 'human' insulin. So 20years later, again we see prescribing choices being denied to healthcare professionals and patients with many being forced to change treatment not for any proven health benefits, but for commercial reasons.

**For both patients and healthcare professionals insulin choices are once again being restricted by the commercial interests of manufacturers. The details of the discontinuations are at the end of this article but the main points are that**

- 'human' Monotard and Ultratard are being discontinued and Novo Nordisk state that there is no direct equivalent insulin.
- Insulatard [human] in the very popular pre-filled FlexPen is being discontinued and their only other long-acting insulin in a FlexPen is, yes you've guessed, Levemir.
- Actrapid [human] in the pre-filled Novolet is being discontinued and the only other short-acting insulin in a pre-filled pen is, surprise, surprise, their shorting analogue, NovoRapid.

So people who want to use a FlexPen will have to change to analogue insulins - NovoRapid and Levemir. To be fair, 3ml cartridges of both 'human' Actrapid and 'human' Insulatard are still going to be available but this will mean a change of pen and patients having to learn how to use one that requires cartridges being replaced.

**Remember!**
In all this, it is important to remember that analogue insulins have only been shown to have minor benefits in some people. They have not been tested in young children, in pregnant women, in people with various complications and above all there is no evidence of long-term safety. No one could possibly claim that these latest discontinuations are in the best interests of people with diabetes or the medical and nursing professionals - they can only be in the best interests of the pharmaceutical industry.

Not unpredictably, the powerful pharmaceutical industry is not only limiting our treatment choices but is dictating our treatment and taking control of our future health. This almost makes nonsense of the government promises that patients' choices should be central to NHS Plan and the National Service Framework for diabetes! For the benefit of all, it is time that the choices of treatment are put back where they belong - with doctors and patients.

**Note!** If there is a good side to this decision by Novo Nordisk, it is that pork insulin is not on their list of insulins to be discontinued. Perhaps when they made their statement that a final decision about future availability of pork insulin was to be made in the summer of 2004, their intention was to include pork insulin on this list of insulins set to disappear. So perhaps we can claim some success here!

**Novo Nordisk insulins that are being discontinued and their recommendations for possible alternative Novo Nordisk insulin preparations.**

| Discontinued | Novo Nordisk Penfill alternative (direct equivalent) | Novo Nordisk Preloaded alternative (direct equivalent) | Novo Nordisk Analogue FlexPen alternative | Novo Nordisk Analogue Penfill alternative |
|---|---|---|---|---|
| Actrapid NovoLet | Actrapid Penfill 3ml | | NovoRapid Flexpen | NovoRapid Penfill 3ml |
| Insulatard NovoLet | Insulatard Penfill 3ml | Insulard InnoLet | Levemir FlexPen | Levemir Penfill 3ml |
| Mixtard 10 NovoLet | Mixtard 10 Penfill 3ml | | | |
| Mixtard 20 NovoLet | Mixtard 20 Penfill 3ml | | | |
| Mixtard 30 NovoLet | Mixtard 30 Penfill 3ml | Mixtard 30 InnoLet | NovoMix 30 FlexPen | NovoMix 30 Penfill 3ml |
| Mixtard 40 NovoLet | Mixtard 40 Penfill 3ml | | | |
| Mixtard 50 NovoLet | Mixtard 50 Penfill 3ml | | | |
| Insulatard FlexPen | Insulatard Penfill 3ml | Insulatard InnoLet | Levemir FlexPen (basal bolus) | Levemir Penfill 3ml (basal bolus) |
| Monotard 10ml vial | No equivalent insulin | | | |
| Ultratard 10ml vial | No equivalent insulin | | | |

Novo Nordisk advise that a change in only administration method ie a change in type of pen, should not warrant any change in dose but transferring to another type or brand of insulin should be done under strict medical supervision. Changes in brand, type, species and/or method of manufacture may result in the need for a change in dose and this may occur with the first dose or over the first few weeks or months after the change.

# What The Papers Say

**24.10.04 The Sunday Express** - new research from Essex University has found that kidney damage in diabetes can be countered by using thiamine [vitamin B1]. It appears that mild deficiency of this vitamin and the thiamine derivative benfotamin accelerates the development of kidney disease.

**26.10.04 Daily Mail** - a small US study published in Diabetes Care has shown that Botox injections, a poisonous toxin commonly used to get rid of wrinkles, have been found to reduce the symptoms of gastroparesis. This is a slowing down of the food as it passes through the gut and is a complication of diabetes caused by neuropathy damaging the vagus nerve which controls the movement of food through the gut. The Botox injections improved the time it took for food to pass through the system and there were no serious side effects although there was weight gain. Gastroparesis is thought to affect up to half of all those with Type 1 diabetes.

**29.09.04 Express and Star, Wolverhampton** - researchers at Kings College, London claim that extracts from the curry-leaf tree which are used in traditional Indian medicines and many curry dishes could aid people with diabetes. The extracts were found to slow down the rate of starch breakdown leading to a more even trickle of glucose into the bloodstream.

**22.09.04 Evening Advertiser, Swindon** - to try to avoid injections, scientists in India have developed a jelly that can be loaded with insulin and swallowed. Previous attempts have failed because the insulin has been destroyed by the stomach acids and enzymes. This new jelly appears to pass through the stomach unharmed and when it reaches the large intestine with more alkaline conditions, the jelly swells and insulin is released. The researchers have warned that it takes time for the jelly to pass through the body and this may influence its effectiveness. Trials are yet to take place so don't hold your breath!

