Insulin Dependent Diabetes Trust

April 2004 Newsletter

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Patient Choice - Rhetoric Or Reality?

In December 2003 the Government published a new paper 'Building on the best'. It outlines plans to put patient choice at the heart of the NHS and it stresses the need for cultural change if the NHS is to be transformed so that patients are not just at the centre of care, but are in control. There is much ado about patient choice - in magazine articles, large expensive conferences to discuss patient choice etc etc. It is treated almost as a new idea!

But when the NHS was formed in 1948 patients were at the centre and they were given the right to have an informed choice of treatment. The Patients' Charter was widely published as a 'new' document by the Thatcher government but it was merely a re-statement of the basic rights of patients under the NHS! This included the right to an informed choice of treatment including risks and benefits BEFORE the patient made his/her choice of treatment. Indeed, doctors' NHS contracts stated that they had to give patients an informed choice of treatment and failure to do so was a breach of their NHS contract.

From all aspects it is seen that patients have the right of choice, we even have the choice to refuse treatment. We have all read the heart rendering cases in the news of people suffering from incurable conditions but without court action, doctors have no power to insist on treatment. Only if patients are sectioned under the Mental Health Act can doctors make decisions for patients.

The General Medical Council guidelines state that if a patient's drugs are changed in hospital while they are not able to make a decision, they should be told immediately they are conscious and offered their original medication - patient choice again.

Although Government has recognised that there are cultural changes that have to be made, it remains to be seen how Government is going to bring about these necessary cultural changes for their policies and beliefs to be implemented. While there will always be some patients who want to be told what to do by their doctors, many patients have changed a great deal over the last few years. Many no longer solely rely on their doctor for information but search libraries and the internet to find more about their health conditions but this is not a criticism of their medical care just a move towards better informed patients who are more able to make their healthcare decisions.

IDDT has very clear evidence that people needing insulin treatment are rarely given the choice of insulin treatment - GM or animal. It is equally clear that even when they are unwell, poorly controlled or have lost their hypo warnings, most people are still not given the opportunity to try animal insulins. So why is insulin treatment different and why aren't people with diabetes given an informed choice? Hard to understand, we can only guess but as far as diabetic treatment is concerned, patient choice is largely rhetoric, not reality. One of IDDT's stated commitments is to ensure that people with diabetes do have the informed choice of treatment that they deserve.

As readers will see in the article 'IDDT goes to Westminster' in this Newsletter, we now have an acknowledgement from the Dept of Health, from Novo Nordisk and from Diabetes UK that some people are unable to tolerate synthetic GM insulin and require animal insulin. Under these circumstances not offering people an informed choice is unacceptable.

After 10 years we admit that simply trying to influence diabetes teams to offer patients an informed choice of treatment has failed and at last year's Annual Meeting there was a unanimous wish that IDDT should take more direct action and reach more people with diabetes. As part of IDDT's 10 Year Anniversary "The Voice for Choice", IDDT is placing advertisements in local newspapers to provide people with an informed choice of insulin treatment including risks and benefits, which, by definition, must include the adverse effects that some people experience when using synthetic GM insulin. As my Dad used to say, if you want a job doing properly, you have to do it yourself.

Action! IDDT Goes To Westminster - Update

We have continued our campaign at Westminster to ensure that animal insulins remain available for the 30,000 people who need them because of adverse effects thay have suffered when using GM insulins. We are extremely grateful for the help and support of MPs and MEPs of all parties who have raised our concerns at Westminster. Numerous Parliamentary Questions have been asked, answered by the Minister of Health, Rosie Winterton, and followed by Supplementary Questions. MPs and MEPs have also written independently of the Minister to the insulin manufacturers. The MPs advised that we should request an evaluation of animal and GM insulins by NICE and this we did in our letter to the Minister. Read on????

Our case is simple:

1. IDDT has collected reports from people with diabetes and so have a list of the clearly defined group of symptoms that this group of people suffered when using synthetic GM insulin. This list is remarkably similar to that found by Dr Natasha Posner in her report for Diabetes UK [then the BDA] which was never published because it was 'too alarmist'.
2. If animal insulins are discontinued, there will be no alternative insulin for people who cannot tolerate synthetic GM insulins and they will be condemned to a life of adverse effects.
3. The Cochrane Review of animal and 'human' insulin provides high quality evidence that GM 'human' insulin is not superior to animal insulin and therefore has no clinical benefits for patients.
4. This Review also provides evidence that there has been no research to compare mortality and complication rates or quality of life with the two types of insulin. Therefore there is no evidence

to show whether mortality and complication rates and quality of life are better, worse or the same with GM insulin as with animal insulins with their long safety record. These are vital issues for the long-term health of people with diabetes.

5. If animal insulins are withdrawn, it will be for commercial reasons ie it is more profitable to produce only GM insulins but generally GM insulins cost the NHS more than animal insulins.
6. People should be allowed the choice of using a GM produced insulin or a natural product.

Where has our lobbying taken us?

- **Agreement that human insulin does not suit everyone**

This has now been acknowledged by the Minister, by the manufacturers Novo Nordisk and by Diabetes UK.

The Minister: *"Some people are better suited to animal insulin"*
[Letter dated 16.2.04]

Novo Nordisk: *"It would be fair if a group of people who had an allergic reaction to human insulin agree to participate in a controlled trial under medical supervision".*
[Letter dated 9th January 2004]

Diabetes UK: *"Some people are not able to manage their condition effectively with human insulin."*
[Letter dated 19.2.04]

IDDT Note: Excellent that there is no longer any question that some people cannot use GM synthetic insulins. Even if these statements do not help our lobbying campaign, they are hugely valuable to people whose doctors and specialist nurses refuse to prescribe animal insulin and appear to insist that GM synthetic insulin is better for everyone.

- **Minister says no evidence of a safety problem**

Although acknowledging that 'human' insulin does not suit everyone, the Minister's response was that a Sub-Committee of the Committee on Safety of Medicines had reviewed the position in 2000 and concluded that there is no evidence of a safety problem specific to human insulin. She also says that the Cochrane Review of 2002 found no significant differences in metabolic control or hypoglycaemic episodes between various insulins, adding "This review included randomised controlled trials of at least one month duration."

IDDT Note: One month is hardly long enough to detect adverse events! Our own survey showed that on average the problems did not occur until 13 months after starting 'human' insulin treatment. But of greater concern to IDDT is the fact that the Minister has failed to consider ALL the conclusions of the Cochrane review, notably that the research was methodologically poor and that no research has been carried out to compare mortality and complication rates or quality of life.

- **Future availability of existing animal insulins in the UK**

The Minister: *"No plans for the withdrawal of animal insulin have so far been made" and "the pharmaceutical companies that supply animal insulin in the UK have given assurances that they will continue to do so for the foreseeable future."*
[16.2.04]

CP Pharmaceuticals: they have no plans to discontinue their pork and beef insulins. Nevertheless, if Novo Nordisk withdraw their pork insulin, this leaves CP as the sole supplier in the UK, not a secure position for people who need animal insulin - what happens if there are supply problems or the plant burns down?

The MD of Novo Nordisk: *"At the moment, we have not yet decided whether to withdraw animal insulin from the UK market. If we do, we will give proper notice and advise alternative treatment. We are continuously discussing with all stakeholders the pros and cons of a possible withdrawal of animal insulin. I expect that we will reach a*

final conclusion before summer this year."
[Letter to MPs 9.1.04]

Note: This is hardly the reassurance that the Minister is attempting to give us and the 'foreseeable future' to which she refers could be a matter of months away.

Just what are the alternatives that Novo Nordisk suggest?
Believe it or not, their answer is insulin analogues! Having already admitted in his first letter that there is no scientific evidence to support this approach, the second letter from the MD of Novo Nordisk says:

"I think it would be fair if a group of people who had an allergic reaction to human insulin agree to participate in a controlled trial under medical supervision where they inject themselves with same of our new insulin analogues of which our company has almost a complete range. An insulin analogue is in principle following the same concept as the animal insulin, in the sense that the insulin molecule is not identical to the human insulin molecule."

IDDT's response was simple:

1. Patients don't have to be fair to the manufacturers - just themselves!

2. Without evidence from clinical trials comparing analogues and animal insulin, this group are being treated as guinea pigs. Meanwhile while they are giving analogues a trial, the sales of animal insulin will be reduced and the company can use this to justify a decision to withdraw animal insulins.

3. Many people have already tried the analogues and have had similar adverse reactions to when using 'human' insulin. Why should they be expected to volunteer to risk going through these experiences again?

