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Insulin Dependent Diabetes Trust

October 2006 Newsletter

More 'Human' Insulins To Go - But Does Modern Mean Best?

In August, Novo Nordisk announced yet further discontinuations of their 'human' insulin range, this time they estimate that this will affect 16,000 people. In a letter to IDDT, Novo Nordisk send their apologies for the inconvenience that it may cause people, so I pass this on to you.

Inconvenience!

'Inconvenience' is used with every discontinuation the company makes but what a word to use! It's inconvenient if I run out of milk, it's inconvenient if the postman's late delivering, it's inconvenient if my computer crashes. But *'inconvenience'* grossly underestimates what is involved for the people who are affected – looking at that remaining choices; once chosen, more blood glucose testing during the changeover period; learning about the peaks and duration of action of new insulin and how it affects you as an individual; perhaps a change in regime from two injections to four injections a day, especially with the removal of pre-mixed insulins.

Only someone without diabetes could describe changing insulin as an 'inconvenience' but as a marketing word to health professionals for Novo Nordisk's policy, it's a good word! Health professionals will be inconvenienced by having to change the insulins of 16,000 people. For people who are happy and managing their diabetes satisfactorily, any change of their insulin type is *unnecessary* - a bad marketing word, not used in relation to insulin discontinuations! It may be necessary for Novo Nordisk to maximise their profits by insulin discontinuations but for people with diabetes, such changes are unnecessary and an unwelcome disruption in their lives.

Change for commercial reasons, not clinical reasons

Yet again we are witnessing a treatment change that is being made for commercial reasons and not for clinical reasons. Yet again 16000 people are having their insulin changed not because they and their doctors have decided that it is best treatment for them but because a pharmaceutical company has decided it is in the best interests for their shareholders. It is a policy that further reduces patient, doctor and prescribing nurse choice and from this perspective, it is a policy that is indefensible. From a wider perspective and equally indefensible, it means that the pharmaceutical industry is dictating treatments - not patient need, not evidence of benefit and not doctors' experience and knowledge.

Belief is not the evidence we need

But Novo Nordisk's defence appears to be that the *'human'* insulins are being discontinued in favour of *'modern'* insulin preparations that the company *'believes'* are best for patients. Dear me – this really does insult our intelligence! Since when has 'modern' automatically meant better? The 'modern' drug for arthritis was Vioxx and how many unnecessary heart attacks and deaths did that cause? Simply calling a drug 'modern' does not mean it is the best treatment or even that it is safe – ***evidence*** of superiority and both short and long-term safety is what we need.

Novo Nordisk says that it *'believes'* that insulin analogues are best for patients but belief is not good enough – we need evidence of what is best for patients! At one time it was believed that the world was flat but the evidence proved otherwise and it is unacceptable in the 21st century the word 'belief' is applied to medicines and treatment choices! Treatment must be based on evidence of benefit, not beliefs or assumptions of benefit. To health professionals Novo Nordisk's explanation for these latest discontinuations on their website is that 'current treatment trends supported by clinical evidence indicate that analogue insulin is now a preferred option to human insulins'. But all this actually says is that analogues are prescribed more frequently but not that the evidence is that they are better than the alternatives. Indeed, even the reference the company quotes only concludes that overall control was similar in people with Type 1 and Type 2 diabetes when comparing pre-mixed analogue with premixed 'human' insulins. Note - not better, just similar. [Diabetic Med, 2002, 19, 393-399]

Further reduction of patient choice

While we cannot doubt Novo Nordisk's belief in their latest products, it is difficult to accept that they also truly believe that reducing choice is best for patients! But it appears that they do as it has been made clear to IDDT that they intend that their range of insulins will be analogues only. This means eventually all 'human' insulins will be discontinued. While this is their choice and their right, it is a policy that ignores patient need, patient choice and even patient safety. What happens to people who have adverse reactions to insulin analogues?

The easy and short-term answer for patients is to use 'human' insulin made by other companies but in the longer term, it really is not that simple. There are only 3 major suppliers of insulin in the world and all three seem to function as if joined at the hip – all going in the same direction, the analogue route. In the US, Eli Lilly, manufacturers of Humalog, discontinued some of their popular 'human' insulins last year and of course, Sanofi Aventis are heavily involved with analogue insulins, Lantus and more recently, Apidra. Novo Nordisk has the largest share of the market and clearly is confident that it can dictate what insulin people will use and remove doctors' clinical judgement and their prescribing freedom. The article in the centre pages of this Newsletter by Dr Katherine Morrison describes how she and her son manage his diabetes with a combination of all three types of insulin - if 'human' insulins are discontinued this option will be removed from them.

Will the marketing techniques work again?

Twenty years ago marketing techniques managed to sell 'human' insulins to the medical profession without any evidence of benefit, just assumptions, and 84% of the diabetic community were transferred to it for no clinical reason. And here we go again, this time the 'human' insulins that we were told were so wonderful 20 years ago, are being discontinued for 'modern' insulins, the analogues!

Have lessons been learnt? It appears not. Will the marketing techniques work again? Will Novo Nordisk's *belief* that their modern insulins are best for patients, be sufficient to sell analogues to the medical and nursing professionals who prescribe them? Being realistic, the answer is, yes probably. This time will diabetes organisations put people with diabetes first and fight for them to keep choices available, to have insulins to suit all their differing needs and to have insulins which have evidence of long-term safety? Will they stand up to defend the health and wellbeing of people who require insulin both now and in the future? IDDT will. IDDT has always believed that people should have the insulin that suits them best and to achieve this, 'human', analogues and animal insulins must remain available and we cannot allow the power and influence of the pharmaceutical industry to dictate our treatment.

Doing nothing is not an option and IDDT welcomes the support of anyone who wishes to add weight to our call for insulin treatment to be prescribed by health professionals in conjunction with patients and not dictated by industry.

So Which Insulins Are Going This Time and When?

Novo Nordisk has stated that the following 'human' insulins are to be discontinued and will not be available after December 2007 [and they could run out before]:

- Mixtard 10 3ml penfill cartridges
- Mixtard 20 3ml penfill cartridges
- Mixtard 40 3ml penfill cartridges
- Mixtard 50 3ml penfill cartridges
- Velosulin 10ml vial

There is no direct equivalent to these insulins and Novo Nordisk advise that the following are the closest available insulin options:

Novo Nordisk alternative products

- MovoMix 30 Flexpen - analogue
- NovoMix 30 Penfill - analogue
- Mixtard 30 Penfill - 'human'

Non Novo Nordisk alternative products

- Humulin M3 [Lilly] - 'human'
- Humalog Mix 25 [Lilly] - analogue
- Insuman Comb 15, 25 or 50 [Sanofi-Aventis] - 'human'
- Hypurin Porcine 30/70 Mix [Wockhardt] - animal

But some are not that close an alternative, so which one do you choose?
Your health professional will have a support package from Novo Nordisk which includes estimated numbers of people in each area affected by this discontinuation, a standard letter to be sent to these patients and all the above information. Health professionals should also have a copy of MIMs that clearly shows the actions of all insulins - the peaks and duration of action and these can be compared with the insulins that are being discontinued. It shows the following:

- Humalog Mix 25 and NovoMix 30 both have a peak of action that starts much sooner and lasts for a significantly shorter time.
- The peak of action of Humulin 3 starts much sooner and lasts longer.
- The peaks of action of all the Insuman Comb insulins are much shorter than the Mixtard insulins being discontinued.
- Mixtard 30 [human] and Hypurin Porcine 30/70 have the nearest and very similar action profiles both in term of duration and peak of action.

So if the latest discontinuations affect you, then your health professional should give you all this information to provide you with an

informed choice of insulins so discuss your options with your health professional and decide on the best insulins for you.

Availability Of Diabetes Products

Finding products to help you manage your diabetes can seem like a search for a needle in a haystack! Medical Shop is a Mail Order service - you can buy products to help manage your diabetes as well as travel products and other health products.

Products include lancing devices, First Aid kits, small sharps bins, skin care products, pill containers cases and cool wallets for carrying diabetes supplies and more…

A Free copy of their catalogue is available or orders can be placed by telephone, by mail order, or online:

Freephone 0800 731 6959, Medical Shop, Freepost OF1727, Woodstock, Oxon, OX20 1BR. Website www.medicalshop.co.uk

"My Clinic is Refusing To Allow Me To Try Animal Insulin"

What does NICE say?
This is something we hear all too often on the IDDT phone line! Don't misunderstand, we want to hear from you but it is the statement itself that we wish we didn't hear. As we know, there are no good reasons for refusing animal insulin but there are wider implications. Firstly, the clinic is not following the National Institute for Health and Clinical Excellence [NICE] guidance on patient education [implementation Jan 2006] which entitles you to an informed choice of insulin. Secondly and perhaps more importantly, there are no NICE guidelines that recommend any particular type of insulin for people with Type 1 or Type 2 diabetes which of course means that there are no NICE guidelines that say animal insulin should not be used!