**16.09.04 Huddersfield Daily Examiner** - scientists in Florida have

discovered that fruit flies have cells that act like a mini pancreas. The human pancreas produces insulin and glucagon to regulate blood sugar levels and it appears that fruit flies have cells that produce both insulin and glucagon which act in much the same way as a pancreas. The scientists think this could help them find a cure for Type 1 diabetes.

**7.10.04 The Guardian** - AstraZeneca, the makers of Crestor, a statin for treating high cholesterol, is reported to be trying to soothe fears about the side-effects. They are to publish all clinical trial data but said that the incidence of a dangerous muscle disease was nowhere near that of Baycol, a similar drug that had to be withdrawn in 2001 after patient deaths.

**7.10.04 Jyllands Posten, Denmark** - a new study has revealed that global insulin sales linked to the treatment of Type 2 diabetes will grow to more than $14.87billion by 2013

## Most Drivers Rely On Warning Symptoms To Detect Hypoglycaemia

In the last Newsletter, we reported that the DVLA are continuing to monitor road traffic accidents where hypoglycaemia is a possible cause. Tight control or aiming for near normal blood glucose levels [between 4 and 7.0mmols/l] increases the risk of severe hypoglycaemia and loss of warning symptoms. If readings drop below 4.ommols/l, this is hypoglycaemia whether there are symptoms or not and abilities and judgements can be impaired. The present recommendations for tight control obviously increase the risk of hypoglycaemia and so it is important that precautions are taken for safe driving.

In the UK people with diabetes are assessed for medical fitness to drive and for car drivers this may involve contacting the person's doctor. However, the information requested may only be to find out if there is normal hypo awareness and if there has been a recent episode of severe [disabling] hypoglycaemia. For an ordinary car licence there is no **legal** requirement to regularly monitor blood glucose as there is to drive large goods vehicles and for a C1 licence. However, in court cases following driving accidents caused by hypoglycaemia, drivers with diabetes have been highly criticised and accused of being irresponsible if they have not measured their blood glucose before driving. So there is a difference between the standard requirements to obtain a licence and the legal attitude to drivers who do not test, so it is important that safe practice guidelines are followed when driving with insulin treated diabetes.

**As if to remind us???**
The Daily Telegraph reported the case of a 47year old man with diabetes for 20years who caused a 4 vehicle road accident by having a hypo while driving. He was accused of dangerous driving and the prosecution blamed him for passing out and of taking a "carefree and reckless" approach to his diabetes. The man said he had not had a hypo for two years, he never used his insulin wrongly and always followed dietary advice but he felt no signs of the oncoming hypo. A medical expert gave evidence that he may not have known about the attack and he was cleared due to insufficient evidence.

But this case does pose problems - it may have been his first hypo without warnings, or he may have had others and not known [because he hadn't any warnings!]. Is he likely to have other similar hypos and if so, should he be driving?

**What does recent research show?**
Research carried out in Edinburgh [ref1] has shown that most insulin-treated drivers comply with statutory requirements to inform the licensing authority [DVLA], and their insurers of their diabetes. However, it also showed that they rely on warning symptoms to detect hypoglycaemia while they are driving and seldom do a blood test before driving. But as we know, many people have reduced or even no warnings of hypos and this is where the danger lies.

The researchers surveyed 202 drivers with insulin treated diabetes,

115 with Type 1 and the rest with Type 2 diabetes. Of the 190 drivers with previous experience of hypoglycaemia, 144 had normal awareness [had warning symptoms] and 46 had impaired awareness [reduced warnings]. The drivers with impaired awareness were more likely to have had a severe hypo during the previous year than those with normal awareness.

**The results also showed:**

**Informing the DVLA and insurers**
21 people or over 10%, had not declared that they were being treated with insulin although almost all the drivers [96%] were aware that they had to inform their insurers and had done so. Of the 96%:

- 195 drivers were aware that they had to inform the DVLA that they were being treated with insulin but 12 had not done so.
- 8 people with Type 2 diabetes had declared their diabetes but had not reported the start of insulin treatment. 7 participants were either unsure about whether they had to report but 6 had done so anyway.

**Testing and driving**
Testing before driving was defined as testing up to 30minutes before a journey.

- 66 drivers [32.7%] said they always have a blood glucose meter with them when driving but 77 [38.1%] said they never have one with them. The remaining drivers said that they would take a meter on some journeys or only on long journeys.
- Only 6 drivers [3%] said that they always test before driving with a further 22 [10.9%] saying that they test on at least half their journeys. Testing frequency tended to increase with the length of the journey.
- The majority of drivers, 59.9%, reported either never testing before driving or only testing if they had hypo symptoms.

**Did drivers know the safe blood glucose levels for driving?**

Drivers were asked what blood glucose levels they considered to be the lowest for safe driving.

- 151 of drivers [74.8%] gave levels of 4.0mmols/l or higher
- 42 [20.8%] gave between 3.0 and 3.9mmols/l
- 9 [4.5%] gave levels below 3.0mmols/l

**Experience of hypoglycaemia while driving**

**64 drivers [31.7%] had experienced hypoglycaemia while driving with 27 [13.4%] reporting hypos during the year before**
**7 reported having had accidents at some time that they thought were cause by hypoglycaemia.**

**Treatment of hypoglycaemia while driving**

- 177 drivers [87.6%] kept carbohydrate in the car at all times with a further 20 [9.9%] doing so sometimes.
- 192 [95%] reported that if hypo, they would stop driving immediately but 13 of these said they would resume driving immediately. Most participants, 128, would wait between 10 and 30minutes and only 28 said that they would wait 30minutes or longer before resuming driving.