4. The fact that analogues are not the same as 'human' insulin is hardly grounds for saying they will work in the same way as animal insulin! Firstly, analogues are made from 'human' insulin and Novo Nordisk have already acknowledged that some people are allergic to it, and secondly their duration and activity profiles are different.

- Cost issues

All the MPs raised questions about the relative costs of animal and synthetic insulins and the Minister provided information about the costs per item of insulin in England to June 2003. These showed that on average the per item cost of synthetic insulins is £10.00 more than the cost of animal insulin per item. While some of this difference may well be the cost of what the manufacturers describe as 'state if the art injection devices', it is clear that animal insulin costs the NHS less and therefore cost to the NHS is not a factor in this issue.

Note: IDDT did point out that at a time when people are being denied vital blood glucose test strips on the grounds of cost by their Primary Care Trusts, it seems illogical nonsense to spend £10.00 per item more on an insulin that has no proven clinical benefits for patients. Savings could be made by prescribing animal insulins that could be used on blood glucose test strips but this does require someone, somewhere to do a bit of joined up thinking!

- **The latest position**

Following the Parliamentary Questions the Minister agreed that we should write to her directly. We did so on December 16th, 2003 and responded to all the points she had already made but also drew her attention to the full conclusions of the Cochrane Review. We also requested a meeting with her as Novo Nordisk have confirmed that their 'foreseeable future' for animal insulin supplies, will be determined before summer 2004.

The Minister replied on February 16th and we were disappointed that she did not respond to our further points as her letter was a copy of that sent initially to the MPs. She is also unable to meet with us due to other commitments but has said that officials from the Diabetes Policy

Section will be in touch to arrange a meeting. At the time of writing, we are still waiting for contact from this Section.

Message for members
We will keep members informed of further news. In the meantime, thanks to all those who asked their family and friends to become 'Supporters of IDDT'. If you have family and friends who will add their names to our campaign to maintain the choice of animal insulin for people with diabetes, please send their names to Bev Freeman, PO Box 294, Northampton NN1 4XS, tel 01604 622837 or e-mail bev@iddtinternational.org

Update From IDDT Winter 2004 Newsletter

Prescribing powers
Forgive me, if the article 'Prescribing powers for designated health professionals' in the December 2003 Newsletter was confusing. It is a complex situation but I will try again!

Patient Group Directives [PGDs] allow trained nurses and pharmacists to prescribe and/or administer certain medicines providing there is an authorisation document, ie an agreed management plan for each patient, signed by the doctor.

Supplementary Prescribing is restricted to nurses and pharmacists who have undergone training and supervision at a recognised academic institution. They then may prescribe or adjust medication within an agreed management plan sanctioned by the doctor and with the agreement of the patient. Diabetes specialist nurses can only prescribe or adjust treatment provided they have trained as a supplementary prescriber and then only within an agreed management plan sanctioned by the doctor. The patient has the choice of whether or not to agree to this arrangement.

One of the major complaints that IDDT receives from people who wish to change to animal insulin, is that their specialist nurse refuses to allow this or gives a variety of reasons for not changing insulins. This is a matter for discussion with your doctor because he is the prescriber who has to sanction the change in treatment. This applies even if your specialist nurse is a supplementary prescriber because it is a change of your management plan.

I hope that this is a little clearer!

Worth a note! In February 2004 *Which?* magazine published the findings of a survey carried out by undercover researchers who visited 84 pharmacies across the UK. They say that they received unsatisfactory advice from 35 pharmacies. *Which?* concluded that it is impossible for consumers to have confidence in what pharmacists or their assistants tell them. The Royal Pharmaceutical Society described the findings as disappointing and they are to investigate the shortcomings and offer support to improve the levels of service. .

Which? said the findings raised questions about Government plans to extend the role of pharmacists suggesting that if they want consumers to rely more heavily on pharmacists then it is vital that they are properly equipped to provide correct information about medicines and to offer general health advice. Pharmacists are to have on-going training which will be monitored by local PCTs.

History Should Not Be Ignored!

A number of people who have had diabetes a long time have contacted IDDT to express their concerns about modern treatment of Type 1 diabetes and some even go so far as to say that they believe that the old, perhaps more restricted regimes of the past, were better.

One person who expressed these beliefs has had diabetes over 50

years. He took part in the Diabetes UK 'Golden Years Project' which looked at 400 people with Type 1 diabetes treated with insulin for over 50 years. They were visited at home and their clinical details recorded and blood tests taken.

The results are fascinating:

- Retinopathy [diabetic eye disease] was common, though not often serious
- Nephropathy [diabetic kidney disease] did not occur at all
- Obesity was very rare
- Blood lipid [fat] levels were extremely good and in particular, there were very high levels of HDL cholesterol, good cholesterol that protects against heart disease.

The clinical details of this group were even more interesting:

- 29% were receiving treatment for high blood pressure
- the average total daily insulin dose was 37.6 units per day
- 73% were on twice daily injections, 10% injected once a day and only 17% were on 3 or more injections per day.
- 75% use synthetic GM insulin, 14% beef and 11% pork insulin
- 86% drank alcohol and the rest drank no alcohol
- 64% were current or ex-smokers

[Diab Med Vol 20, 808-811]

The researchers have set up a DNA bank of genetic material to look at whether this group of people have protective genes that help them to live long and healthy lives.

It may be that there is a common gene, but perhaps we should look at what else they share. They were diagnosed around 1950, so the biggest part of their lives with diabetes was spent in a very different era. It is well worth taking a look??.

For a large part of their 50 years on insulin there were:

- **NO disposable syringes** - these were generally not available and when they did become available only people that could afford them used them. Pen injection devices did not appear until the mid-1980s.
- **NO home blood glucose testing** - it was not available until the 1980s but most people did not use it until later when strips became available on the NHS. Urine testing was the only guide to control but this was very inaccurate by today's standards.
- **NO HbA1c test** - so no 'spies in the camp' and people could, and no doubt did, cheat, or not confess to 'bad' results, at the clinic visit.
- **NO diabetologists and NO diabetes specialist nurses** - they are both a relatively recent innovation. DSNs did not appear until the 1980s.
- **NO high carbohydrate diets including eating refined sugars** - the diet was more restrictive with carbohydrates counted in lines or 10gm exchanges, fats were not restricted.
- **NO synthetic insulin** - for a large part of, if not all their 50 years, the Golden Years people used animal insulin with lower peaks of action longer duration.
- **NO multi-daily injections** - for most of their diabetic life the majority of people injected a mixture of short and long-acting insulins twice daily.
- **NO very fast-acting insulin** - so no attempts were made to reduce postprandial [after meal] high blood sugars. But then they didn't have high carbohydrate diets, so perhaps they weren't needed because postprandial blood sugars didn't rise as high?

So what did the Golden Years people have?

- **Regular hospital visits** - it was normal to be seen at least 6 monthly and often 4 monthly by a doctor at the hospital even if everything was running smoothly, not just an annual MOT visit, as now.
- **Education** - the regular 4-6 month visits with the doctor provided the opportunity to talk to the doctor, discuss problems or ask him/her questions at regular intervals.

- **Dietitians** - played a greater role at these clinic visits so providing a greater understanding of food, its effects on blood sugars, exercise and insulin dose.
- **A wide variety of insulin choices** - many different companies made insulin so providing a wider choice of insulins with different action times and different peaks of action to suit all needs.
- **Regular eating patterns and carbohydrate controlled diet** - 3 meals a day with snacks between each meal and before bed. While it was more restrictive than modern 'healthy eating diets', it provided people with a better understanding of the contents of the food they were eating and enabled them to learn to match carbohydrate intake with insulin dose and exercise. They counted the carbohydrate content of vegetables and fruit to provide an accurate match to insulin intake. The diabetics' bible - Carbohydrate Countdown listed the carb content of nearly every food imaginable!
- **Restriction of refined sugars** - foods containing refined sugars were very restricted and classed as a special treat or saved to treat a hypo.

The developments that have had the most effect for people with diabetes

The practical development has to be home blood glucose monitoring and the research that has had the most effect is probably the DCCT, Diabetes Control and Complications Trial, published in 1991.

Home blood glucose monitoring

Its introduction during the 1980s meant that for the first time people actually knew what their blood sugars were at any given time and could take steps to avoid hypos and highs. Knowing their blood sugars gave people more confidence and freedom than ever before.

The DCCT

This study had the greatest impact on changing treatment of Type1 diabetes as it 'proved' that tight control of blood glucose levels reduced diabetic complications, especially retinopathy. However achieving 'tight control' increased the risk of severe hypoglycaemia threefold - the daily, acute complication of diabetes most feared by people with diabetes and their family carers. The results were quickly put into practice in the wider diabetic population apparently without considering how a threefold increased risk of severe hypoglycaemia would affect people in their ordinary lives and without questioning if the new targets were actually achievable and sustainable in real life.