NICE guidelines for Type 1 diabetes state:

Prescribe the type of insulin that allow people optimum well-being.

- Use multiple insulin injection regimens in adults who prefer them in an integrated package with education, food, skills training and appropriate self-monitoring.
- Advise twice daily insulin regimens [often bi-phasic pre-mixes: analogues in those prone hypoglycaemia at night] for those who want them, who find adherence to lunchtime insulin injections difficult, those with learning difficulties who may require assistance.

NICE guidelines for Type 2 diabetes state:
Insulin maybe used to help control your blood glucose level if other medicines have not brought your HbA1c down to your target. Your doctor will talk to you about the different types of insulin that are available and when they should be taken so that you can agree on the one that will suit you best.

Are there guidelines that say that animal insulins should not be used? NO!
In fact, NICE guidelines do not make any specific recommendations about the type of insulin to be used. Indeed, NICE clearly emphasises that the needs and wishes of the patient with the use of phrases such as *'in adults who prefer them', 'for those who want them' and 'so that you can agree on the one that will suit you best'.*

Nowhere does NICE state that animal insulin should not be used. The only insulins to which that NICE says NO are long-acting insulin analogues in people with Type 2 diabetes, except under special circumstances.

What can we conclude?

- The key recommendation is that the insulin used should be the ones that will allow patients the optimum 'well-being'. The dictionary definition of well-being is "a contented state". So for whatever reason, if you are more 'content' using animal insulin, then you will be using the insulin that provides you with optimum well-being!
- NICE guidelines do not make any specific recommendations about the type of insulin to be used.
- NICE emphasise the importance of the needs and wishes of patients.

So it does seem that if your clinic is refusing to prescribe animal insulin, then the clinic is NOT following NICE Guidelines and you can use this to argue your case.

Hand Luggage - Update August 2006

As a result of recent events hand luggage on aircraft is restricted to a bag the size of a lap top and the rules for medications have been tightened. At the time of writing the position is as follows.

The advice for the UK is a bit 'iffy' but we have gathered what we can:

- Carry a letter from your GP explaining that insulin, syringes, pens and needles are essential for the journey and must not be separated from you.
- Speak to the supervisor at the check-in desk and explain the situation and also explain to the cabin crew that your diabetes supplies must stay with you on the journey.
- All diabetes equipment should be placed in a plastic bag.
- Up to 50mls of insulin is allowed on board a plane.

Warning!
The Dept of Transport is advising that if more insulin is required, then it should be packed in the suitcase that goes in the hold. However, as readers will know, we have always been told that insulin should NOT go in the hold because of the risk of it freezing. Freezing insulin makes it inactive and it would then have little or no effect on blood sugars. This issue was highlighted by someone with diabetes in the Birmingham Mail [17.8.06] and the Dept of Transport said that this matter had not been raised with them but they would now be seeking advice. In the meantime, the airline gave special dispensation for all her insulin to be onboard the aircraft.

Additional advice from the American Transport Security Administration [TSA] and issued by the American Diabetes Association is well worth following:

- Insulin and insulin loaded dispensing products should be clearly identified and labelled. In other words keep your insulin in the packet with your name and details on it, even if the vial/cartridge is in-use.
- Glucagon emergency kit should be clearly identified and labelled.

And for pump wearers
Although insulin pump manufacturers indicate that pumps can safely go through airport security systems, pump wearers may request a visual inspection rather than walking through the metal detector or being hand-wanded. Note that this may subject you to closer scrutiny or a "pat-down."

- Advise the screener that the insulin pump cannot be removed because it is connected to a catheter inserted under your skin.
- Insulin pumps and supplies must be accompanied by insulin with a label clearly identifying the medication.

Note: Any medication and/or associated supplies that cannot be cleared visually must be submitted for x-ray screening. If you refuse, you will not be permitted to carry your medications and related supplies into the sterile area.

IDDT Goes To Westminster

Thanks to your help and that of your MPs, Parliamentary Questions were asked up to the summer recess of Parliament all relating to the need for an insulin strategy that ensures that choice of insulins remains available with special reference to animal insulins. These have been answered by Minister of Health, Andy Burnham MP.

Update:
Second supplier - following the meeting at the Dept of Health in May, it is now in the public domain that Wockhardt is looking to pass its technology for manufacturing animal insulins to another company and they have expanded their production facilities. So it seems that the contingency plans that we have been requesting are likely to be put into place so in the event of production/supply problems at their UK plant, there will still be a second supplier.

Patients having a fully informed choice of all insulins – we know that this does not really happen and so a Parliamentary Question asked what plans the Minister has to ensure that diabetes patients receive a fully informed choice of all available insulins and their risks and benefits, despite the absence of NICE guidelines.

The Minister's answer is significant in particular: 'from January 2006, NICE has required all primary care trusts to implement NICE guidance on patient education by providing all people with diabetes with high quality, structured education which should include information on insulin use.'

Referring all insulins to NICE - IDDT believes that all insulins should be referred to the National Institute for Clinical Excellence [NICE] for guidance on their clinical effectiveness and their cost effectiveness with a view to developing standard guidance regarding their comparative safety, efficacy and cost effectiveness. However, the Minister has continually refused to do this and a further Question asked on what grounds the Minister made this refusal. His answer is significant as it once more publicly emphasises that synthetic human insulins have no advantages over animal insulins and that patients have the right to be involved in decisions about their insulin options.

'NICE's clinical guidance on the management of both type 1 and type 2 diabetes conclude that the majority of studies indicate that both human and animal insulins are equally effective and report no significant differences in hypoglycaemic episodes and glycaemic control between insulin of human and animal structures.

I understand that the choice of insulin is influenced by other factors such as delivery systems and cultural preferences, and so the decision to use one or other of the insulin types rests entirely with the physician in consultation with the patient.'

All Party Parliamentary Group for Diabetes [APPG] - while the above answer is significant, without NICE involvement there is still no guidance or assessment of the various insulins, so we have to pursue this. Thanks to the help and support of Philip Dunne MP, IDDT was invited to make a presentation to the APPG to present the case for NICE guidance on all insulins. Following the presentation and various questions, the APPG agreed to support our request and follow this up with the Minister. IDDT prepared a paper for NICE and we are waiting for news on this.

Carcinogenic potential of insulin analogues - a Parliamentary Question asked what action the Dept of Health has taken following the European Agency for the Evaluation of Medicinal Products [EMEA] recommendations regarding further investigation of the carcinogenic potential of insulin analogues. The answer was unsatisfactory - the Medicines and Healthcare products Regulatory Agency [MHRA] continually monitor the safety of human analogue insulin and the MHRA have not requested pre-clinical studies specifically on this issue. This answer fails to recognise it is further pre-clinical research that is needed as recognised by the European Agency [EMEA]. MHRA standard monitoring of adverse reactions will not pick up possible tumours at this stage because they take years to develop.

So what's in the pipeline?
During the summer we have been assessing our strategy, especially in view of Novo Nordisk's intention of reducing insulin choices even further with the eventual aim of only analogue insulins being available. As this decision affects people with diabetes globally, we are meeting with colleagues from other countries to discuss a joint strategy to protect the health and interests of people with insulin-requiring diabetes.

We are still hoping for an Adjournment debate in the House of Commons and thank David Amess MP for his support with this. Following the Earl Howe's meeting with the Minister on our behalf, he received a written response and we shall be discussing with him further steps that we can take.

We are planning an Early Day Motion [EDM]. EDMs are a little strange because they ask MPs to sign to show their support for a motion but there is no obligation on the part of government to act on this. Nevertheless, EDMs with lots of MPs' signatures are an indication of strength of feeling, so we will be asking for your help with this in the coming months. No longer is this an issue that just affects people who need animal insulin but all those who want choice of insulins to remain available.