**Recommendations**
The researchers recommend that patient education should emphasise the importance of blood glucose monitoring in relation to driving and highlight that driving performance can deteriorate when blood sugar levels fall below 4.00mmols/l.

They have developed an advice sheet for insulin treated people in their own clinic and it includes the following:

- fast acting carbohydrate should be kept in the vehicle
- blood glucose should be measured before all journeys and at regular intervals during long journeys
- driving should not take place if there are hypo symptoms or if the

blood glucose is below 4mmols/l
- a snack should be eaten if the blood glucose is below 5mmols/l
- regular meals, snacks and rests should be taken on long journeys
- if a hypo occurs while driving, the vehicle should be stopped, the key taken out of the ignition and the driver should get out of the driver's seat. Driving should not be resumed until 45minutes after blood glucose has returned to more than 4.0mmols/l.

**It is always important to remember that minor hypos themselves may not be dangerous, but where you have them can be. Having a hypo while driving, however minor, put lives at risk.**

Ref 1 Diab Med 2004; Vol 21,9:1014-1019

**Two motor accidents and doctors slightly re-think - control can be too**
Tight control of blood glucose levels became the recommendation for people with Type 1 diabetes following the Diabetes Control and Complication Trial [DCCT] 1993. This was classed as a landmark study as it proved what had always been assumed - that near normal blood glucose levels reduce the risk of long-term diabetic complications but it also showed that tight control increased the risk of severe hypoglycaemia threefold. However, the study had its faults, the participants were highly selected and not typical of the wider population with diabetes and also that the participants received very high levels of care from health professionals, not affordable for any healthcare system. Although the DCCT actually concluded that tight control was not suitable for everyone, this seemed to be ignored and tight control became the recommendation for everyone.

The United Kingdom Prospective Diabetes Study [UKPDS] 1998, showed that in people with Type 2 diabetes, tight control of blood sugars [and blood pressure] reduced the risk of complications and so a more aggressive approach to the control of blood sugars was also recommended for people with Type 2 diabetes.

The American Diabetes Association's [ADA] January 2004 guidelines recommend that HbA1c levels [the average blood sugars over the last 6-8 weeks] should be less than 7% in most people, although 6% could be a goal for some. The ADA's Vice President for clinical affairs says that the guideline is a goal and all goals will not be achieved but the closer to the goals the better.

**But some doctors say that this message can get lost in the pursuit of lower HbA1cs and the burden on patients can be significant.**

AM NEWS [7.6.04] in the US reported that as a result of two separate car accidents in which it was thought that low blood sugars were responsible, Dr Cohen, from the University of Cincinnati, has slightly revised his thinking on tight control. Although he believes that tight control is a good recommendation as a general principle, he is no longer sure that it works for everyone. Dr Cohen said that he always thought that tight control was the best course of action to try to reduce the risk of long-term diabetic complications but these two car accidents involving his patients caused him to have a re-think and become a little bit more moderate in his goals. In reality good blood sugars are somewhat pointless if you are injured or you injure someone else [or worse] while driving!

He is not alone in being concerned about the increased risks of hypoglycaemia with tight control. Dr Dugdale of Washington University told AM News:

*'Sometimes people who don't need a complicated regime get prescribed it anyway - that's hazard of tight control. There are incidents of hypoglycaemia, a known risk. It can cause situations ranging from the unpleasant to the tragic, particularly for elderly patients. It has to be a dialogue. You don't want to give patients a sense of failure if they don't achieve the results - that can cause them to be less engaged in treatment rather than more'*

Here are two doctors that understand that not only do people with diabetes have to manage their diabetes but also hypoglycaemia and real life! The goal of aiming for near normal blood sugars maybe right, but it is not necessarily right for everyone.

**Several years after the end of the DCCT, the participants who maintained tight control during the study, did not maintain it afterwards. So is it truly achievable?**

Dr H Pillsbury, North Carolina University, who has diabetes says: *'Physicians should keep working with diabetes patients. The problem with these guidelines is that if you create a threshold for success that is so high, they give up. It's not going to happen overnight, but it's worth it.'*

But perhaps the Dr Suzanne B Johnson of Florida University hits the nail on the head: *'An awful lot is expected of the [diabetic] patient in terms of their day to day care. They need a lot more than 15 minutes in the clinic or just being handed a brochure. If we're going to expect tight control from patients, we have to be willing to put in healthcare money to help these people do it.'*

## Annual Report Of Islet transplant Results

Naturally we all watch the islet transplantation research with great interest and hope. A recent report from researchers at 12 medical centres in the US and Canada shows that islet transplants have been carried out on 86 people with Type 1 diabetes. The islet transplants were carried out in people with Type 1 diabetes that has been difficult to control. The insulin-producing cells from donor pancreases were infused through the portal vein of the liver and when successful the transplanted cells reside in the liver's small blood vessels and begin to produce insulin. The report analyses the many factors that can affect the outcome of this still experimental procedure.

**The results showed that:**

- the people receiving islet transplants had all had diabetes for an average of 30 years and received a total of 158 infusions of islets with 28 people receiving one islet infusion, 44 receiving two and 14 receiving three.
- 6months after the last infusion, 61% of the recipients no longer had to inject insulin and one year after, 58% still did not have to inject insulin.
- Some of the people not receiving insulin injections did have higher than normal blood glucose levels and they are being monitored to see how long they remain independent of insulin.
- There were 45 serious adverse events but no deaths and the 27% of events that were classed as life-threatening were linked to the transplant procedure itself and to the medications that suppress the immune system [anti-rejection drugs].