This question was perhaps answered eleven years later with publication of the results of a follow up study carried out seven years after the end of the DCCT [JAMA 2002;287:2563-2569]. It showed that the glycaemic control of those on 'tight control' had narrowed to become indistinguishable from those on conventional insulin therapy although tight control even for the length of the study had a beneficial effect on the development of complications, especially retinopathy. Nevertheless, the DCCT resulted in new targets for blood glucose levels being set for everyone, HbA1cs of 7% but without the high level of support the participants in the DCCT received. **Valuable lessons to be learnt**

Treatment of Type 1 diabetes has changed and so has its name, but the condition itself has not. History should never be forgotten and there are valuable lessons to be learnt from the Golden Years people as they remain remarkably free from complications, are not obese and have good cholesterol levels. During the majority of their 50 years of diabetes treatment and care was very different from today, so it is understandable that people wonder if history is being ignored and even whether today's treatment is 'sensible treatment'. Sometimes the big picture can be forgotten.

Cochrane Reviews

Home-based management of children at onset of diabetes may be as safe as hospital-based management [The Cochrane Library, 2004 Issue 1]

Traditionally children newly diagnosed with Type 1 diabetes have been admitted to hospital to make sure that blood glucose levels and symptoms are controlled and also to teach the child and his/her parents how to manage diabetes. About half of children are not severely ill at diagnosis and may not need to be admitted to hospital but may be admitted as a matter of routine. Being in hospital can often be stressful for the children and their families and home-base care may provide a more natural environment for them to learn how to deal with diabetes. This review investigated whether there are any benefits or dangers from using this type of care.

The reviewers concluded that the only studies that have been carried out are of low quality and the results are inconclusive. Generally they seem to suggest that home-based care of newly diagnosed children does not lead to any disadvantages in terms of metabolic control, acute diabetic complications and hospitalisations and behaviour or total cost and so for children who aren't very ill, care at home may be a viable option. However, they recommend that further high quality research is carried out.

Inhaled Insulin still under review
This involves an inhaler with either a dry powder or aerosol for short-acting insulin and long-acting insulin still has to be injected. It is only available for people in trials and Cochrane reviewers concluded that while it is early to assess this new method, so far it appears to be as effective as injected insulin and most of the people in the trials found it more convenient than injections. However, they also concluded that it is too soon to know the effects on people's lungs and that it will be 10 years before we can be confident about the long-term safety of inhaled insulin. Research is still needed for its safety in people with asthma and smokers.

Note: there have been newspaper reports that inhaled insulin is soon to be on the market. All the major insulin producers are developing versions of inhaled insulin, the Aventis/Pfizer version, Exubera, has been delayed for several years after studies showed that the inhaled insulin may cause breathing difficulties and long-term may cause lung damage although Aventis has now applied to the EU for marketing approval. Recently published research comparing the Novo Nordisk version, AERx, with injected insulin in people with Type 2 diabetes showed that although inhaled insulin improved blood glucose control initially compared to injected insulin, this was not maintained after 12 weeks as there were no improvements in HbA1cs. [Diab Care January 2004] Obviously as a new method of insulin delivery, none of the studies have been able to evaluate the long-term effects on the lungs.

Further information - full Cochrane Reviews can be found by visiting www.update-software.com or the easier versions for those of us who are less scientific, can be found by visiting the Cochrane consumer's website www.informedhealthonline.org

Attention Members In The US And Canada

Clarification of pork insulin availability in the US and Canada
Pam Maples and Carol Baker from IDDT-US and IDDT-Canada respectively, have both been receiving calls and e-mails from people having difficulty obtaining pork regular [soluble] and pork NPH [isophane] made by Eli Lilly. Pharmacists have been telling people that these insulins are no longer available - not true, only pork lente has been discontinued. IDDT-US has followed this up with Lilly and it appears that often the wholesalers are not even checking availability with Lilly but saying that pork insulin is no longer available because the expiry dates are short. They do not wish to supply in case the patients fails to collect the insulin!

In Canada both pharmacists and endocrinologists are telling people that pork insulin is discontinued when it isn't! Here is a note from one of our Canadian members:

"Thank you for sending me the information about pork insulin. I am

still amazed at how easy I was able to get pork insulin after 7 years of being told by my Endo that it was no longer being made. All I had to do was get a prescription from my family doctor, bypassing my Endo, and give my pharmacy a few days notice to special order it for me.

It has already started to make an impact for after only using it for 10 days I feel lows coming on, this being the most important side effect for me. I have also been able to halve my daily insulin intake. Once again thank you for all your help and support, you do not know what this means to me."

I think we do!

Lilly have NOT stopped producing pork insulin, they will start another production in February 2004. If you have any problems obtaining your Lilly pork insulin, contact Pam [pam@iddtus.org] or Carol [iddt_cda@yahoo.com]

and they will help.

Rae Price's Diary

When we last heard from Rae she had just started using an insulin pump. Now read on??..

November 2003
Getting used to the pump now but still waiting to hear about the islet transplant. Looks like I'm going to have to be a patient patient once again! The really nice thing is forgetting that there is a little plastic tube inside you and just getting on with your life.

December 2003
Christmas is coming and I'm getting stressed, the blood sugars stay steady for up to 3 days and then whooomph it goes totally out of sync. Roll on the New Year and getting some info on the transplant. The pump has a small tube running from it to the sticky bit where it goes into you, the problem with this is getting it caught and you have to make sure it's tucked out of the way. Luckily I haven't managed to rip anything out so far but it's been close a couple of times. I've decided to start a yahoo email group called Diabetes Facts to try and get more information and news to other people. To join just go to: diabetesfacts-subscribe@yahoogroups.com

January 2004
Decided to give Consultant a ring and find out what's going on with the transplant. He talked about Edinburgh gathering islet cells and Leicester lagging behind but didn't mention when he wanted me to go for the next couple of tests. The psychological profile I don't have a problem with as I've always known I'm totally bonkers and the clamp study (owww, sounds painful!) just tests you don't have any hypo awareness. Well that's not difficult! I remember a time when you knew at least 30 minutes before a hypo struck because the physical effects were so profound, sweating, shaking and getting snappy were hard to miss even for a kid.

The e-mail group is going well and all sorts of people have joined from long termers like me to Type 2 who are having problems with their weight. We've been talking about all the different diets available, especially ones like the Atkins and South Beach that restrict your carbohydrate intake. Hmmm can't decide if it's New Year, new diet time. The last one I tried was Slimfast and I put on 10lb in the first 2 weeks!!

February 2004
Been trying to contact Consultant for a couple of weeks now but it's been like chasing a ghost. After taking advice from a good friend I've decided to try doing some exercise at my local gym. The first session was filling forms in and I ended up laughing. The second session was a little more interesting as we went round the equipment working out which ones I could and couldn't use. The exercise bikes are great because they have a normal seat and your weight is off your feet so

I can manage to do some. They've put me on what they call a buddy body builder system which means I've got one of their experts with me all the time I'm in the gym. This is fantastic because it's like having your own personal trainer all the time.

Tried ringing Consultant again today but told to ring him back tomorrow afternoon and still get the impression I won't be getting a solid date. It's been 10 months now since I first got a sniff at this transplant and if it doesn't happen I'm going to be a very unhappy puppy and probably end up playing the Enola Gay with the health service.

I'm now totally depressed after talking to the Consultant as it seems the 2 people that have been transplanted so far are both still on insulin. Some of the people from the Canadian study have needed 3 or 4 transplants before they could come off insulin altogether. He seems to think Glargene (Lantus) is the answer and wasn't over happy when I told him I'm allergic to it. Then there's the problem of still having to take insulin and anti-rejection drugs too and all their side effects. I very gently tried to explain to him that after nearly 32 years I've basically had enough and you name the place I've had a needle stuck in it. It looks like I might be able to persuade him to refer me to Edinburgh, the next centre to be ready to do one, but I suppose there are loads of other consultants out there with more worthy recipients. Take no notice; I'm just having a winge.

Availabilty Of Hypurin Cartridges

CP Pharmaceuticals have been TEMPORARILY out of stock of 3ml cartridges of Hypurin Porcine Neutral, Hypurin Porcine Isophane and Hypurin Porcine 30/70 Mix. By the time you read this, they should all be back in stock but we wanted to reassure you that these insulins are still being produced. When this situation arose, several people reported that they were told by their pharmacist and/or healthcare professional that these insulns are not being made anymore. Not so! Please do not believe these stories and rest assured that IF this ever came about, we would immediately send a letter to all our members but if in doubt contact IDDT on 01604 622837.