For Readers In Australia

On August 25th Australian Health Minister, Tony Abbott announced that following a recommendation by the Pharmaceutical Benefits Advisory Committee [PBAC], long-acting insulins, Lantus and Levemir will be subsidised from October 1st for treatment of Type 1 and Type 2 at a cost of $145million [over £58million] during the next 3 years. Reports describe the negotiations to achieve this as 'protracted and difficult'.

About 210,000 Australians will qualify for these insulins and the government expects about 110,000 to use them in the first year with a rise to 160,000 by 2009. The subsidised cost to patients is expected to be $9.40 for concession card holders and $59 for non-concessional patients for a years supply.

Well Worth A Read...

TESTING TREATMENTS Better Research for Better Healthcare

Imogen Evans, Hazel Thornton and Iain Chalmers
In out Newsletters we frequently talk about looking at evidence to support treatment decisions, such as a change of insulin and how often have I said that GM 'human' insulin was introduced as first line treatment on assumptions of benefit and not on evidence of benefit? 'Testing Treatments' is a book well worth reading and makes what could be a complicated subject easy to read and easy to understand for patients as well as for doctors and health professionals. As Nick Ross says in the foreword, *'Once you have read this book you will never feel quite the same about your doctor's advice again'.*

The book demonstrates the uncertainties about the effects of treatment - how two doctors can give opposing advice for the same condition and highlights the need for rigorous testing of treatments in order to ensure that we, the patients, receive treatments and interventions based on available evidence.

While the book points out that many medical practitioners are sincere and skilful, they are not always aware of what makes good scientific evidence and their treatment recommendations may be based on what they were taught at medical school, what other doctors do or what has worked in their experience. The book points out that this can be very misleading and ultimately harmful. Nevertheless the book does not disparage doctors or modern medicine but aims to encourage better

research, more informed decision-making and therefore healthcare.

It is well worth obtaining a copy: Testing Treatments, Better Research for Better Healthcare is published by the British Library, ISBN 0 712 3 4909

Very different books but useful to dip into…

Diabetes for Dummies
Dr Sarah Jarvis and Alan L Rubin, MD

Like all the Dummie books, this is a book for beginners, those who are new to diabetes who will come across many questions as they learn to live with their condition. It is useful to have around to dip into when these questions arise.

Published by Wiley, ISBN 0-7645-7036-6

The GL Diet for Dummies
Nigel Denby and Sue Baic

GL stands for Glycaemic Load and again this book is one to dip into, it helps to provide a better understanding of what many of us have come to know as the glycaemic index of foods. It is not specifically for people with diabetes but provides useful information and recipes.

Published by Wiley, ISBN 0-470-02753-3

And Well Worth A Watch...

Philip Johnston of The Small Video Company has produced a range of DVDs about various aspects of diabetes. The DVDs were produced with the help and advice of doctors and so are reliable educational sources of information that can be watched and re-watched as the need arises.

The DVDs are as follows:

- **Childhood Diabetes 60mins** - for the family or carer of a child with Type 1 diabetes. Produced with Dr Kenneth Robertson, Dr Louise Bath and Dr John Schulga.
- **Teenage Diabetes 60mins** - for teenagers with diabetes covering topics like blood glucose monitoring, hypos, drinking, smoking, exercise. Produced with Dr Mike Small and Dr Kenneth Robertson.
- **Pregnancy and Diabetes 42mins** - a teaching aid for women with Type 1 diabetes who are planning to have a baby or are in early pregnancy. Produced with Dr Donald Pearson , Dr Judith Steel and Dr Mike Small.
- **From Pills to insulin 42mins**- a positive outlook for people with Type 2 who have to go through the progression from pills to insulin. Produced with Dr Chris Kelly and Dr Andrew Gallagher.
- **Type 2 Diabetes** - The No Nonsense Guide 73mins - for people with Type 2 diabetes, especially those who are newly diagnosed in primary care, their family and carers. It also has a 43minute bonus feature containing 6 mini features ranging from ‘Foot care’ to ‘Holidays’. Produced with Dr Ann Gold, Dr John Knight and Dr Andrew Collier.

The DVDs normally cost £10.00 each including delivery for orders in the UK but there is a £1.00 discount if you order as a result of reading this. So mention IDDT when ordering and the price to you will be £9.00. The DVDs are available from: Philip Johnston, The Small Video Co Ltd, 19 Broomieknowe Gardens, Glasgow G73 3QA, Tel 0141 647 4857 e-mail smallvideo@mac.com or visit the website www.diabetesdvd.co.uk Payment can be by cheque or credit card.

[Further discounts are available to health professionals for the use in diabetes clinics, if they mention that they heard about the DVDs through IDDT’s Newsletter]

Research News

'Human' insulin molecule produced in safflower
A Canadian company has achieved 1% insulin accumulation in safflower which is a commercially viable level. It means that they can produce over one kilogram of insulin per acre of safflower production - enough to supply 2,500 people for a year. The company, SemBioSys Genetics, believe that they could supply the world's total projected insulin demand in 2010 with less than 16,000 acres of crop production. They plan to scale up production for sufficient insulin to start clinical trials.

Marijuana Compound May Help Stop Diabetic Retinopathy
Researchers are studying a compound found in marijuana, cannabidiol, because there are indications that it may protect the eye from growing new leaky blood vessels - one of the main problems with diabetic retinopathy. They are looking at the role of cannabinoid receptors in the body and trying to modulate them so they can defend the eye against diabetic retinopathy by intervening early in the process of the development of retinopathy. [American Journal of Pathology, January 2006]

Insulin itself may be the trigger for Type 1 diabetes – research from two teams suggests that insulin itself may be the trigger that actually causes Type 1 diabetes. One team cloned immune cells from people with Type 1 diabetes and healthy people and discovered that the cells from the people with diabetes reacted to insulin but those from the healthy people didn't. The second team genetically engineered mice so they lacked normal insulin but still had a form of insulin hormone that is not recognised by immune cells. None of the mice with the modified insulin developed diabetes. The researchers say that if these results can be confirmed, it could be that insulin is the driving force behind Type 1 diabetes and the next step would then be to test the hormone to see if it can be manipulated to prevent the condition.

We now have diabetes Type 1.5!
This is a new term used to describe a group of people who have diabetes but do not seem to fit into either Type 1 or Type 2 diabetes. In this group of people there does not seem to any evidence of autoimmunity as there is in Type 1 diabetes when the body's own immune system kills off the insulin producing cells. Equally, there does not seem to be any evidence of insulin resistance as seen in Type 2 diabetes. Usually this group have good control by using medications that increase insulin secretion but do not respond to those that improve insulin resistance such as metformin or the glitazones [Actos and Avandia]. After some years they may require insulin injections.

Tighter Targets - Can We Do It? Yes We Can!

By Dr Katherine Morrison

So we are being set tighter targets for diabetes [IDDT Newsletter July 2006]. This is not likely to be achievable by people with diabetes who stick to the advice given to them in hospital clinics across the land. In a recent article in the BMJ [ref1], only 37% of pregnant women had an HbA1c of less than 7% at 13 weeks of pregnancy.

Pregnant women run very high risks for themselves and their babies if they have high blood sugars, Extensive pre-natal and peri-natal counselling and dietary advice is given to this group, yet this most highly motivated group is not getting anything like normal blood sugars.

Many people who read this Newsletter know that they can achieve very good blood sugar results and a major reason for this is that they never abandoned their low or restricted carbohydrate diets in favour of the more popular high carbohydrate, low fat diet.

If 50% of NHS dieticians are not happy about their own knowledge of carb-counting, how do they expect patients to do it? Certainly in my own area carb-counting is simply not on the agenda whatsoever, even

for people who are insulin dependent. In her article I was struck to see Jenny's simply suggestion that an egg-sized portion of mashed potato amounted to 10g of carbohydrate. This is the sort of eyeball technique tip which I suspect is almost second nature to more experienced people who have had diabetes for many years. It concerns me that this expertise could be lost if we do not record these sorts of tips for posterity.

The NHS is not going to educate the newly diagnosed on carb-counting for the foreseeable future, but can you realistically match insulin to carbohydrate intake when you haven't got a good idea how much carbohydrate is in the food you intend to eat? I have struggled with various techniques to estimate carbs. Reading labels, weighing food, using carb factors, using nutritional scales have all been helpful but when you go into a restaurant, you really just have to guess. This Newsletter is in electronic format on the web and could be accessible for many years to come by people newly diagnosed with diabetes who would value your help. I would therefore wish to ask readers to please put pen to paper or phone in and give us some of your tips.