**Who had islet transplants?**

- 66% were women and the average age was 42 years ranging from 24 to 64 years and the average weight was 143lbs
- nearly half were previously on an insulin pump and most had recently had at least one episode of severe hypoglycaemia with dangerously low blood glucose.
- Their average HbA1c, a reflection of the blood glucose control over the last 3months, was 7.7% where the normal is classed as 6%.

**Major obstacles**

Because only 6,000 donor pancreases become available each year, many of which are used for whole organ transplantation, the shortage of islets poses a major obstacle to wider testing of islet transplantation. Other research is investigating understanding the insulin-producing beta cells and their regeneration to try to develop alternative sources of beta cells.

**For more information, the Report can be viewed at www.citregistry.org**

# Animal Vs GM Insulin Hits The Media Again!

**“Diabetic dilemma?”**

**BBC Politics Show, South West, September 12th 2004**
Peter Cox, a solicitor and a Conservative Prospective Parliamentary Candidate, read one of IDDT’s adverts in his local paper. The ad asks if people are aware that animal insulin is available, that some people have adverse reactions to synthetic GM insulins and then lists the main 6 symptoms. Peter ticked all 6 symptoms as those his wife, Shelley, was suffering. Shelley was diagnosed with type 1 diabetes 18months earlier and after 9 months on synthetic GM insulin had started to become ill. She had to stop working, could not cope with lights, could hardly get out of bed, all her joints ached and she put on ‘an alarming’ amount of weight. She was tested for ME and rheumatoid arthritis but all the tests came back negative.

After seeing IDDT’s advert, Shelley immediately went to the Diabetic Clinic and asked to be put on animal insulin. Almost immediately she felt better than she had for 10months and only twelve hours later she went out for a celebratory lunch with her husband! The next day she went to the garden centre and went riding - the difference was incredible! Now of course, like many others, Shelley and Peter are concerned that animal insulins remain available so that she is not once again condemned to a life of ill health.

The local paper covered Shelley’s story and from this, BBC South West took up the story for the Politics Show on Sunday, September 12th 2004. Shelley and Peter were interviewed as was the local consultant. Interestingly he did not comment on Shelley’s improved health but did criticise IDDT’s advert saying that it had caused him and the local diabetes nurses a lot of work with people ringing up. He said that the symptoms could be caused by many other conditions - true, but he did not seem to appreciate that our advert stimulated people to seek help for them, whether or not they were caused by the type of insulin! He also said that if a patient requests a change to animal insulin, he would tell them that he didn’t think that it would make any difference but if they chose to stay on animal insulin he would support them in their choice. Amazingly, he didn’t seem to mind at all acknowledging to the wide world that he doesn’t give his patients an informed choice of treatment!

**Note**: The following week BBC South West reported that they had received more responses to this issue than any other that they had raised - rather says it all!

**“In sickness and in health: diabetic treatments need an injection of common sense”**

**Dr James Le Fanu, Sunday Telegraph October 31st 2004**

‘Medicine is, for the most part, a sane and scientific enterprise but it can be surprisingly intolerant of even the most well intentioned criticisms’ are the opening words in this article by Dr James Le Fanu. He points out that it would not be expected that adverse effects would occur from modern insulin regimes for treating diabetes, but this happens and the reports from patients have fallen on deaf ears, with serious implications.

He cited IDDT’s Co-Chairman, GP Dr Matthew Kiln, as just one person who on changing to ‘human’ insulin found that he had wildly erratic blood sugars, loss of hypo warnings and that his personality changed so he was more irritable and argumentative. When Dr Kiln changed back to animal insulin he became his old self again. Readers know that IDDT is also concerned for the people who came after this time, those who have automatically been prescribed GM insulins.

**One of the standard, and very irritating, answers given by defenders of this policy is that the adverse effects only happen to people who have used animal insulin. IDDT knows from members that this is just not the case - they can and do occur in people who have only ever been treated with GM insulins.**

So it was just wonderful that Dr Le Fanu cited another example -

again a doctor, Dr Ann Robinson but she has only had diabetes for 2 years so only treated with GM insulin. This kept her blood sugars within the normal range but she felt terrible. *'I did not feel like me with and illness. I felt like someone else, I became a zombie. I could not concentrate for more than a few minutes and the least amount of exercise caused my blood sugars to drop through the floor.'*

After five changes in her insulin regime and no improvement, she had no alternative but to take early retirement on medical grounds. Later she read an article by Dr Kiln in a medical journal, rushed to her doctor and persuaded him to change her to pork insulin. Within a couple of days her life changed - she woke feeling hungry for the first time in 2 years, she could concentrate again, her joints loosened up and her personality returned, *'I was me again'.*

In the article, Dr Robinson expresses the same concerns as IDDT: how many others are there like her, children, for example, whose behavioural and learning problems are blamed on being diagnosed with diabetes or many other things, but who would become 'themselves' again of they were switched to pork insulin?

Dr Le Fanu ends his article by expressing surprise that no one really wants to know about this issue especially when "it is scarcely revolutionary to propose that some of those with diabetes might do better with animal-based insulins?". But he ends with the suggestion that this is perhaps not unrelated to the fact that animal insulins are far less profitable to the drug companies than the much more expensive human forms and 'Enough said'!