New NICE Guidelines

January 2004 - the National Institute for Clinical Excellence [NICE] has issued new guidelines which include the following topics:

- Type 2 Diabetes and Footcare
- Eating disorders

If you have access to the internet, these can be viewed by visiting www.nice.org.uk or copies can be ordered from the NHS Response Line on 0870 1555 455

Guidelines in the pipeline:

- The draft guidelines for Type 1 diabetes are going through the consultation process and IDDT has made a submission about animal insulin to NICE. We will give you more details when these guidelines are issued.
- A combination of drugs is often given to treat high blood pressure and the results of seven major trials involving over 70,000 people have found that treatment with thiazide diuretics and beta blockers increases the risk of developing diabetes. The leader of the review said that the risk is small but measurable and some people would be better changing their treatment. NICE is due to publish its guidelines on treating high blood pressure later this year which doctors will receive.

IDDT 10th Anniversary Conference

'The Voice for Choice'

Saturday, October 9th 2004, The Paragon Hotel, Birmingham

Cost for the day is £20.00 per person or a reduced rate of £15.00 for senior citizens and for parties of 4 or more people. We will provide you with details of overnight accommodation.

As this is a special year for IDDT, we hope that you will come along and join us, so please put the date in your diary. We have an interesting programme for you that includes group sessions on various aspects of diabetes to offer information and discussion on topics of interest to you - insulin and different regimes, handling hypoglycaemia, diabetes and coeliac disease, diet, living with diabetes and a session for parents and partners.

We will be sending you the programme and application form in May. If you can help to publicise the conference to other people with diabetes and their families and would like extra programmes, do please let us know by contacting Bev Freeman, IDDT, PO Box 294, Northampton NN1 4XS, tel 01604 622837 or e-mail bev@iddtinternational.org

Even Doctors Are Confused About The In-Use Dates Of Insulins!

The in-use date for insulin is not the expiry date but the date after which the insulin you are using should be discarded because it may have lost some of its potency and therefore could be responsible for variations in blood glucose levels. However, the information about in-use dates is confusing and this was demonstrated by a joint letter from physicians published in Diabetes Care [Vol 26;9:2665-2669 Sept 03].

They expressed concern about conflicting information on insulin in-use dates stating that the information is often contradictory. Diabetes Care considered this issue to be of such clinical relevance that the insulin manufacturers were asked to make statements for publication. However, to add to the confusion, IDDT found that the information in this US publication varied considerably from the information for the same products in the UK! Here are some examples:

- **Novo Nordisk information in the UK** advises a 6 week in-use date for 'human' Actrapid, Insulatard and Mixtard 30 in vials although in 2001 they informed IDDT that it was 28days. For these insulins in Penfils Novo Nordisk advise up to 6 weeks in-use dates in the UK but in the US they advise only 28days for Actrapid, 14 days for Insulatard and 10days for Mixtard. For the analogues, NovoRapid is 28days in the US and the UK but for NovoMix30 4 weeks in the UK but only 14days in the US. IDDT asked Novo Nordisk why their recommended in-use dates differed between the US and the UK but we were not offered an explanation.
- **Eli Lilly information for the UK advises** that the in-use dates for ALL their insulins is 28days and this appears to be regardless of insulin type or whether it is in vials, cartridges or pre-filled pens. However, Eli Lilly information for the US states that in-use dates vary according to the type of insulin, its container ie vial or cartridge, the temperature and regulatory requirements. They also state that the in-use dates for Humulin insulin vials is 28days but for cartridges and pre-filled pens it is shorter then this due to reduced volumes, increased agitation and potentially variable temperatures, the latter two from carrying them around.

There is no wonder that physicians are confused, to say nothing of patients! Is the information we are being given in the UK accurate enough? The stability of insulins surely doesn't vary from country to country, does it? If people in the US need this more detailed information about in-use dates, then don't patients in the UK require similar information?

IDDT Updated leaflet - 'Looking After Your Insulin'
This leaflet has been updated to include the latest information on in-use date times of insulins and we have also included the US in-use dates, where known. This provides you with a more informed choice of how you take care of your insulin. It also contains helpful tips about holidays and they will be upon us soon!

If you would like an updated copy of this leaflets, please contact IDDT, PO Box 294, Northampton, NN1 4XS, tel 01604 622837 or e-mail leaflets@iddtinternational.org

Cars To Detect Hypos!

Headline! ***'Renault has unveiled a working model of equipment fitted to a car to provide medically-supervised continuous blood glucose monitoring while driving.'***

Renault have teamed up with medical experts to develop special equipment that checks blood sugars while you are driving. The press blurb rightly points out that there have been reports of serious and fatal accidents occurring when drivers with diabetes have hypos, usually caused by loss of hypo warnings. Having said this, the Daily Record [6.2.04] starts the article with *'The plight of diabetic drivers could shortly by eased thanks to a new system that might well save thousands of lives'.*

'Saving thousands of lives' may be press exaggeration, but such statements are likely to fuel already expressed public concerns about the safety of people with diabetes driving cars.

Research looked at diabetic drivers
There appear to be no accurate figures for the number of accidents caused by hypos at the wheel. However, research [Diab Care, August 2003] carried out in seven US and four European cities suggests that people with Type 1 diabetes are "at an increased risk of driving mishaps" but people with Type 2 diabetes, even those taking insulin, are apparently at no higher risk of driving accidents than the general population.

During routine clinic visits in these various cities, 341 people with Type 1 diabetes, 332 with Type 2 and their non-diabetic spouses acting as controls, completed a questionnaire about driving. The results showed that:

- 19% of people with Type 1 had had accidents during the previous 2 years compared to 12% of people with Type 2 and 8% of the non-diabetic control group.
- 18% of those with Type 1 diabetes reported having one hypoglycaemic event while driving compared with 5% of those with Type 2.
- 15% of those with Type 1 had been cited for moving violations compared to 8% of those with Type 2 and 10% of the control group.
- Crashes among people with Type 1 diabetes were associated with less frequent blood glucose testing before driving and also with the use of injections rather than pump therapy.

The research also showed that 50% of the Type 1 and 75% of the Type 2 drivers had never discussed hypoglycaemia and driving with their physicians although perhaps this should be written the other way around - that physicians had never discussed hypos and driving with such a high proportion of their patients! Surely this issue should be part of the basic education package for people with diabetes?

However, there is an unresolved difficulty for patients here. Driving in the UK is illegal for people with loss of hypo warnings, so there is a fear that a discussion with their doctor about loss of warnings may lead to their driving licence being removed. Indeed, when one member requested a change to animal insulin, his unwilling doctor asked if that meant he was informing him that he had loss of warnings because if so, he would have to report him to the DVLA. Hopefully this attitude is rare, but it does highlight the difficulties faced by diabetic

drivers who want to discuss with their doctor improvements in their control to avoid hypos and loss of warnings.

The DVLA position on driving and hypoglycaemia

The DVLA asks in depth questions about hypoglycaemia and loss of warnings on driving licence application/renewal forms - and rightly so! In addition, the letter that accompanies a new driving licence also states that you must test before driving and test every 2 hours on a long journey - again rightly so! It is difficult to know whether this is a legal requirement or just advisory but if you have an accident and you have not followed this advice, then the net result could be the same as the court may decide that diabetic driver has not shown a responsible approach.

It is worth noting that an article in Practical Diabetes International, Sept 2002, stated "National legislation may soon include blood testing before driving". Logically this would mean that everyone at risk of hypoglycaemia would have to use a blood glucose meter with a memory, otherwise there is no way of proving when and how often tests have been carried out. But whether advisory or mandatory, the DVLA advice is well worth taking because hypoglycaemia while driving is dangerous, not just to the driver but also to the general public.

Let's take a look at the Renault development

Is it in the best interests of people with diabetes and the general public?

Is it actually going to prevent accidents?

To try to answer this question we have to look at how the equipment works. The driver wears a wristwatch sized continuous blood glucose monitor that communicates with the car's mobile phone. This reacts in one of two ways. When a fall in blood glucose level is detected that could lead to a 'crisis' [a hypo] in 10 to 20 minutes, an alarm sounds to warn the driver to eat glucose. If the 'crisis' is more immediate, the system sets off an alarm and automatically dials an emergency call centre, sends off the blood glucose curve and video images of the driver via a web cam. It also sends a series of geographical positions so the car can be traced and a call centre operator can speak to the driver to tell them the nearest car park and/or emergency services.