From my previous article you may know that my son Steven is a teenager with Type 1 diabetes. I found that initially keeping 100g of carbohydrate or less a day gave him excellent blood sugars with an HbA1c of around 5.0%. Now he has come out of the honeymoon phase and is also undergoing a growth spurt he is needing extra carbohydrate and insulin to keep up. We also cannot fully compensate for the dawn phenomenon [highs in the morning]. Currently his HbA1c, some 3 months after starting a 100-200g carb diet, is 6.0% but this has been at the expense of blood sugar swings. We reach target blood sugars about 60% of the time but he has hypos [below4] about 10% of the time and high blood sugars [over 8] 30% of the time. These figures include post-prandial [after meal] peaks and delayed sugar rises which can often be due to protein or higher fat content with higher carb meals.

In order to attempt to get some control over this I have come up with some tips of my own which I am happy to share. I also hope there will be more contributions from readers.

Insulin Tips

Tip 1: Steven takes Levemir [long-acting analogue] as a basal insulin but during the summer we found that he had to have less in the morning than at night because of inexplicable afternoon hypos. [Jenny's comment after 30 years: maybe the hypos aren't that inexplicable - hot weather causes hypos and may be extra exercise.]

Tip 2: We found that 3am is a good time for checking basal insulin night levels provided that Steven has gone to bed with a normal blood sugar, hasn't had a bedtime snack and is not unwell or has taken unusual exercise that day.

Tip 3: We find that Actrapid is an excellent insulin to cover high-protein and high-fat meals. At the current time the only availability in cartridge form is Wockhardt's pork or bovine Neutral insulin but it is a pity that this is not available in half-unit pens. [I have stockpiled a large supply of Actrapid and will simply have to keep an eye on its potency]. Actrapid is also very helpful given in the mornings not only to cover a high protein breakfast, but also to deal with the dawn phenomenon and insulin resistance which is definitely more active in the morning for most people with diabetes.

Tip 4: To cover meals with high protein content, 2 units of Actrapid per deck of cards size of meat works well to reduce delayed blood sugar rises.

Tip 5: NovoRapid [analogue] works quickly and is good for correction doses if blood sugars are high and also for higher carb meals, such as when at a restaurant.

Tip 6: After school we have added exercise as an alternative to insulin injections for correction of high sugars. We've got a rowing machine and it is very surprising how little you have to do to bring sugars down abruptly with this, much more rapidly than with insulin - a cycle ride is

also effective.

Tip 7: Because Steven's bedtime snack is at 9.00pm we tend to give NovoRapid with his evening meal so that there is enough time for the insulin to be spent before any other insulins injections are given. For Actrapid he needs a 5 hour interval if possible but this is not always achievable.

Tip 8: In order to prevent any spiking of blood sugars at all after meals, Dr Richard Bernstein has worked out that 12g of slow-acting carbohydrate is the most that can be consumed with each meal but this can be too restrictive for many people. From experimentation I have found that carbohydrate:insulin ratios seem to work out reasonably steadily up to 30g of carb but after 30g blood sugars after meals tend to be much higher than expected and I found that we need to add an extra 0.5 units for every 10g of carbs up to 80g. After 60g results are getting a bit unpredictable and really after 80g results become so increasingly unpredictable that I don't recommend going over that in one meal. This is of course, perfectly adequate for even the fussiest of eaters. I call this tip "weighting" the insulin.

Tip 9: Steven has a survival pack which he takes to school with him everyday containing: his insulin pens, mobile phone, money, carb-count list, pastilles to cover exercise, glucose for hypos, spare needles and his glucose monitor, Freestyle to school because its smaller.

Tip 10: Because I am worried about night-time hypos , which indeed he has never had, we go easy on the insulin and give him only 2/3 of the estimated dose prior to bed time. Because I am not adequately covering the insulin we stick to 35g or less at bedtime, with most of the time any bedtime snacks being considerably less than this. I try to get a good amount of fat and protein into him at this time too as this slows down the absorption rate of the carbohydrate making it last longer.

Tip 11: Whenever possible we wait for the insulin to act before eating, 15minutes for NovoRapid and 45 minutes for Actrapid. These times can be extended to drop the blood sugars if blood sugars are unusually high. The combination of "waiting" and "weighting" seems to work well. Use the right insulin for the meal. Wait for the insulin to work. Wait for the blood sugar to drop. Weight the insulin according to the carb content of the meal.

If you have any tips that you would like to share, especially those from the good old days, then call Jenny at IDDT on 01604 622837 or write to her at IDDT, PO Box 294, Northampton NN1 4XS.

Ref 1 Peri-natal mortality and congenita; anomalies in babies of women with Type 1 or Type 2 diabetes in England, Wales and Northern Ireland. Mary C M McIntosh et al, BMJ 22 July 2006.

Test your knowledge and learn some carbohydrate values…

1. A normal blood sugar before meals is:

(a) 15
(b) 10
(c) 4.7
(d) 2.5

2. A normal blood sugar 2 hours after meals is:

(a) 20
(b) 10
(c) 8
(d) 6

3. Your blood sugar is starting to be too low when it is:

(a) 1.9
(b) 2.9
(c) 3.9
(d) 4.9

4. The Dawn phenomenon affects teenagers [and others] and:

(a) Makes their blood sugars particularly high when they wake up
(b) Makes them sleepy and unable to get up in the morning
(c) Makes their breakfast digest more slowly than usual
(d) Makes the gut release glucagon

5. If your blood sugar is unexpectedly high:

(a) You could have an infection brewing somewhere
(b) You have been drinking too much diet fizzy drinks
(c) You could have given yourself too much insulin at the last injection
(d) You may have eaten too little carbohydrate with your last meal

6. 12g of carbohydrate is present in all of these except:

(a) One thin slice of bread
(b) One cup of broccoli
(c) One cup of rice
(d) Half a grapefruit

7. 15g of carbohydrate is present in all of these except:

(a) Half a cup of beans
(b) Half a cup of cereal
(c) Half a medium roll
(d) One hamburger bun

8. 15g of carbohydrate is present in all of these except:

(a) One large banana
(b) One medium apple
(c) 3 pear halves in juice
(d) 3 medium satsumas

Answers
1 (c), 2 (d), 3 (c), 4 (c), 5 (a), 6 (a), 7 (c), 8 (d), 9 (a)

Analogues - The Evidence

Germany - Short-Acting Analogues Are Not To Be Funded For Type 2 Diabetes

Recommendations have been made to the Ministry of Health in Germany that health insurers [thus the taxpayer] should only be obliged to pay for short-acting analogue insulins for people with Type 2 diabetes in the event that they are no more expensive than human insulin. And they are not! The decision was based on whether the use of an analogue insulin would result in an additional benefit for the patient that would justify its additional cost and to date the pharmaceutical industry has been unable to demonstrate such a benefit. The majority of people with Type 2 diabetes can be treated perfectly adequately with the cheaper human insulins. [There are some exceptions to this recommendation such as those who are allergic to human insulins.]

Report from the Institute for Quality and Efficiency in Health Care [IQWIG]

This organisation is Germany's equivalent to NICE in the UK and its final report on the use of rapid-acting analogues for the treatment of Type 2 diabetes resulted in the above recommendations. The Report concludes that:

"For patient relevant outcomes, there is no convincing evidence of a superiority of rapid-acting insulin analogues compared to regular human insulin [short-acting] in diabetes mellitus type 2 therapy. Rapid acting insulin analogues have not been sufficiently investigated with regard to their potential long-term beneficial and harmful effects."

The key points in the Report summary are:

- No relevant and fully published study was found on insulin aspart [NovoRapid] only an abstract in 1999 and Novo Nordisk was not prepared to provide study data if these data were to be published in this report. No relevant studies were found on pre-mixed

formulations of rapid-acting insulin analogues or short-acting human insulin combined with longer-acting insulins. [Important lack of research considering Novo Nordisk's removal of pre-mixed human insulins in the UK!]

- None of the studies were designed to investigate the effect of rapid-acting insulin analogues on the reduction of diabetic complications or total mortality.
- For hypoglycaemia, no clear advantage was shown with analogues compared to human insulin with regard to severe, symptomatic or nocturnal hypoglycaemia.
- Quality of life studies were limited but no clear advantage was shown with analogues compared to human insulin and no definite conclusions could be drawn about patient satisfaction as the studies were unsatisfactory.
- There was a tendency towards more people dropping out of the studies due to adverse reactions in those treated with analogues compared with those on human insulin.
- In so far as reported, there were similar weight increases for both patients receiving analogues and those receiving human insulin.
- As the maximum study period was 12months, no studies could show the safety of long-term use of analogues in people with Type 2 diabetes. Unless proved otherwise by adequately designed studies, the potential for mitogenic potency of insulin analogues [cell mutiplication and formation of tumours] as described in pre-clinical trials, is to be seen as a potential safety risk for long-term treatment of people with Type 2 diabetes.