This excellent article resulted in many people, including parents, expressing gratitude to Dr Le Fanu and contacting IDDT. Once more people recognised their own experiences when reading about Doctors Kiln and Robinson with several people saying they felt better just knowing that there was an alternative and they could see light at the end of the tunnel.

For internet users the article can be found by visiting website www. telegraph.co.uk Click health then search on James Le Fanu.

**Note: It is interesting that in these media reports both Mrs Cox and Dr Robinson were using insulin analogues.**

## Are Your Blood Glucose Strips Being Resricted?

**Research shows that people with diabetes must test more.**
Researchers from John Hopkins University pooled data from 13 earlier studies involving 10,000 people and concluded that people with Type 1 and 2 diabetes should check their blood glucose levels more frequently to make sure that glucose levels do not exceed the target levels and to prevent diabetic complications. [Published in the Annals of Internal Medicine, Sept 04]

**Perhaps the PCTs that are restricting or denying people their blood glucose test strips should look at this research!**

## From our own Correspondents

**One parent's experience**
Dear Jenny,

Reading "One parents experience - but she's not alone" in the October Newsletter, I was extremely sad and upset. John, who is 15 and the same age is as my daughter, and his mother are not the only ones who are suffering as a result of the ignorance of other people, especially teachers.

My daughter has had Type 1 diabetes since she was two when she was put on GM insulin and had no hypo warnings at all and was generally

unwell. At the age of seven and with the knowledge of others who live with diabetes and IDDT we had her insulin changed to porcine. Like John, she changed overnight, was healthier, happier and most of all she could recognise a low blood sugar. For the first time she told me that she was hungry and felt funny - I cried with relief.

As time went by she learnt to manage her diabetes but like John, she has encountered a great deal of ignorance from teachers who think that they know all about diabetes. They particularly do not seem to understand the need for her to eat if she is hypo. Last week she was told off for eating and when she said that she had to eat because her blood sugars were low, she was told off for her tone of voice!

It now seems that the school wants her to go to the office every time she feels low even though this will mean walking there on her own when she is already hypo!

All this causes my daughter stress and upset. I hope that one day she will be able to shrug off upsets like this and not let things get to her.

Mrs K.J.
Sussex

**Find a clean hospital**
Dear IDDT

As usual, I find myself reacting to almost every piece in the Newsletter, talking out loud to myself at the breakfast table! I frequently intend to put my reactions in writing; today, for once, I am doing so.

First, I'd like to reinforce the warning that we should always check what insulin has been dispensed. We were alerted to this issue by a scary experience when travelling.

My partner, Colin, is on a pump and can only use pork neutral insulin. Our local Porthmadog pharmacist is so accustomed to this that he always has a few bottles in stock. We had, I suppose, become complacent: everyone knows what Colin needs, there are no problems, no arguments.

Last year, we were visiting St Leonards in Kent, hundreds of miles away from home, when I noticed that the insulin I was drawing out of a new bottle to fill Colin's pump was cloudy. Looking more closely at the bottle, I realised we'd been given pork isophane insulin - a form that Colin can't take. So I went to the nearest chemist and asked if they had pork neutral.

I discovered, with mounting panic, that not only did this pharmacy not stock animal insulin but neither did any of the others in St Leonards. Apparently, nobody in the area uses animal insulin! All the pharmacists were helpful, most suggested I try the local hospital; but I reasoned that (1) hospitals take ages and Colin's need for insulin was urgent; and (2) if the local diabetologists have put every single patient on GM insulin, the hospital pharmacy is unlikely to carry stocks of the insulin we needed. One pharmacist took the trouble to ring every shop in the area, and eventually located a single pack of cartridges for pens in the central branch of Boots in Hastings.

I dashed over there. I persuaded the pharmacist to get a prescription from my local GP by phone and fax, and I took the cartridges back to the hotel. Filling the insulin pump reservoir from these was awkward but we managed.

Just remembering the experience makes my heart beat faster with anxiety! I now double check each time I pick up Colin's insulin - and discovered recently that the same mistake had been made a second time. Now, every time we travel, I pack two bottles of the correct insulin, lest we should find ourselves in an animal insulin black hole.

Which makes me wonder how many other areas are like Hastings/St Leonards? How many places are there in the UK where you simply can't get animal insulin?

I'd like to tell a happier story now, about hospitals. I would urge every

IDDT member to identify a local hospital that's clean, where the staff look after patients well, and where you don't have to argue about who manages the patien's insulin.

We never go to our local hospital (Ysbyty Gwynedd, Bangor), having had dreadful experiences there. But Wrexham Maelor is wonderful. Colin had an emergency operation at Wrexham last autumn- and not only did they leave him in sole control of his diabetes, they actually left his pump undisturbed throughout the operation, so that he could continue to have his normal insulin at his normal rate. The staff were very interested in his pump and his insulin needs, and accepted that he was the expert in this aspect of his care. Whenever Colin needs to go to hospital, I drive him to Wrexham. It is further, but it's so much better than Bangor, we don't think twice.

Arabella Melville
Carer

**More on aspartame!**
Hi Jenny,

Some information I would like to tell is that for over 25 years I have used sweeteners in all hot drinks until recently that is. I have suffered with mouth ulcers every month for what seems all my life. I am a shift worker (12 hours ) switching from days to nights and had put the ulcers down to this and tiredness. My wife and I heard about people having problems with aspartame and I thought give it up and go back to sugar. I have been off them for about three months and I feel the start of an ulcer coming, but it never really comes to anything. There has been no change in my lifestyle or diet so I think that this simple change has done the trick. I remember in 1979 measuring out how much sugar I was consuming each day. And so decided to make the switch over to sweeteners to cut down the weight. What a bad decision!