Renault may have consulted medical experts but have they consulted patient and carer experts? What will be the reaction of the DVLA?

My first reaction was to laugh and then I thought a bit more deeply. Having dealt with hypos and loss of warnings while my daughter was using synthetic GM insulin, I have to say that these 'experts' really do not understand what happens to people when they're hypo! If they have sufficient warnings to be able to know that they will be significantly hypo in 10 minutes, then they don't actually need an alarm but if they don't know, then they have loss of hypo warnings and shouldn't be driving! If the so-called 'immediate crisis' occurs [presumably a severe hypo without warnings] then the alarm and the operator speaking to the driver probably won't have any effect at all. People who are this hypo simply do not know what they are doing, if they did they would have already stopped and eaten something sugary! To think that they can be guided into the nearest car park beggars belief, to say nothing of the fact that they could have an accident while they are doing so! At best, they should be told to stop the car immediately in the hope that they are able to do this safely.

Note: If blood sugars drop below normal [usually classed as below 3.9mmols/l] then research shows that concentration is affected. Fleeting lack of concentration can cause accidents whether you have diabetes or not.

But let's look a bit further

- What happens if there is an equipment failure?
- Is buying a car with this equipment, in itself an admittance that you have lost your warnings and so will the DVLA remove your licence anyway?
- Alternatively could the DVLA, in the future, decide that everyone

with diabetes will have to have this equipment while driving? The BIG BROTHER in your car would at any time be able to provide evidence of your blood sugar levels while driving and could be required as evidence for renewal of your driving licence or if you have an accident, whether your fault or not. Perhaps all this seems a bit farfetched but 20 years ago who would have thought that children would have been walking down the street using mobile phones?

But the problem needs tackling, not the end result!
Perhaps the full impact of loss of hypo warnings can only be truly understood by people with diabetes and their families but we must never forget that driving with reduced or lost hypo warnings is not safe. Clearly Renault and medical experts have also recognised this but this car development is attempting to deal with the end result and is not getting to the root of the problem - the avoidance of hypos and prevention of reduced or loss of hypo warnings. Loss of hypo warnings can be a consequence of long-term diabetes but this is not always the cause. Here are a few choices you may wish to discuss with your doctor to avoid this situation:

- Consider raising your target blood sugars a little higher. This may help to avoid hypos because tight control increases the risk of severe hypos and hypos themselves can cause loss of warnings. Raising blood glucose levels may mean that you do not achieve the targets set by the clinic to reduce the risks of long-term complications but this difficult choice is yours to be made in discussion with your doctor.
- Consider a change to natural animal insulin which is slower and less aggressive than GM insulins. Although often not believed by health professionals, evidence from significant numbers of patients shows that GM insulin treatment can cause loss of warnings or reduced warnings and warnings can return with a change to animal insulin.
- Consider lowering carbohydrate intake and lowering the insulin intake. A high carbohydrate diet requires larger doses of insulin which in turn means that the insulin peak of action will be higher and the drops greater making hypos more likely.
- Consider the type of carbohydrate eaten. Long-acting acting carbohydrate is an essential part of the diet to balance with the longer acting insulin to prevent hypos.

Driving - Warinings To Everyone!

The Sunday Independent in Ireland [1.2.04] reported the case of a diabetic driver who was banned from driving for life after driving erratically. It transpired that he had forgotten to have his lunch and went hypo at the wheel - obviously he didn't have any hypo warnings! Clearly the driver was irresponsible because he failed to test his blood sugars before driving and failed to ensure that he ate properly, but a ban for life seems extreme and does not give the driver a chance to change his habits.

The Hexham Courant [26.12.03] reported the case of a man with Type1 diabetes who crashed his car because his blood glucose levels had dropped but he admitted that he had not informed the DVLA of his diabetes. He was given an absolute discharge after the court heard that he had never been told to notify the DVLA although he had been totally honest about his diabetes with his insurance company. The driver also said that he had managed his diabetes perfectly well for 20 years but he had been changed to a different insulin just before the accident. [No prizes for guessing the type of insulin he must have changed to!]

Messages here are:

- The DVLA and your insurance company must be informed if you have diabetes and any other material health changes.
- It is not legal to drive if you have loss of hypo warnings. With any change of insulin, close blood glucose monitoring is essential.
- Blood glucose testing is essential before driving and every 2 hours

on a long journey.

- If a hypo occurs when driving, there is only one way to deal with it: stop the car, get into the passenger seat and eat or drink something sugary followed by longer-acting carbohydrate, such as a sandwich.
- Diabetes education programmes must include details about driving regulations. It is not sufficient to just explain about driving and diabetes at the time of diagnosis when other aspects of being diagnosed may seem far more important, it must be an ongoing part of education.

Bits And Pieces

Blanket ban on people with diabetes joining the police is to be lifted this year
The police force has previously banned applicants with diabetes from joining and officers who develop diabetes while in the force have often been given a desk job. The Disability Rights Commission say that people with Type 1 diabetes should have individual risk assessments rather than a blanket ban. Changes in EU law in October 2004 are expected to remove employment bans.

Audit Commission Report on diabetes services in Wales - highlights the inconsistencies in the prevention, detection and treatment of diabetes. Among the Commissions findings was that less than half of GP practices offer structured education for people with diabetes. [Welsh Daily Post, 4.12.03]

GM food labelling
From April 2004, foods containing genetically modified [GM] ingredients must be labelled as such to comply with EU legislation. Labels have to say whether GM ingredients have been used, not just whether they are detectable in the end products. The use of GM processing aids, such as enzymes still don't have to be declared.

Groups opposed to new EU rules on vitamins and food supplements win court victory
The European Commission wants tighter rules on food supplements from August 2005 so that only vitamins and minerals on an approved list can be used in supplements and that there are upper limits on vitamin doses. The aims are to protect the public by ensuring that vitamins and minerals used in food supplements are safe and properly labelled. Companies have until 2005 to put forward a safety record but as the cost of doing so could be up to £250,000, it is likely that many products will no longer be available. Industry and some patients groups opposed the EU Directive on the grounds that it is unlawful and would unfairly affect millions of people, threatening both health and trade. At the High Court in London, January 30th, the Judge ruled that their case can be taken to the European Court of Justice.

How Accurate Are Blood Pressure Monitors?

Increasingly people are buying blood pressure monitors over-the-counter from chemists or via the internet. There have been reports that some monitors under-record blood pressure which could adversely affect some people, especially those with high blood pressure. An expert group set up by the Chief Medical Officer, Sir Liam Donaldson, will look at the accuracy and use of different types of monitors. Their findings will be reported to doctors who will be able to pass on the information to their patients.

Automated monitors are more popular than mercury monitors but concerns have been reported about their accuracy, especially for conditions such as pre-eclampsia and cardiac arrhythmias [heart rhythm problems]. Most monitors used by doctors have been validated and it is the monitors sold in chemists that are causing the greatest concern. It also appears that just buying the most expensive monitor does not mean that it is any more accurate than cheaper ones. So if you use a blood pressure monitor, be aware of this situation. The

British Hypertension Society suggests that people considering buying a blood pressure monitor visit their website to see which monitors they recommend. This can be found at www.bhsoc.org

News About Insulin Analogues

This is difficult to write but??
We have always tried to be honest and to keep you informed. We believe that honesty is the best policy but sometimes being honest can cause alarm and it can also result in IDDT being accused of being alarmist. Information about insulin analogues that may cause alarm has reached the media in an EU country and therefore it may reach the press in the UK. So the Trustees have been faced with a dilemma. If we don't inform you, you may read it in the press and you could rightly accuse us of withholding information from you and of being hypocritical because we advocate informed choice for patients. This could or would affect your trust in IDDT. In reality we are not telling you anything that is not in the public domain anyway but most people would not find it easily.

The EU approval documents and Scientific Discussion Documents for all the insulin analogues currently in use [Humalog, NovoRapid and Lantus] all refer to the formation of tumours in the trials carried out with RATS AND/OR MICE when extremely high doses of the insulin analogues are used. I stress that this is with very high doses - far higher than would ever be given to a human being.

These possible carcinogenic effects IN RATS are thought to be caused because analogues are closer in structure to insulin growth factor. They were referred to in a paper by Professor Amiel [Diab Med 15:537-538.1998] after the introduction of Humalog: "There remains a risk of unexpected problems with any new agent and the structure of the new insulin [analogue] is a little closer to IGF structure than the old."