The full report is available in English online at:

http://www.iqwig.de/index.media.538df941a1d274bea0b8b1f9ae06921b.pdf.

Note: Later this year and early next year IQWIG is to produce Reports for [i] short-acting analogues for Type 1 diabetes [ii] long-acting analogues for Type 1 and [iii] long-acting analogues in Type 2 diabetes.

So where is the UK in all this?
As readers know, IDDT has have requested that NICE assesses all insulins and issues guidance on their use as part of our lobbying campaign to ensure that animal insulins remain available and people with diabetes have an informed choice of ALL insulins. However, the UK Minister of Health has so far refused to do this and without any satisfactory explanation. Clearly Germany is doing it, so why aren't we?

IDDT is mainly concerned about the unproven long-term safety of insulin analogues but we are also concerned about the significant extra expense to the NHS [again the taxpayer], especially as the evidence suggests little benefit for the majority of people. The German Reports may well not affect UK Dept of Health attitudes, but at least we, as patients and carers, can have the benefit of their work to help inform our treatment decisions. UK doctors and health professionals can also benefit from the evidence provided by the German Report. In the absence of appropriate reports in the UK to protect patient safety, and taxpayer interests, we must all be grateful for the work being carried out in Germany.

Latest Research On Analogues And Long-Term Safety

A Danish study [ref 1] involving patients with type 1 diabetes acknowledges that diabetic patients are at higher risk of cancer than the non-diabetic population. It also states that it is still unknown whether lifelong treatment with the analogue, NovoRapid, will lead to an elevated IGF-1-like bioactivity and subsequent mitogenic potency, especially in a subgroup of patients who have high levels of insulin antibodies.

- The question of carcinogenicity of insulin and insulin derivatives is of growing relevance, because it is increasingly recognised that

insulin is a growth promoting hormone, and is associated with colorectal cancer [ref 2]. Furthermore, it is becoming increasingly clear that there exists a genetic predisposition for carcinoma development, which is likely to be linked to the insulin/insulin-like growth factor system. People with such a genetic background may be particularly harmed by compounds like insulin analogues, the carcinogenic properties of which are unknown.

- Recent research presented at the American Diabetes Association Conference [ref 13] has shown that all insulin analogues tested were more mitogenic than insulin [caused cell proliferation that can lead to benign or non-benign tumours]. It also showed that this mitogenic effect was greater in cells from patients with a high IGF-1 receptor system expression putting such patients at greater risk than those with a low IGF-1 receptor system expression.

Ref 1. Chen J W, Frystyk J, Lauritzen, Christiansen J S. Impact of insuin antibodies on insulin asoart pharmackinetics and pharmacdynamics after 12-week treatment with multi daily injections of biphasic insulin aspart 30 in patients with type 1 diabetes. European Journal of Endocrinology [2005]; 153: 907-913

Ref 2. Yang YX,Hennessy S, Lewis JD.Insulin therapy and colorectal cancer risk among type 2 diabetes mellitus patients. Gastroenterology 2004;127:1044-1050

Ref 3. Kristian Eckardt, Claudia May, Marlis Koenen, Juergen Eckel

Enhanced Mitogenic Potency of Insulin Analogs in Human Fibroplasts and Smooth Muscle Cells is mediated by IGF-I Receptor Signaling Diabetes, June 2006 Vol 55 Suppl 1 463-P

How Can The Experts Come To Such Different Conclusions Using The Same Evidence?

I crave you indulgence here for a little musing but I can't help but wonder what is going on. You see when high quality reviews or reports on the evidence of benefit of drugs are carried out for organisations such as NICE in the UK, IQWIG in Germany and CEDAC in Canada, searches of all the studies carried out throughout the world are made. It is the close examination of these studies that produces the evidence on a particular drug or treatment. Of course the results can vary from clear evidence of benefit, lack of evidence of benefit to evidence of harmful effects but the main point seems to me is that searches are carried out to find all the studies, therefore one would be expecting the experts to be looking at the same evidence, so why do we have different conclusions?

Bee in my bonnet, yes but let's just take a look at the analogue insulins:

- CEDAC in Canada is not recommending funding for Lantus for either Type 1 or Type 2 diabetes for lack of evidence of benefit for high costs but NICE in the UK does recommend it for Type 1 but not Type 2 diabetes and neither Canada or the UK have reported on the use of Levemir, so is it recommended or not?. Australia is recommending both Lantus and Levemir for Type 1 and Type 2 diabetes. Germany has yet to report on both and the FDA in US just seems to give market approval and doesn't look any further!
- In terms of short-acting analogues, Germany is not recommending them for Type 2 diabetes and has yet to report on them for Type 1 diabetes. NICE in the UK hasn't looked and the FDA in US just seems to give market approval and doesn't look any further! The Cochrane Review says they have little benefit for the majority of patients.
- The International Diabetes Federation Position statement, with the world's experts involved, says that analogues offer potential advantages but they have not been proven to deliver real long-term benefits safely and affordably.

The only conclusions that are common to all are [i] that the long-term safety of analogues is unknown and [ii] concerns about their potential for carcinogenic effects.

I don't claim to be brain of Britain but I feel as if I am missing something here. Why do some countries feel there is a necessity to assess all the analogue insulins for clinical effectiveness, safety and costs, while others, such as the UK, don't?
How can experts in different countries look at what should be the same evidence and come to different conclusions and recommendations? Do the experts assessing the research and making recommendations to their governments have a range of skills, some good and some not so good? If this is not the reason, then one has to ask what the other reasons could be? Is there influence of some sort.....?

My final musing of the month is wondering just what would drug companies do if all countries came to Germany's conclusions of not funding short-acting analogues for people with Type 2 diabetes or indeed, Canada's conclusions of not funding long-acting analogues in both Type 1 and Type 2 diabetes? Would the price come down, would the companies' share prices fall or would they just remove all other types of insulin to force the use of analogues????? But more worryingly, what would happen if the necessary research was carried out and it confirmed the fears of the carcinogenic potential of analogues?

Exercise And Lantus - To Change Dose Or Not?

Some research really does make you wonder!
Research [Diabetes Care, March 2005] suggests that exercise does not appear to increase the rate of absorption of Lantus [glargine], the long-acting insulin analogue. So the authors suggest that Lantus can be safely and effectively administered without a dose change during exercise but then they go on to note that the study does not rule out the possibility of late exercise-induced hypoglycaemia and "Lantus reduction may be warranted depending on individual patient responses." They caution against over interpreting these results saying that real-world exercise or activity may have different effects on the absorption of Lantus.

So what does this really tell us of value? Not very much but even less when you find that the research was carried out in only 13 people. First the researchers conclude that [i] exercise does not require a dose adjustment with Lantus, but some people might and then [ii] we should be cautious over-interpreting these findings! In other words perhaps we shouldn't take any notice at all! Why does anyone even consider carrying out a study in only 13 people when the insulin under investigation is used by thousands of different people of different ages and health status and different insulin regimes? And why is it published?

Lantus - The Once Daily Insulin, But Is It Really?

It was someone in the US who first reported to IDDT that Lantus [glargine] really only worked for him if he used it twice daily, so why should he use it at all as he was happy with his previous twice daily insulin that was much cheaper! As he pointed out the whole selling point of Lantus is once daily injection. Recent UK research in unselected people with Type 1 diabetes has compared Lantus with NovoRapid at meals given once or twice daily. [Diabet Med 2006 Aug;23(8):879-86]

The results were interesting:

- HBA1cs and pre-breakfast blood glucose levels were no different between once and twice daily Lantus.
- Blood glucose levels after breakfast, after lunch and before dinner were lower with twice daily compared with once daily dinner time Lantus.

- 24hour average blood glucose levels were lower with twice daily Lantus as was within day variability of blood glucose levels.

The researchers concluded: that in some people with Type 1 diabetes blood glucose levels rise in the late afternoon due to falling insulin levels towards the end of the 24hour period after injecting Lantus once a day at dinner time. This can be prevented by twice daily injections of Lantus.