Mr P.B
e-mail

**Jenny's comment**: there is a great deal of information about many adverse effects of aspartame and one of them reduced salivary secretions so perhaps this contributes the cause of the mouth ulcers.

**My mother was betrayed**

I read with interest the article in this weeks Sunday Telegraph [31.10.04]. My late mother was a long standing diabetic (over 50 years at her death) and was removed from animal insulin to human in the 1980s. She had problems from then on as described in your web site. You seem to have amassed a lot of evidence, but if I can provide any more information do let me know.

The latter part of her life especially was made even more difficult and unhappy because of the stubborn refusal of these so called "experts" to acknowledge what she knew all along - the human insulin did not suit her and was making her life a misery. I feel that she was betrayed by the medical profession.

Best wishes with your campaign

Mr J.D.
E-mail

**Very, very angry!**
Dear IDDT,

Thanks to your advertisement in our local newspaper I am now on pork insulin. I was on GM synthetic insulin and had many health problems. These were so bad that I was unable to carry on doing my job and had to resign in 1998. I am feeling so much better since I started using pork insulin and have now taken on a part-time job.

It has made me feel very, very, very angry that my doctors did not identify that it could have been GM insulin that was the problem. I would like to take them to court for negligence as I lost the best part of my earning period due to ill health that could have been avoided.

Please advise me.

I would like to thank you for all the work you do.

Mrs P.L
Leicestershire

**Jenny's comments**: while we fully understand Mrs P.L's anger at her years of unnecessary ill-health, it is not for IDDT to advise on legal action. We have advised her to contact an organisation that will be able to advise her, they are:
Action for Victims of Medical Accidents, 44 High Street, Croyden, CR0 1YB

## Mixing Your Cloudy Insulin In Pens Correctly

Cloudy insulins such as Insulatard or Isophane [NPH] contain a predetermined combination of insulin and solvent and premixed insulins contain a fixed amount of cloudy longer acting insulin [NPH] and clear soluble [short-acting] insulin. In order to ensure that the correct dose of insulin is given all cloudy insulins must be mixed sufficiently to avoid variability in diabetic control.

Before the introduction of pen injection devices, the advice was that vials of cloudy insulin should be gently tipped up and down about 20 times in order to re-suspend the insulin so that the correct dose is given. However, it is more difficult to suspend insulin in pens compared to vials because the diameter is smaller.

Research in Kirkaldy [Diab Med 21 604-608] showed that most of the 180 patients under investigation do not mix their insulin correctly and did not use the methods described in the Patient Information Leaflets. At the time of this study the advice from the insulin manufacturers for cartridges and disposable pens was as follows:

**Novo Nordisk** - the pen or cartridge should be turned up and down end over end through 180° at least 10 times until the liquid is white and uniformly cloudy.

**Lilly** - the pen or cartridge should be rolled back and forth 10 times and then gently up and down 10 times until the insulin is evenly mixed.

The authors of the Kirkaldy study say that a lot of attention is paid to correct injection techniques and the variability of insulin absorption but more attention should be paid to teaching patients exactly how to mix insulin in pens and cartridges as this could be affecting diabetic control. No reason why people in Kirkaldy patients should be any different from anywhere else, so do you mix your insulin properly?

## A 16 Year Old Tells Us About Diabetes In Ethiopia

The information we get from the internet is often criticised but if you are in a position of having very little information, then these criticisms count for nothing. Beakal Tesfaye, a 16year old girl diagnosed with Type 1 diabetes two years and a half ago, is just such a person. Through the internet she found IDDT's website and became our first member from Ethiopia! We have sent her information leaflets that she can share with her friends with diabetes. Here Beakal tells us about diabetes in Ethiopia.

**Facts**

- Type 1 diabetes is by no means rare. At Yekatit Hospital, one of the government hospitals, almost 8% of people with diabetes were diagnosed under the age of 15 but most people are diagnosed after the age of 25 and between 35 and 45% of them require insulin.
- Most Ethiopians with diabetes are thin. Obesity is only common amongst the older women with diabetes and most older people

don't care about their body weight making this difficult to treat.

- There are no statistics available for life expectancy but the most common causes of death are ketoacidosis, renal failure or hypoglycaemic coma.
- Ketoacidosis is common among young people with diabetes, the most common cause being the omission of insulin for lack of affordability or simply because the insulin is not available. Severe hypos are also common in those taking insulin.
- Retinopathy, neuropathy and renal failure are common in people who have had diabetes more than 20years. About 35% of young thin, Ethiopians with diabetes have neuropathy with symptoms.

**Poor economic situation**

Most Ethiopians are very poor and the high costs of insulin and other supplies compared to their incomes means that many cannot afford medicines and medical check ups. Some people stop taking insulin when they have no money and then start again when they can afford it, obviously creating problems with their diabetic control and management. When government pharmacies have no insulin available, most people cannot afford to buy it from private pharmacies.

There is an erratic supply of drugs, so insulin and the other drugs they require are not always available, especially in rural hospitals and clinics or the type of insulin they can obtain will vary.