Information can be found in the European Medicine Evaluation Agency documents for all the analogues by visiting their website www.emea.eu.int or if you want to discuss this further, please don't hesitate to call me -
Jenny Hirst on 01604 622837 or e-mail jenny@iddtinternational.org

I hope that you will understand the difficulty that this decision has posed - as Trustees is it right that we have more information than you to inform our own health care decisions? The answer to this is clearly 'No' and if we are accused of causing unnecessary alarm, then this is something we will have to carry.

Novo Nordisk Approval Of Levermir [Determir] Delayed In The States, But The EU Giver It A "Positive Opinion"

Levemir [insulin determir] is a new long-acting insulin analogue from Novo Nordisk. It differs from Lantus [glargine] in that it is more of an intermediate acting insulin and not a 24hour acting insulin so presumably it will have to be injected twice a day.

Applications for marketing approval were made in the US and Europe in October 2002 but both the FDA and the EU requested that Novo Nordisk provide additional information before approval could be granted. Novo Nordisk announced that they expected approval in early 2004 but in February 2004, approval was delayed again by the FDA in the US and Novo Nordisk announced that the launch of Determir [Levemir] will not be until mid-2005 and then this will conditional on the results of further clinical studies. Clearly the FDA, the US drug regulatory authority, are not satisfied with the evidence before them. However on February 27th Novo Nordisk announced that the EU's Committee for Proprietary Medicinal Products [CPMP] has "adopted a positive opinion recommending granting marketing authorisation

for Levermir". Hence Novo Nordisk expects to receive EU marketing approval within the coming months and that Levermir will be launched in the second half of 2004.

It seems reasonable to question the difference in the two assessments of Levermir - the FDA in the States requires more research before allowing it to be marketed but the EU doesn't.

What do we know about Levermir?
Basically only what Novo Nordisk tell us and they say:

- it is a long-acting insulin analogue that *'provides more consistent day-to-day control of blood glucose levels compared to conventional insulin preparations'*. Remember that by 'conventional' preparations they mean 'human' insulin not animal insulin.
- In one press release they say *'Among the benefits for people with diabetes it has been demonstrated that Levermir reduces fasting blood glucose and the risk of hypoglycaemia, especially at night time'. However, in a different statement, it is stated that 'In clinical trials, the overall frequency and pattern of adverse events was similar to Insulatard [NPH] insulin'*. So where's the improvement - hypoglycaemia is an adverse event!
- Finally they say *'Studies have shown that people using Levemir do not experience the undesirable weight gain so often associated with conventional insulin preparations'.*

Readers forgive my anger!
For years we have stated that one of the adverse effects for some people on GM 'human' insulin, is 'undesirable weight gain', to quote Novo Nordisk! Never admitted before by the manufacturers, by doctors or by healthcare professionals but now there is a new insulin that does not cause the undesirable weight gain that was never admitted!!!! On the very day of writing this article, I received a call from a lady whose so-called 'undesirable weight gain' has been 4stones [56pounds!!!] in the two years since she has been on synthetic insulin and no one can explain why she's putting it on. We frequently receive calls from people who have put on a 2stones since going on to insulin - GM insulin. Will Levermir help them to lose this weight or just stop them from putting it on? Only one thing resulted in my daughter losing the 3 stones she put on while using GM insulin and that was natural animal insulin. Forgive my outburst, my anger and my frustration - being proved right gives no satisfaction when people have suffered all the consequences of this huge weight gain.

Lantus - Additions To Patient Information

There have been additions to the patient information documents for Lantus [24hour acting] particularly in relation to hypoglycaemia and its consequences:

- The prolonged effect of Lantus may delay the recovery from severe hypoglycaemia due to the longer action of Lantus.
- Intensified blood glucose monitoring is advisable in patients with significant stenosis [narrowing] of the coronary arteries or blood vessels supplying the brain and in patients with proliferative retinopathy, particularly if not treated with photocoagulation.
- If normal or decreased HbA1cs are noted, the possibility of unrecognised hypoglycaemia [especially nocturnal] must be considered.
- There is less nocturnal hypoglycaemia but more early morning hypos should be expected [not new - just a reminder]

Clearly Lantus is NOT the insulin for everyone, despite its apparent very widespread use in such a short time after approval. As MIMS suggests to doctors for all new drugs, it should be treated with caution!

Treatment of children with Lantus
Lantus has been approved for use in children over 6years old. Here are the results of a recent study in the US. 37 children and adolescents whose original HbA1cs were above 8% were evaluated after treatment with Lantus [glargine]. After 6 months 30 children had

an average drop in HbA1c from 10.3 to 8.6% but 7 participants did not respond to Lantus and they showed an average rise in HbA1cs from 9.5% to 10.4%. Apparently 62% of the children took their Lantus injections at lunchtime at school where they were supervised and the researchers suggest that this may have contributed to the most significant improvements in HbA1cs. [Ped Diab June 2003]

Just a note: *'Violent diabetic to sue maker of wonder drug' is the headline of an article in Times on Line, 7.12.04. Joseph Callery, a computer operator aged 34, insists that Lantus made him violent. Joseph has had diabetes for 31 years said that after starting Lantus he had two severe night hypos, he developed holes in his nails, stiffness in his hands and became more aggressive. He attacked colleagues at work and twice tried to strangle his girl friend after minor disagreements. After the second attack, he came off Lantus. Joseph's wife is quoted as saying "It was totally out of character. He was like a man possessed. He was never like that before he was on Lantus and since he has been off it he has been completely back to normal."*

The article points out that although Lantus was hailed as the biggest advance in the treatment of diabetes for 80 years, the Medicines and Healthcare Products Regulatory Agency [MHRA] has received 99 reports of adverse reactions associated with Lantus since it was introduced in August 2002. Joseph wants to launch a legal action against Aventis.

From Our Own Correspondents

Interesting - the medical profession still insist that 'human' insulin is better than animal for everyone!
Dear Jenny,

Congratulations on reaching IDDT's 10th Anniversary - keep up the good work!

I recently saw a new diabetic nurse and she was surprised that I am *"still on pork insulin"*. I explained my awful experiences with synthetic 'human' insulin and my happy return to CP pork insulin. But she was still keen to put me on to one of the fast-acting synthetic analogue insulins stating that they were vastly improved since synthetic insulins were first introduced saying "*Novo Nordisk and Lilly are putting a lot of research and money into improving 'human' insulins and management regimes."* I still declined to change. It is interesting how professionals still persist with their insistence that 'human' insulin is better than animal insulin for everyone!

Mr B.J.
e-mail

I was waiting for a pump, but not anymore
Dear Jenny,

You may remember that when I came to the Conference in October I was anxiously waiting for a pump as a possible avenue of achieving a bearable life with Type 1 diabetes. While I was waiting I decided to change from synthetic insulin and to try pork insulin. I was amazed at the results, in only 3 weeks all my joint pains have completely gone. Now I don't have the nightmare swings in blood sugars and on top of all this, I have lost a stone in weight! As I am at present, I am no longer going to bother with the pump as it will be a lot of bother for only the marginal improvement it can now give me.

The NICE guidelines certainly make it easier to obtain a pump. They say that people have to try Lantus before they can be considered for a pump on the NHS. I tried this with Humalog and it was my nightmare spell of this regime that made me look at the different behaviours of different insulins - maybe I should be grateful for the experience! Perhaps NICE needs to look at the validity of other non-pump alternatives?

Mrs E.J.
Midlands

Jenny's comments: the NICE guidelines on pump therapy on the NHS do say that patients should first be treated with Lantus and if this does not offer good control, then pump therapy at the cost of the NHS can be considered. IDDT did partake in the NICE public consultation for the pump guidelines. It will come as no surprise to readers to know that we did propose that patients should also first try animal insulin to see if this provides better control. Perhaps it will also come as no surprise to readers to know that animal insulin was not included, just the then new Lantus with no history of safety and efficacy! Mrs E.J. has rather proved our point.

Milk allergy
Dear Jenny

I am writing to let you and other readers know how the discovery that I am allergic to milk has changed my life around. I have been taking 8 tablets a day for Type 2 diabetes and was feeling very low, only half alive, joint pains in shoulder and wrist plus side effects and toilet problems from the drugs!

In August 2003, at my own instigation I was tested for many food items to find out if I am allergic or partially allergic to any of them. I was proved to be positive to all cows and goats milk products, egg yolk, apple peel and potato skin and had a partial reaction to sugar. I was given a very different diet to follow and cutting out milk and all its hundreds of products has proved quite difficult but it is a sensible diet because I am left with all home made fresh organic produce and know exactly what's in it. I managed the diet without milk using a product called Rice Dream as a replacement and all milk products were removed completely. I have also been very careful with all sugar products.