This gives rise to several questions:
Why change to Lantus if it loses its main attraction of being a once daily injection? Is the action of Lantus really flat and peakless? If so, why do blood glucose levels rise towards the end of the 24hour period after injecting?

Pregnancy And Diabetes

'Together We Care' - IDDT partners the Royal College of Midwives

The Royal College of Midwives [RCM] has produced the second edition of 'Together We Care' - a publication that offers reassurance and advice to pregnant women. It also contains the latest information about current practices of early parenting to help new parents make the best decisions for them and their baby.

IDDT was invited to be a partner in this project as the RCM believe that it is important that mums-to-be have someone they can talk to for support on specific concerns such as diabetes. Pregnant women with diabetes need a lot of care as do those with gestational diabetes, estimated to occur in between 3 and 5% of all pregnant women.

The book will be given free to every expectant mum in the UK by their midwife and it can also be ordered from the website www.togetherwecare.co.uk

IDDT Pregnancy Information Pack

IDDT has prepared a Pregnancy Pack which contains the following information specially for pregnant women and their partners and we are also happy to supply it to healthcare professionals. The Pack contains:

- IDDT leaflet 'Pregnancy and Diabetes' which has recently been updated
- A new leaflet 'Gestational Diabetes'
- An Information Sheet on the 'The use of insulin during pregnancy'. This is a gathering of information from the Specific Product Characteristic [SPC] documents of insulins that provides details of which insulins can safely be used during pregnancy. For example, trials of some insulins have not been carried in pregnant women, or only limited trials have been carried out. This is important so that women have an informed choice of insulin during this very important time for them and their baby. [SPCs published when drugs are approved by the MHRA.]

If you would like a FREE IDDT Pregnancy Pack or leaflets, just call IDDT on 01604 622837, e-mail enquiries@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS

Winter Coming - Flu Or A Cold?

Colds and flu are both caused by viruses and many of the symptoms are the same and so it can be difficult to tell the difference between the two.

Colds - there are more that 200 viruses that can cause colds and most of them cause mild infections. You cannot get a cold from being out in cold weather or getting physically cold but stress may make you more prone to getting a cold. Cold symptoms usually start 2 to 3 days

after being infected.

Flu - there are 3 families of flu viruses. The symptoms start 1 to 4 days after being infected and it can be passed to others before you realise you have it.

Difference in symptoms - we are all aware of the symptoms of colds and while some of these are similar to flu, there are symptoms which distinguish a cold from flu:

- fever,
- headaches,
- aches and pains
- extreme exhaustion
- there can be diarrhoea and vomiting, especially in children.

Flu is more serious and can cause serious complications such as pneumonia and so there may be problems with diabetes control. Flu jabs in the autumn can reduce the risk of getting flu and people with diabetes are treated as a priority to receive them. Injections to reduce the risk of pneumonia are also available through the NHS.

Cochrane review on flu vaccines
The number of people having flu vaccines is increasing, so before winter it seems sensible to look at the evidence relating to fu vaccines. The Cochrane Vaccines Field based in Italy conducted a review of research of nearly every existing flu vaccine. It has concluded that flu vaccinations do not work very well in the elderly, don't work in children under two and have low effectiveness in adults and older children. Elderly people, especially those living on their own, get much less benefit from flu shots than previously thought. However the good news for elderly people is that it does offer significant protection against complications from flu such as pneumonia, hospitalisation and death.

One if the reasons that flu vaccinations are not very effective is that there are many different viruses and it is unlikely that a single vaccine aimed at a tiny proportion of these will be very effective. The two commonly used drugs to prevent flu are Symmetrel and Flumadine and human flu bugs are very quickly becoming resistant to these two drugs but they still have a place for controlling flu epidemics and preventing elderly people from getting very sick.

More Driving Warnings!

Informing the DVLA about health conditions
Researchers from Auto Express say there is evidence suggesting that about a million drivers with a notifiable medical condition have not informed the DVLA of their condition. The police suggest that this figure could well be an underestimation. Crashes involving drivers with a medical condition have risen by 75% over the last 3 years and last year there was an increase in the police notifications to the DVLA related to medical conditions. A motorist with one of the notifiable medical conditions who does not report it to the DVLA faces a fine of up to £1000.

Diabetes, when treated with insulin and with tablets, is one of the conditions where the DVLA have to be informed. People with diabetes are not being singled out or discriminated against, there is a list of 22 conditions where it is necessary to inform the DVLA.

DVLA updated guide for people treated with insulin, May 2006

Revised information on the DVLA website states: 'You must inform the DVLA if your diabetes has become worse since your last licence was issued'. Forgive the sarcasm but is what this meant by this??? They do go on to mention changes in the following:

- Eyes - vision, visual fields or having retinopathy treatment in both eyes
- Hypoglycaemia - impaired awareness of hypos, a disabling hypo at the wheel or frequent hypos

- Limb problems - such that these problems are overcome by restricting driving to certain types of vehicle eg automatics
- Nerve problems or circulation problems in your legs

If you are completing application forms D1 or D2, you simply fill in details about your condition in the health section. If you already hold a licence when the condition is diagnosed, then you write to Drivers Medical Unit, DVLA, Swansea SA99 1TU or phone 0870 600 0301 or e-mail eft@dvla.gsi.gove.uk

Latest on Inhaled Insulin

In August Pfizer launched the new inhaled insulin, Exubera in the UK. It is licensed to treat Type 2 diabetes that requires insulin and for Type 1 diabetes in conjunction with long- or immediate-acting insulin. The National Institute for Health and Clinical Excellence [NICE] final guidance is expected in early October 2006.

NICE's second draft guidance for consultation, June 2006 - still does not recommend Exubera, for people with Type 1 and Type 2 but has agreed to some exceptions:

1. it should an option for people who have HbA1c levels of 9% or higher, who are unable to inject because of a proven injection phobia diagnosed by a psychiatrist or psychologist,

2. because of severe persistent problems with injection sites, eg as a result of lipohypertrophy.

It also states that starting inhaled insulin and monitoring its effects should only be done by a specialist centre which must collect the results as part of an observational study.

Interesting that one of the arguments used in favour of inhaled insulin in people with Type 2 diabetes is that many people delay going on to insulin to avoid injections, increasing their risk of complications. Strange logic as long-acting insulin would still have to be injected but it seems that more recently a real hole is blown in this argument! A new drug for Type 2 diabetes, Byetta, has proved so popular in the US that there are insufficient supplies and doctors have been advised to delay prescribing it for new patients - and Byetta has to be injected twice a day!

And by the way…

Novo Nordisk is pursuing final studies on their version of inhaled insulin with plans to launch in 2008 and Technosphere's inhaled insulin is entering the last phase of clinical trials of a much smaller inhaler - it fits in the palm of your hand which could be a big plus if it reaches the market.

From our own Correspondents

Tightening Targets
Dear Jenny,

I was interested in the article on Tighter Targets [July 2006 Newsletter] and agree that this does encroach a lot on lifestyle and day to day living. As a child I was required to keep below 10 mmols/l and managed well without the continual blood testing I need to do nowadays. I was a happy child, teenager and young mother and do not remember ever being ill until the controls got tighter and tighter. YES the stress of trying to be good does affect personal relationships with friends and family as one is seen as being either nitpicking or autocratic about mealtimes and food!!!!! One appreciates that there are overall health effects of tighter control but the mental strain and the high incidence

of lows are not to my way of thinking a progressive step towards a happy lifestyle.

Mrs M.B.
By e-mail

Thank you for thinking about us
Dear Jenny,

Thank you so much for the information that we in the US can now get pork insulin online from Canada. It is so wonderful of you to keep us in mind. I will let my sister know right away about this new development. Unlike some people she was lucky enough to get a letter from her physician and she has received her first shipment of pork insulin from the UK and has been very pleased with it.

Miss L.E.
By e-mail from the USA

I feel much better back on beef and pork insulin
Dear Jenny,

Thanks for the information about obtaining pork insulin from the UK. I did find a doctor who signed the necessary letter and I did receive the import permit from the USDA.

I appreciate all of the help that you have given to me. I feel much better now that I am on the beef and pork insulin combination and as such, I have much better blood sugar control and I am able to do many more things and go many more places.

Mr L.D.
USA

Don't forget the good work
Dear Jenny,

I know that it is unfair and perhaps unjust that people are being denied the insulins that suit them best and I understand the concerns about the power of industry. But I think that sometimes you are in danger of forgetting the good work that our researchers and our doctors do.