**Imbalance of healthcare professionals and patients**

Doctors in Ethiopia have so many patients they are often exhausted. A person with diabetes can see a doctor once in 7 or 8 months but cannot see a doctor in between if problems occur. There are no doctors that specialise in children.

Education about diabetes is a problem and results in many people finding it difficult to accept injecting themselves so they stop taking their insulin. Many parents of children with diabetes find it difficult to give the required care because they are not educated and do not know anything about the condition.

**The cultural, religious and social beliefs**

- Ethiopian culture is different and our preparation of foods and eating habits are different from other countries which makes it difficult for people with diabetes. People with diabetes have to eat smaller amounts of food at regular intervals and this is not possible in our culture as we Ethiopians eat three times a day.
- Most people in Ethiopia even with diabetes don't care about the food they eat because they follow the culture and this means eating foods with too much fat, eating large amounts and eating whenever they like. It is difficult to measure the amount of carbohydrate it contains.
- Ethiopians are known by their social life such as the coffee ceremony where they invite their neighbours for coffee each day. In the coffee ceremony there are many things to eat because of the culture, it is not possible to say "No I don't want to eat because it is not my time". Even if the person with diabetes does refuse to eat, the other people will force him/her to do so and in this way the social interactions can also affect the management of diabetes.
- Religious practices have many effects - most Orthodox Christians omit insulin and breakfast on fasting days and many people from other churches and monasteries stop taking their medications. This is one of the biggest problems in Ethiopia.

## Reminder - IDDT Collects Insulin to Help People In Poor Countries

Beakal reminds us of just how fortunate we are in this country. Our health system is far from perfect but we are not denied life-saving insulin because we can't afford it. IDDT would like to take this opportunity to thank everyone who sends us unwanted, in-date insulin and other supplies to help people in poor countries. We are very grateful for all the supplies you send to us. The amount we are now receiving has increased considerably and so through the organisation, 'Insulin for

Life', we are now able to help people and children in several different countries. If you would like to know more visit www.insulinforlife.org Please keep your unwanted supplies coming - just send them in a jiffy bag to IDDT, PO Box 294, Northampton NN1 4XS.

## Bits And Pieces

No wonder doctors believe GM insulin is better - I just happened to be reading a review of developments in Type 1 diabetes in the British Medical Journal [BMJ 2204;328:750-754 27.3.04] and looked at the summary points. Believe it or not, the second point is: *"Genetically engineered human insulins have improved care of type 1 diabetes, and devices for continuous glucose monitoring may revolutionise care."*

There's absolutely no evidence to show that genetically engineered insulins have improved the care of Type 1 diabetes! Blood glucose monitoring, yes, but just where is the evidence to show that GM insulins have revolutionised care? At best the Cochrane Reviews have shown that there is no difference but they also showed that the research has not been done to look at mortality or complication rates when comparing animal and all the GM insulins!

So how do authors from a reputable Diabetes Centre make such a misleading and unsupported statement? Or may be why do they make it and why are they not challenged? While we might not have answers to these questions, one thing we do know for sure, when such statements are published in a reputable journal like the BMJ, they are believed by readers and in this case the readers are the doctors who treat us. No wonder so many of them tell us that GM insulins are better than animal insulins!

**Increase in diabetes** - a Diabetes UK report [October 2004] says that the1.8million people live with diabetes and the numbers affected have grown by 400,000 in the past eight years, a 28% increase and are likely to almost double by 2010. The figures show that while Type 1 diabetes has increased only slightly, the increase is largely due to the increase in Type 2 diabetes which is directly linked to obesity. The UK has the fastest growing rate of obesity in the developed world. Within 7 years one pound in every 10 spent on the NHS will be spent on diabetes.

**Disability Act 1995, Part III** - came into force on October 1st 2004 and the new law will apply to all businesses and service providers, except the armed forces. Previously businesses employing less than 15 people were exempt from the law. The Act now also protects people with 'hidden' conditions such as dyslexia, epilepsy and diabetes. All business and service providers will have to:

- be accessible to people with a disability
- make necessary 'reasonable adjustments' to prevent disabled employees being placed at a disadvantage.

The new rules on employment will apply from the interview stage onwards so that it will be illegal to refuse someone a job solely on the grounds of their disability. People already in a job who develop a disability will also be protected to maintain their job.

Patients reporting of adverse reactions to drugs - the never ending saga! Readers may remember that probably over 2 years ago the government announced that patients will be able to report their own adverse drug reactions instead of having to rely on doctors and healthcare professionals. Then they arranged a pilot scheme so that patients could report through NHS Direct but only in two areas. This didn't work - hardly surprising as it was not rteally any different except that patients were reporting to a nurse and not a doctor and the system still relied on the nurse to decide whether or not to report to the Medicines Health products Regulatory Authority [NHRA]!

Now Lord Warner has announced that the MHRA will begin “a pre-pilot survey this year” into the best way to bring about patient reporting! A pre-pilot survey is unbelievable and just puts the time when patients will be able to report adverse effects even further away! Have they forgotten that the NHS Direct system was supposed to be a pilot study? When he made the statement did he realise that there was only 8 weeks left of this year? This certainly does not seem to be a priority and one does wonder if there is a desire for it never to happen. Is it a promise that will never happen, especially as we shall have a general election before it gets far off the ground?

## Are We beginning To See A Turnaround In Attitude To Diet?

For some people the introduction in 1986 of the recommended high carb/low fat diet as dietary treatment for diabetes has never quite made sense. The low fat part - yes but the high carb, where’s the logic?