My blood sugars, usually readings of 9 to 12 fell and fell to 4 to 5. I reduced my medication and still they stayed at 4 to 5. I have lost some weight, have no joint pains anywhere and feel much better, a really alive feeling with much more energy.

I have recorded all my blood test results and I am no longer taking any medication to treat Type 2 diabetes. I have yet to have a doctor's blood test to prove my point and I hope he 'understands'!

Ms S.R
South West

Lantus - can you help me please?
Dear Jenny,

I have been on Lantus insulin and NovoRapid since March 2003. My weight has gone up by 21pounds. I am worried about my weight gain and I have noticed that my ankles are swollen.

I told my diabetes specialist nurse about this and that the Information Leaflet lists one of the side-effects as temporary build up of water in the body with swelling in the calves and ankles. All she said was "Oh, they put all that in to cover themselves". I am concerned because I have intermittent claudication. *[Claudication is usually caused by narrowing or blockage of the arteries in the legs causing pain when walking].*

I also did not like the Lantus Optiset pens but this was ignored. Anyway I persisted and last week they admitted that they have received a lot of complaints about the Optiset and that I should throw them away. They have prescribed an Autopen Reusable pen which is a lot easier to use. Are any of your other members having troubles like me?

Mrs M.K
North East

Jenny comments: Mrs M.K is correct, the Patient Information Leaflet [PIL]for Lantus does list "temporary build up of water in the body with swelling in the calves and ankles" as a rare side-effect. The manufacturer's advice in the leaflet is: *"Tell your doctor or pharmacist if you notice any of the side effects listed above or any other unwanted or unexpected effects. To prevent serious reactions, speak to a doctor*

immediately if the side-effect is severe, occurs suddenly or gets worse rapidly." Our advice to Mrs M.K is to speak to her doctor about this side-effect as he is the person who can prescribe a change of insulin and report this adverse effect to the Committee on Safety of Medicines. Worth noting that the PIL for Hypurin animal insulins does not list swelling of ankles and calves as an adverse effect.

A bit of praise
Dear Jenny,

I have had diabetes for over 50 years but when I go to the hospital clinic, I am made to feel as if I know nothing. If only they said 'well done' now and again instead of almost threatening or frightening the patients to try to make us all achieve better results.

Mrs S.B
e-mail

National Servie Framework For Rental Services

The National Service Framework [NSF] for renal services has been published and government has pledged that more kidney patents will be able to receive dialysis treatment at home. The NSF sets out five standards that must be met by 2014 and calls for the information given to kidney failure patients to be improved, individually designed dialysis treatment and better access to kidney transplants. Local renal care will be audited and examples of good practice will be passed on to other areas.

There are currently 30,00 people with established renal failure in England and about half of them have had a kidney transplant but the remaining people have to undergo 4 hours of dialysis three times a week and frequently have to travel long distances to the nearest renal unit.

The Health Secretary, John Reid, says that the NSF for renal services will provide home dialysis where appropriate and cut travel times by putting haemodialysis stations where they are most convenient for patients. However, the Chairman of the National Kidney Federation said that while this NSF is desperately needed, it lacks 'enforcement of the implementation' of the standards and also lacks targets and costings which would enable them to hold government and service providers to account. Sounds rather like the NSF for diabetes - it will require more resources to implement.

Apologies About The Post!

The postal deliveries in January appear to have been pretty awful and some people did not receive their January Newsletter, both here and abroad. We suspect that the problems arose as a result of the postal strike towards the end of 2003 and can only apologise to those who did not receive the January Newsletter. We also learned that in March one of our post boxes was set alight and some of our Information Packs may not have arrived. If you were expecting mail from us and it has not arrived, please give us call.

Pharmaceutical Company News

Wockhardt to consolidate its UK companies - Wockhardt, new owners of pork and beef insulin manufacturer, CP Pharmaceuticals, also own Wallis Laboratories in the UK and they are consolidate to the two companies to form Wockhardt UK Ltd. CP and Wallis products will continue to be marketed under their respective brand names.

Artificial pancreas - Medtronic, a US medical device producer is developing an artificial implantable pancreas intended to mimic

the way a healthy pancreas works by releasing insulin and other hormones. Medtronic expect it to be available in the next 5 years. [Glasgow Herald, 20.11.03]

Glaxo drug in the pipeline - GSK have a new diabetes drug in the pipeline that lowers blood sugars by promoting the elimination of glucose through the urine. GSK Chairman described it as a 'chemical Atkins Diet' that could also have an effect on obesity as it lowers insulin and glucose in the same way as a low carbohydrate diet. [The Daily Telegraph, 4.12.03]

High court judge may report drug company executive to the attorney general - in a court hearing of a patent action against GlaxoSmithKline [GSK] by a generic drug company, Cipra, the judge is considering reporting the director of pharmacology at GSK to the attorney general because he threatened an expert witness appearing for Cipra that he would get no more funding for research from GSK. The judge pointed out that the function of an expert witness is to help the court, not to assist any particular party. The attorney general can take proceedings against the GSK director for attempting to interfere with a witness, penalties range from a fine to a prison term. [BMJ 31.1.04]

Medically Necessary Crisps - What Next?

The Mail on Sunday [16.11.04] carries an article about a 9year old girl with diabetes whose father complained to the head teacher because the school's new fruit-only snack policy prevented his daughter from eating "her medically necessary crisps"! He accuses the school of victimising his daughter for forbidding her to eat crisps when all the other children had to have fruit. The family backed by the Disability Rights Commission won their case and the school was ordered to change its policy and apologise.

It seems the world has gone mad - since when have crisps been a more healthy snack than fruit for anyone with diabetes to say nothing a being medically necessary? Perhaps the family and the Disability Rights Commission need some dietary education. We old stagers know that a piece of fruit contains 10 gms of carbohydrate and does not contain any fat!

Children And Young People

Springtime hypoglycaemia in children

The suggestion that hypoglycaemia in children with Type 1 diabetes might be more common in Spring has been around for a long time and Bandolier 118, Dec 2003 looked into this. Two studies have investigated the link between the timing of hypos and seasonal variations of HbA1c results in intensively treated children, ie those treated with four injections a day.

The first study [ref1] looked at children between the ages of 1-18 in an area of Sweden with an average age of 13 and average HbA1c levels of 7%. The children or parents were asked to register every severe hypo and hospital admission during 1994 and 1995, 126 and 122 children respectively.

The yearly incidence of unconsciousness and severe hypos without unconsciousness were recorded. The results showed:

- in each year the incidence of unconsciousness was 0.2 per patient year, with 12% of children unconscious.
- The incidence of severe hypos without unconsciousness was 1.3 per patient year, with 34% of children experiencing this.
- There was no difference in the HbA1c levels between the children who experienced unconsciousness and those who did not.
- Unconsciousness occurred more frequently in Spring than at any other time of year.

The second study [ref 2] looked at 810 HbA1c levels of 114 children aged 2-18 throughout a year. Lower values were found in Spring and Summer despite no change of insulin.

The Swedish authors suggest that the increase in hypos in Spring and Summer could be associated with the change from lesser activity during the winter months to greater activity in Spring and Summer. Bandolier point out that there is very little evidence on this topic so perhaps the best message for children and parents is to expect an increase in hypos in the Spring.

NB It was noticeable to IDDT that in the very hot summer of 2003 a great many people with Type 1 diabetes reported increased hypos, irrespective of increased activity. In fact it was so hot that many of us probably took less exercise than usual! Hot weather itself seems to increase hypos in some people.

Ref 1 Adverse events in intensively treated children and adolescents with Type 1 diabetes. Acta Paediatrica 199 88:1184-1193

Ref 2 Seasonal variation of HbA1c in intensive treatment of children with Type 1 diabetes. Journal of Pediatric Endo and Metab 2000 13:529-535

NHS News

Millions to ensure that patients have access to GP cover at nights and weekends

Under the new GP contract GPs will be able to opt out of out of hours care and primary care trusts [PCTs] will take over by the end of 2004. Government is making another £28million available to ensure that PCTs will be able to cope after the changeover and spending on out of hours care is set to double from £42million to £92million a year. Much of the money will be spent on extra staff and some areas are expecting to employ nurses and paramedics to do the job, not doctors. A survey for PCTs showed that 95% of doctors intend opting out of working nights and weekends. Out of hours cover is presently provided by the National Association of GP Co-operatives.