Ms D.L.
In a telephone conversation

Jenny's response: I hold my hands up and say, yes I am and I'll try harder in future.

And Here's A Way Us Members Can Support IDDT

My 15year old has diabetes - I want to support IDDT
From Teresa Steadman

I live in the USA and I have a special interest in diabetes and the work that IDDT does because my own 15 year old son has Type 1 diabetes, and I would like to make sure that the Pork insulin stays available for his sake, and others.

I have put up ads on bulletin boards and in some local papers to try and help get the word out about IDDT and I would also like to raise funds to help. I sell bath and body products and I will donate a portion of all sales to IDDT - 10% of retail sales and 5% of wholesale.

I have some wonderful catalogs with bath & body products that I will send to anyone who requests it. My company is Northwest Natural Soaps & Gifts, located at 661 10th St. Challis, Idaho 83226 USA, tel. (208) 879-5580 and email nwsoaps@email.com

So if you live in the US and would like to support IDDT, please do contact Teresa.

IDDT Annual Report

Members of IDDT are receiving a copy of the Annual Report with this Newsletter and will see that we have had another year of hard work but a successful year which leaves us in a financially stable position to carry on our activities. These have not changed and the Report confirms that our aims are to help and support people with diabetes and their families and to campaign for the continued availability of animal insulins and to ensure that people receive an informed choice of treatment. The Trustees are delighted that our membership is steadily growing and that we are seeing a marked increase in the number of health professionals who are requesting our Newsletters and leaflets. We would like to thank everyone for their continued help and support and take this opportunity to thank our two full time members of staff, Bev and Michael for all their hard work.

Copies of the Annual Accounts are available and we are happy to send them to anyone who wants to see them. For copies contact IDDT, PO Box 294

Northampton NN1 4XS, Tel 01604 622838 e-mail enquiries@iddtinternational.org

Talking Meter Price Reduced!

As members will know, IDDT and other organisations have been lobbying government and manufacturers to try to make sure that this very vulnerable group of people are able to reliably measure their blood sugars to maintain good control and just as importantly, their independence. In April 2005 a new talking meter, the SensoCard Plus, was launched for visually impaired and blind people. The original cost was £149.00 but new distributors, BBI Healthcare, have greatly reduced the price to £49.99.

The SensoCard Plus meter is the size of a credit card and the test strips are available free on NHS prescription. The important details of the meter are:

- Results in less than 5 seconds
- Memory stores the last 150 results with built in 7-14-28 day period average calculation
- Only small blood sample required
- Easy to operate - automatic operation on strip insertion.

IDDT member, Alison Blackburn who is registered blind has tested the meter says:"The meter is fantastic. Without it, I would have been really stuck on a solo trip to Japan and China. This meter will, quite literally, be a lifesaver for blind and visually impaired people."

To order or for further information about the SensoCard Plus meter contact:

BBI Healthcare on 01792 229 333, or email info@bbihealthcare.com

United Nations Resolution For Diabetes

The International Diabetes Federation's Unite for Diabetes campaign aims to highlight the alarming rise of diabetes worldwide and the UK government, along with governments around the world, is being asked to support it. The hope is that where governments do so, then they will also take active steps to make diabetes a priority health area for action.

The Resolution points out that:

- new data shows that more than 230 million people have been diagnosed with diabetes and that the number of people living with diabetes is expected to grow to 350 million in less than 20 years if

action is not taken

- diabetes is one of the major causes of premature death worldwide, as every 10 seconds a person dies from diabetes-related causes and death rates are predicted to rise by 25% over the next decade;
- the World Health Organisation research predicts that the condition could reduce life expectancy globally for the first time in 200 years and that almost 6% of the world's adult population now live with diabetes.

Naturally the IDF campaign and the Resolution has IDDT's full support.

Novo Nordisk's Misleading Advert In The Lancet

Jenny Hirst

In December 2005 The Lancet published an advert from Novo Nordisk for NovoMix 30 insulin entitled 'Diabetes Insights'. The advert gave incorrect information by stating that premix insulins came in only two types, human or analogue. But as we all know, or should know, pork premix is available in the UK. As Co-Chairman of IDDT I wrote a letter to The Lancet expressing my concern that they had published an advert containing inaccurate and misleading information. I also pointed out that if a journal of this calibre contained wrong information, then it is not surprising that doctors are passing on incorrect information to their patients - that animal insulins are no longer available when they are!

Unbeknown to me this was investigated by the MHRA as a complaint. The complaint was upheld and 'Novo Nordisk agreed to review their company procedures to ensure that materials published in the UK including materials from their international head office comply with the Advertising Regulations'. A summary report to this effect will be published.

Are There Errors Just Waiting To Happen?

A Parliamentary Question that arose several times in the last session was how many people accidentally overdose with insulin. The answer from the Minister was that records are not kept and while that maybe so, the question is an important one because insulin is extremely powerful and can be dangerous. So we thought that we should look at where some errors can occur.

Human error! There are a couple of relatively common but understandable ones - not being able to remember whether of not you did an injection and as soon as you start to think about it, you can't remember whether you are thinking about today or yesterday! Giving the morning dose instead of the evening dose or giving short-acting instead of the long-acting insulin or vice versa is another error. These errors are just what they are called - human errors, they shouldn't happen but occasionally they do because we are not concentrating or something else is going on at the same time. But there are other errors that can occur and we can be aware of these in advance.

Meter reading errors

Meters can go wrong and give the wrong results so if the results seem odd or unexpected, consider the possibility that your meter may be giving false results. A faulty meter reading can result in the wrong insulin dose being given. In the US the FDA [regulatory authority] issued 20 different Class 1 High Risk Recalls for faulty blood glucose meters during 2005. [Class 1 means that there is a reasonable chance that the product will cause serious problems or even death.]

Insulin analogues are clear

Both short- and long-acting insulin analogues are clear and therefore there is a greater chance of getting them mixed up. For 70 years long-acting insulins were cloudy and short-acting insulins were clear so easily distinguishable and according to Dr Irl B Hirsh [DOCNEWS May2006] errors were relatively uncommon. Even when the first, clear short-acting analogues came on the market, the only long-acting insulin was still cloudy, so there was less risk of mixing them up.

However, the introduction of long-acting insulin analogue, Lantus added to the risks of mix-ups. There are subtle differences in the vials of Lantus compared to other insulins - they taller and skinnier and the vial top is a different colour but do people notice this unless the two vials are standing together? But now the short-acting analogue, Apidra, has come on the market and it is in the same shape vial as Lantus so increasing the risk of errors. Yes, the colour of the top is different, but this is not of help to people who are colour deficient or have become colour deficient after laser treatment.

One way to reduce the possibility of a mix-up is to use a pen for the meal time injections of short-acting analogues and a syringe for the long-acting insulin. But people using Novo Nordisk's long-acting analogue, Levemir, cannot do this as Levemir is not being supplied in vials in the UK.

Pens

Although very popular, pens have the potential for errors. Depending on the type of pen, the insulin is not always visible so it is impossible to see if clear and cloudy insulins are being used so this has the potential for mix-ups.

The imilarity of the pens also adds to the risks of mix-ups. Lantus and Apridra cartridges are administered in the same pens and the pens for NovoRapid and Levemir are very similar. For people using Hypurin animal insulins, there is now only one Autopen so it is no longer possible to have different coloured pens for short and long-acting insulins. Again, the way around this is as above - pens for pre-meal injections and vial/syringe for the long-acting insulin, except Levemir users can't so this.

Another potential problem is that the markings on the pen can wear off so it is good idea to replace your pen regularly.

The messages…

- Insulin is powerful and dosing errors can have serious effects.
- It is likely that the risk of errors or mix-ups has increased with the latest developments and these errors can be made by people themselves, by hospital staff and by staff in residential homes.
- We all need to be aware that insulins, vials and pens in their present shapes, sizes and colours can easily cause mix-ups and dosing errors.
- Drug companies need to ensure that pens are made in several colours so patients can use one colour for their short-acting insulin and a different colour for their long-acting insulin.
- Drug and device regulatory authorities need to look again at the standardisation of insulin packaging - better and brighter colour coding, perhaps vial shapes being according to the length of action of the various insulins and cartridges for the pens not being interchangeable for long and short-acting insulins.

Needles

Needle length for pens

We have learnt that some people using pens are unaware that there are various size needles and with the exception of the OptiPen Pro 1, they can all be used with any brand of pen. The available lengths are 5, 6, 8, 12, and 12.7mm and in four gauges [widths] of 28G, 29G, 30G and 31G. Discuss with your nurse which length of needle is most suitable for you - generally speaking people with more body fat should use longer needles and thinner people need shorter needles to avoid injecting into muscle and so running the risk of a hypo. Children and people who are needle shy should use shorter needles.