High carb intake requires more insulin, more insulin means greater fluctuations in blood glucose levels because there is a greater peak of action and further to fall increasing the risk of hypos. Less insulin means smoother blood sugars and less risk of hypos, so if you take less insulin to try to achieve this, how do you control blood sugars with less insulin? You eat less carbohydrate!

Many people who have had diabetes a long time never did change to the high carb diet. They stuck to their carb-controlled diet or they went further to a low carb diet, which contrary to popular belief, does not have to be high fat! The tide seems to be turning and there are signs that doctors and healthcare professionals may be doing what Mrs Thatcher never would - a bit of a U-turn.

***“Atkins alternative-style diet could be the key”***. This was the message from a diabetes expert, Dr Mark Daly, in The Lancet [3.9.04]. In the article Dr Daly suggests that avoiding certain types of carbohydrates in an “Atkins alternative-style diet” could be the key to a reduction in cases of heart disease in people with diabetes. He calls for more research into carbohydrate free diets.

**Low carb vs low calorie**. Research in the US has shown that low carb diets are equally as effective as low calorie diets in helping people who are overweight or obese to lose weight, decrease body fat and lower blood pressure. According to the study people following either a low carb or a low calorie diet for 10 weeks showed significant weight loss. However, people on the low carb diet showed a significant decrease in circulating insulin levels with the advantage of their bodies not pushing out unnecessary, high amounts of insulin.

## Snippets..

**Civil servants at lower pay grades have an increased risk of Type 2 diabetes** - a study following over 10,000 civil servants between the ages of 35 and 55 for 10 years has shown that 4% developed diabetes. Men working in lower employment grades had almost three times the risk of developing diabetes, and women a 70% increased risk, than their colleagues in higher grades.

**Handwashing is an effective way of stopping colds and flu** - a study had children washing their hands when they arrived to school, before lunch, after lunch, at break time and finally before leaving to go home. After a month of this consistent hand washing, the results showed the children had 24 per cent fewer days off school from colds and the flu and an amazing 51 percent fewer sick days due to gastrointestinal problems such as stomach cramps and diarrhoea.

**Sun and Vitamin D** - according to a report published in September

millions of people in the UK are lacking in vitamin D which protects against many conditions including rickets, diabetes and cancer. Sources of vitamin D are egg yolk and oily fish but 80% of vitamin D is obtained through the conversion of chemicals in the skin by sunlight. It is suggested that the protection from sun we are all advised to take because of the fears of cancer, may be partly responsible for this vitamin D deficiency. So once again, we can't win!

**GM foods in the US** - a pole has shown that only a quarter of Americans report having eaten GM Foods but if they randomly pick an item off the grocery store's shelves, they have a 70% chance of picking a food with genetically modified (GM) ingredients. This is because at least seven out of every 10 items have been genetically modified. Most Americans are not aware they are eating these foods because there are no labelling requirements for GM foods. Another pole found that 92% of Americans want mandatory food labels on GM foods.

## A Mixed experience With Determir

**By Anne St Aubin Roberts**

I was started on 'human' insulin for Type 1 diabetes in April 2003 and had six changes of regime because I kept getting worse, not better. Within 15 months I was mentally and physically disabled. My young and enthusiastic diabetologist is very helpful, but neither he, nor I [also a doctor], realised that 'human' insulins can have side effects. Thank goodness I discovered IDDT and finally got onto pork insulin - unfortunately too late to keep my job and career.

I wanted to comment on detemir [Levemir], which I took twice daily with Novorapid 3-4 times daily. I switched from glargine [Lantus] to detemir because of intolerably painful injections and day-time hypos. Detemir kept my blood glucose completely stable overnight. Therefore for people who can tolerate 'human' insulin, and who've been plagued by nocturnal hypos, it could be really helpful. Unfortunately I still had all the other symptoms of 'human' insulin intolerance, and one additional side effect of the detemir was severe day-time hypos with any exercise, however mild [despite insulin and carbohydrate adjustments].

As a doctor I was able to report my side effects to the Committee on Safety of Medicines. The government is planning a system for non-medical patients being able to report directly to them too. The CSM have had other reports on adverse reactions to detemir and glargine. When the number of reports reaches a 'critical mass', information on side effects should be published to doctors and on patient information leaflets. Hopefully this will help all diabetics to get onto the right treatment for them more quickly and more smoothly.

To IDDT - keep up the fight!

## DDT Supported My Swimming Career

I would like to thank IDDT for all the support you gave me back in 2001 with my swimming career and helping to raise awareness of diabetes in sport. Since then I have won many county and Midlands titles and competed in national championships and remained one of the world's number top diabetic swimmers. I have since taken up water polo and I am playing in the local team. I have been playing now for 3 months and I aim to reach the England squad within 2 years.

Readers may be interested to know how I manage my diabetes and my swimming and training. I am now on NovoRapid before every meal and before any large snacks that I need to top up. I have found that Mixtard 30/70 is best at night for my longer-acting insulin because the advantage is that it wares off through the next morning. If I have a longer-acting insulin in my system when I am training hard for say 1-2 hours, I find that my blood sugars can drop much faster. This is really

the only allowance I make for my routine. My blood sugars are well controlled and I am now training an hour a day in the water, 2hours water polo training a week and 3 gymn sessions a week and I work 50 hours a week!

Many thanks to IDDT for your support.

Matt Bett, Northampton

## Date For your Diary!

IDDT's Annual Conference will be held on October 15th 2005 in Birmingham.

**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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