Patients to get copies of doctors' letters from April 2004

From April 2004 you should receive copies of any letters about your care that are sent between doctors treating you so any letters from your hospital doctors to your GP and vice versa, must be copied to you. If you find that you are not receiving copies of doctors' letters, then according to the Dept of Health, you have the right to complain. They recommend that you ask your GP surgery and/or the strategic health authority what they are doing to implement this policy. If this fails then you can write to John Reid, the Secretary of State for Health.

End of Community Health Councils [CHCs] but website available.

Patient and Public Involvement Forums are replacing CHCs despite many concerns being raised about this change. The national body of CHCs is keeping their website live for the next 2 years because it holds a wealth of expert information. It can be reached by visiting www.achcew.org.uk Key reports are also available on CD-ROM tel 020 7609 8405

Proposals to change the NHS complaints procedure

Under the proposed changes to the NHS complaints procedure, it is expected that patients and their families will not have to go through a formal complaints procedure that can drag on for months or even years. It is also expected that they will help to make the NHS a patient-centred organisation and they should cut bureaucracy and NHS costs.

The proposals extend the time for a complaint to be made from 6months to a year and patients will have greater freedom over how they make the complaint. For instance if there is a problem with the GP, then the complaint can be made to GP or to the local primary care trust. The new NHS 'watchdog', the Commission for Healthcare Audit will be responsible for reviewing cases where the patient is not happy with the way the complaint has been handled.

NHS targets
In a speech on February 10th, the Secretary of State for Health, John Reid told NHS chief executives that in future the focus will be on delivery and quality of care and that from 2005-6 there will be fewer performance targets and the emphasis will be on quality of care.

More NHS Walk-in Centres
In January 2004 the Government announced that eleven new NHS walk-in centres are to be set up making 64 around the country. The aim of the centres is to provide quick access to advice and treatment for minor ailments without the need for an appointment. There have been 4 million visits to the 42 centres since 2000. However, research showed that a walk-in centre in Loughborough had not significantly affected the number of people going to see their GP and the BMA has warned that there is little evidence to prove that the centres are a cost effective way of providing NHS care.

NHS teams up with Weight Watchers
In an attempt to tackle the countries obesity problems a pilot study is being carried out in three cities - the NHS has teamed up with Weight Watchers. Doctors and nurses ask overweight patients if they would like to attend a local slimming club meeting and those interested in attending are given discount vouchers. The scheme was launched in London in September 2003 and is now getting underway in the Midlands and the North of England.

Problems With Devices!

Medisense G2 Sensors
Readers may remember a rather exasperated letter from Mr JB about the new MediSense G2 blood glucose testing strips. He had many failed attempts at blood testing with them. Within 24 hours of the Newsletter reaching members, IDDT received calls and e-mails from members who had similar experiences. Many people found that the new strips were unsatisfactory and more fiddly than with their old strips, especially for people with rheumatism/arthritis in their hands. Here is just one experience: “After contacting MediSense and being told how to get the blood on to the strip, I still found it difficult so after 2 weeks of failed tests, I phoned them and told them I would have to change to another company’s meter. They immediately said they would upgrade me to an Optium Plus meter and this works fine.”

So it seems that the answer is to complain to MediSense. Many thanks to members for offering the information - we hope it helps!

Aventis Optipen Pro

Again readers will recall reports of our members having problems with the Aventis Optipen Pro for use with Lantus, well now the Medicines and Healthcare Products Agency [MHRA] has issued an alert on this pen system as there can be plunger and dose setting problems. In February Aventis announced that they have applied for marketing approval in Europe and the US for a new re-useable pen, the OptiClik.

Disetronic Infusion Pumps not for sale in the US or Canada

The Food and Drug Administration [FDA] inspected the Disetronic Infusion Pump manufacturing plant in Switzerland early in 2003 and found that it did not conform to the regulations in a number of areas. In the absence of compliance with these regulations the reliability of these pumps cannot be guaranteed which could result in the pump under or over dosing insulin infusion. As a result of this Disetronic pumps will not be sold in the US or Canada until the manufacturing processes have been improved and approval granted by the FDA. IDDT is not aware of the situation in the UK but we have received a report of the unavailability of Disetronic pumps.

Lifescan One Touch test strips

Lifescan UK has issued a warning that a ‘small’ number of people have incorrectly received the wrong OneTouch test strips from their

pharmacies. These strips have been imported to the UK and are not calibrated for the OneTouch Basic, OneTouch Profile and the OneTouch ll meters and the blood glucose readings will be significantly higher than they actually are - which could cause real problems!

The incorrect imported packs are different and on the front they contain the words '50 Test Strips, Vial Packed' whereas the correct UK packs say '50 Test Strips, Whole blood calibration'. If you are in doubt, phone OneTouch customer service on 0800 121 200.

Snippets

World record for longest trolley wait!
The world record for the longest wait on a hospital trolley was in 2001 at Princess Margaret Hospital, Swindon. Tony Collins, with diabetes and a virus infection waited 77hrs and 30min before being treated. Mr Collins later fell ill again but this time 'only' had to wait 60 hours before being treated at the same hospital.

Cinnamon
Research carried out by the American Dept of Agriculture apparently suggests that cinnamon can reduce blood glucose levels and cholesterol by up to 20%. The article suggests that a teaspoonful might help to prevent adult onset Type 2 diabetes as cinnamon appears to mimic the effects of insulin. Don't stop taking your insulin or other medications!!!! [Daily Telegraph 31.12.03]

Sage can boost memory!
The Medicinal Plant Research Centre at the universities of Newcastle and Northumbria are testing many old-fashioned claims about the healing powers of herbs and flowers. They studied 44 people who were either given sage oil tablets or a dummy pill and found that those taking sage performed much better in a word recall test. The research centre has already started a study to test sage in Alzheimer patients. Sage was first described as being 'good for the head' in 1597 by the herbalist John Gerard. [Pharmacology, Biochemistry and Behaviour,August 2003]

A glass of red wine in a pill!
Many studies have shown that a glass or two of red wine is good for health. Now scientists in Italy are developing a pill that will have all of the health benefits of a glass of red wine, but without the alcohol. Amazing! Providing people do not exceed the recommended safe limits for alcohol of 14 units a week for women and 21 units for men, why not enjoy the alcohol rather than taking yet another pill! [New Scientist, January 2004]

For low carbers!
Nimble have a new bread called Low Carbs which is 7.6gms of carbohydrate per slice. It's a bit more expensive but for those who like a sandwich, you can enjoy one and keep the carbs down.

Atkins diet, company says eat less fat
The company marketing the Atkins diet now say people should not gorge themselves on fatty foods and that the intake of saturated fats should be limited to 20% of total calorie intake. [The UK Food Standards Agency say it should be 11%.] The company maintains this is just a clarification of their position, necessary because the media and opponents of the Atkins diet have sensationalised the diet as the all-the-steak-you-can eat-diet. They rightly point out that not all fats are bad for you. [BBC News 19.1.04]

Worth Noting!

Edwin Gale, Professor of Diabetic Medicine in Bristol, writing about troglitazone, the Type 2 drug from the Avandia and Actos family that had to be withdrawn [Diabetes Digest;Vol 2 Number 4,2003] says, "Big pharmaceutical companies see clinical studies as a means of satisfying the regulators and promoting sales, not of providing

information. Published reports are not designed to help clinicians persuade us to use the new agent effectively: they are selected and slanted in such a way as to persuade us to use the new agent. Hence the huge amount of junk literature of irrelevant and badly reported studies with misleadingly optimistic titles."

Of troglitazone Professor Gale goes on to say:

"No one will ever know how many people it killed, perhaps between 200-1000, yet the culture of secrecy protected the industry from full and timely disclosures of the mounting evidence of risk??.Not one physician stood up to say that the evidence base was inadequate and that no drug for diabetes is worth dying for??..Our profession did nothing to protect the public. No one wants to remember troglitazone. It is treated as an unfortunate aberration of the system. It was not. It was a consequence of the system. Finding that out certainly changed my life."

IDDT Comments:

Nearly all Professor Gale's comments could be applied to the introduction and continued use of synthetic GM insulin! Will we ever see such honesty about synthetic GM insulins?

Your Eperiences Needed Please

One of our members who is using the low carbohydrate diet would like IDDT's Newsletter to publish other people's experiences of lowering carbohydrate, lowering insulin, numbers of injections and types of insulin used. If you would like to report your experiences, please write to Jenny Hirst, IDDT, PO Box 294, Northampton NN1 4XS or e-mail jenny@iddtinternational.org

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

IDDT
PO Box 294
Northampton
NN1 4XS

Name: ——————————————————————————

Address: ——————————————————————————

——————————————————————————

Postcode: ——————————————————————————

Tel No: ——————————————————————————

From Your Editor – Jenny Hirst

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