By the way… Cardiff University has developed new micro-needles that are long enough to go into the skin but will not reach the pain receptors under the skin. They come in a patch that is less than the size of a penny so that people who don't like needles will not actually see the needle. Trials have already been done with insulin but further testing is needed before they will reach the market.

More On Neuropathy

Charcot foot
Some time ago, one of our members pointed out that the Newsletter has not provided information about Charcot Foot, well here goes…

It is a non-ulerative foot condition that can occur in people with diabetes and is associated with nerve damage [neuropathy]. It is a condition that affects people who have lost their sense of pain in their feet. Pain protects the feet as it warns people that they are doing too much walking, standing or exercising. In Charcot foot the foot changes shape due to destruction of the bones and joints and this is not caused by infection.

However, it is difficult to detect and is often treated as an infection because areas of the foot become red and swollen. It may also be mistaken for cellulitis. Another problem with diagnosis is that the initial X-ray of the foot may appear normal. Sometimes people are alerted to Charcot foot if they have a history of injuries caused by tripping or falling. If the condition goes untreated or is badly managed, then it can have very serious results. Despite difficulties with diagnosis, immediate diagnosis and putting the foot out of action is essential.

The treatment of Charcot foot is continuous foot care education, protective footwear and routine foot care to prevent the formation of ulcers.

Reducing pain - thinking outside the box may be worth a try for those with painful neuropathy

Research has confirmed that listening to music can have a significant positive impact on perception of chronic pain. [Journal of Advanced Nursing May 2006] The effect of music was tested on 60 patients who had endured chronic pain from osteoarthritis, disc problems and rheumatoid arthritis for an average of six-and-a-half years. Some listened to music for an hour everyday for a week while others did not. Those who listened to music reported a cut in pain levels of up to 21% and associated depression of up to 25%, compared to those who did not listen. Music also helped people feel less disabled by their condition. Other studies have also shown that music can have a beneficial effect on the perception of pain. Previous research has also shown that listening to 45 minutes of soft music before going to bed can improve sleep by more than a third.

Laughter Is Good For You

A small study [ref1] showed that people with Type 2 diabetes may achieve better control of their blood sugars after meals if they laugh. The researchers found that people with diabetes who watched a comedy show had a smaller rise in their blood sugar after meals than when they listened to a non-humorous lecture. The same effect also happened in people without diabetes. Researchers are not sure why laughter appears to reduce blood sugar, but suggested that it might increase the consumption of energy by using the abdominal muscles, or it might affect the neuroendocrine system, which controls glucose levels in the blood.

Previous research has shown that laughter can be beneficial to the cardiovascular system, respiratory system, muscular system, central nervous system and the endocrine system. What we do know is that laughing increases endorphins, decreases blood pressure, decreases pain, decreases anxiety and it reduces stress.
Ref 1 Diabetes Care May 2003;26:1651-1652

Getting Your Wrists Slapped For Putting On Weight!

One of the frequent cries from people with diabetes taking insulin is

that they cannot lose weight no matter how carefully they eat and do all the right things. The clinic visit is the opportunity to seek help from the professionals but all too often rather being given advice, people are made to feel as if it is their fault for not obeying the rules or for not trying hard enough. When you are really trying hard, this is very disheartening and not what you want or need to hear. Is it yet another case of not believing patients or for some reason, believing that they are not telling the truth?

Well, there's a few reasons that can make losing weight difficult even when you try hard and carefully you follow the rules and it's not always your fault!

- The Diabetes Control and Complications Trial (DCCT) showed that tight control with multi- dose daily insulin treatment reduced levels of LDL cholesterol and triglycerides but increased the risk of major weight gain. [Circulation. 2005 May 2] So people on 3 or 4 injections a day are at risk of weight gain - regime fault, not yours!
- High carbohydrate diets require larger doses of insulin, insulin itself increases weight, so it is the fault of the recommended diet, not yours! [Less carb requires less insulin and therefore less weight gain.]
- Does the term 'high carbohydrate diet' imply the wrong meaning so that people eat more than is necessary? It is said that carbohydrates don't increase weight but eating more food than you use up in energy, will put weight on.
- Some people have experienced large weight increases with GM insulins added to which most GM insulins are of shorter duration than animal insulins and therefore more daily injections are necessary and the DCCT showed that this increases the risk of weight gain - a double whammy and not your fault.

Good News For People In The US

For Americans wishing to import pork or beef insulin from Wockhardt in the UK for personal use, a permit is necessary from USDA as well as a doctor's letter. See our website for details http://iddtinternational.org/iddtinternational/us/import.html

USDA permit - the fee for the USDA permit is currently not being charged. It is also now possible to obtain this import permit online: http://www.aphis.usda.gov/NCIE/pdf/epermitslttr.pdf

Doctor's letter - Lilly's discontinuation of pork insulin in the US at the end of 2005 has caused much distress and people have been desperately searching for a source or pork insulin. Importing from Wockhardt in the UK is one option but as we reported in the last Newsletter, the stumbling block has been that many doctors are refusing to write the necessary letter and prescription. Now that Hypurin pork insulin is available in Canada and as an over-the-counter drug, going over the border and buying in Canada is an option that some people have been trying. After much searching, IDDT-US has found a couple of online pharmacies that will provide ***Hypurin Regular Pork*** [short-acting] and ***Hypurin NPH Pork*** [intermediate-acting] insulins without a doctor's letter and without all the other form-filling!!! This has been tried and tested and works - one of our members has already obtained pork insulin this way.

If you need pork insulins and want to order online here are the details:

http://www.getcanadiandrugs.com

Pharmawest Pharmacy
101 20560 56 Ave
Langley, BC Canada, V3A3YB
USA Toll-Free: 1-877-530-0799 USA Toll-Free Fax 1-877-530-0700

Also according to information from Nucro-Technics, the Canadian distributor, Hypurin Regular Pork and NPH Pork are also available from eDrugs Canada and a prescription is not required, nor is a doctor's letter. They can be ordered at the following number: 1-866-229-1999 and shipped direct to the United States.

Snippets

Milk in schools - tinkering at the edges
From September 2006, state schools in England must give whole milk to pupils aged 3 to18 but only semi-skimmed and skimmed varieties. The ban will apply to canteens, vending machines and dinner menus and somewhat contradicts guidelines which recommend whole milk for children under 2 and semi-skimmed for over 5s. As an attempt to combat obesity, this may not be very effective as its fat content is relatively low - under 4% for whole milk and 1.7% for semi-skimmed milk. However milk is rich in calcium, iodine, potassium and other bone-building nutrients, as well as in important B vitamins such as riboflavin.

Choice of hospital is not the public's top priority
A British Medical Association survey asked 2000 people to rank 10 NHS spending priorities. The findings showed that the government policy of having a choice of hospital came 10th and having good service in a clean, local hospital was top of the list, followed by improved A&E Departments and shorter out-patient waits. These were followed by research into new treatments, funds for prevention, better out of hours care, extended GP services, more time with a doctor, better hospital food and then finally, choice of hospital!

NOP poll looks at people with chronic conditions - the Centre for the New Europe published a survey on the views of people with chronic illnesses towards their medicines. The NOP poll found that more than a third of those quizzed would stop taking their medication if side effects occurred and worryingly, without informing their doctor. [Obviously this can't apply to insulin!]

Chili may help reduce insulin spikes
- research in Australia in healthy, non-diabetic people showed that the insulin spikes produced after eating were less in a meal spiced up with cayenne chili compared to the same meal without chili. The researchers are not sure how chili helped to reduce insulin spikes, but they note that capsaicin (the fiery chemical in chili) and chili's antioxidants might play a role. The researchers call for more studies on chili's effects on insulin.

Obese people unfairly treated at work - a survey of 2000 human resources professionals carried out found that 93% of them would choose a job applicant of "normal weight" over an obese applicant if they were of the same experience and ability. 30% believe that they can refuse to employ someone on grounds of obesity as a valid medical reason and 10% think that obesity is a fair reason for dismissal [it's not]. Clearly this is discrimination and overweight people are being given fewer opportunities than their slimmer counterparts.

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

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Name: ——————————————————————————

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Postcode: ——————————————————————————

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From Your Editor – Jenny Hirst

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