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Insulin Dependent Diabetes Trust

April 2005 Newsletter

Not Listening To Patients - Is It Instinctive?

As I write this, Spring has arrived in the UK but thanks to a bout of flu, I have had a lot of time for thinking. Recently one of our members mentioned to her specialist nurse that Novo Nordisk are to make a final decision about discontinuing animal insulin and the nurse's immediate reaction was "of course Novo Nordisk wouldn't do such a thing!" and accused IDDT of being alarmist! The nurse even rang the company and, of course, the person at the end of the phone denied any intention of discontinuing animal insulin. Who did the nurse believe? Not her patient or IDDT but a telephonist at Novo Nordisk who's hardly likely to be involved in major policy decisions!

Then this week a lady phoned to say that she is having awful trouble with her diabetes and her doctor has tried virtually all the GM insulins and analogues. She got out some IDDT literature and asked if she could try animal insulin. He didn't listen, just said no and that we [IDDT] are a bunch of 'idiots' who don't know what we are talking about. We are used to this and I just smiled - the treatment he was giving was clearly not working for her and animal insulin just might have. But why didn't he listen and offer her a reasoned and logical explanation of why she could not try animal insulin? [I know there isn't one but he could have tried!]

So is there an almost instinctive reaction on the part of professionals not to believe patients or does the answer lie elsewhere?

Maybe it lies in a tongue-in-cheek letter entitled 'The laws of diminishing objectivity' from a surgeon about surgeons. [The Lancet:Vol 363:March 20,2004] The author says that whenever a clinical issue is discussed

that is important to the surgeons he is with, the objectivity of the debate declines. He is not surprised that his colleagues feel strongly about the issues under discussion, but what is striking to him is the predictable way in which dispassionate examination of the issues breaks down. He suggests that *'in matters of clinical controversy, the vehemence with which a position is held is inversely proportional to the evidence available to support it'.* In other words, in debate on a controversial issue, the less evidence there is to support a particular view, the greater is the defence of it. He also suggests that the more eminent the person, the more vehemently they hold their position!

The author goes on to point out that this is seen in other aspects of life and uses the example of the rightness of a political belief being unprovable but human beings develop violent emotional attachments to such beliefs.

Is this what has happened with physicians and healthcare professionals with the GM synthetic/animal insulin debate? Has dispassionate examination of the issues broken down? From the early 1980s when the adverse effects were first reported, the response from doctors and healthcare professionals was neither objective or logical and nor was it based on scientific evidence - there was no evidence of benefit. The loss of hypo warnings with 'human' was known BEFORE it reached the market and the joint/arthritic problems were known BEFORE it reached the market. Above all it was a new product made by a new and untried method and experience dictates that there could be unexpected adverse reactions.

The objective and logical approach would have been to acknowledge these adverse effects, report them to the Committee on Safety of Medicines and change patients back to the insulin that had previously suited them. The dispassionate approach would have been to ask themselves why patients should make up claims about the adverse effects to synthetic 'human' insulin and why would they put their driving licences at risk by making up claims of loss of hypo warnings? But the majority of doctors didn't do this, so does the answer lie in 'the laws of diminishing objectivity'?

The Sudan 1 scare also hit while I had flu and I dwelt on this one too! We saw hundreds of foods removed from supermarket shelves because they had been or might have been contaminated with the banned substance, Sudan1. Sudan1 is banned because it has the potential for carcinogenic effects, in other words it can cause tumours in rats. So the Food Standards Authority acted to protect the public by removing all risks. Why are drugs different? Why is it OK that insulin analogues have the potential for carcinogenic effects and can cause tumours in rats but they don't get withdrawn? A family might only eat the products once or twice a week but insulin analogues are being injected three and four times a day, everyday for life. Has flu flawed my logic or are we back to diminishing objectivity?

The good news to show that IDDT is listening!
We have had increasing numbers of parents of children with diabetes contacting us and as you will have read in previous Newsletters, one of the major concerns for parents is school and in particular, issues relating to hypos. What happens if their child has a hypo at school? Will the teacher recognise a hypo from bad behaviour? Will it be treated correctly?

To help parents and their children IDDT is reaching 26,000 primary schools through a magazine for head teachers. The centre pages are having a colourful pull-out poster showing hypo symptoms and what to do if a child in their school goes hypo. We are also having a flier for parents and information for teachers about children with diabetes. To accompany this we have a Parents Pack and a Teachers Pack and we hope that this will be the start in developing help and support for parents and for children. If you would like more information or would like to get involved, then contact Bev Freeman at IDDT, PO Box 294, Northampton NN1 4XS, tel 01604 622837 e-mail bev@iddtinternational.org

The Importance Of Good Foot Care

Neuropathy is one of the most common long-term effects of diabetes and is believed to be as a result of fluctuating blood sugar levels. However, even in well-controlled diabetic patients, it still tends to develop over time, particularly in the feet. Patients typically begin to lose sensation and, conversely, may experience tingling, discomfort or extreme pain the feet. The resulting inability to judge temperature and pain has important consequences, commonly including lack of awareness of foot damage such as heel fissures, blisters or dry skin, and accidental scalding of feet from stepping into hot bath water.

Unfortunately, patients can easily overlook what might at first appear to be quite trivial damage to their feet, but even small cracks can begin to bleed and quickly develop into quite severe and difficult to heal wounds that, in time, ulcerate. The risk of ulceration in people with diabetes is intensified by dry, cracked skin resulting from loss of nerve supply to sweat glands, reduced healing as a consequence of poor blood circulation and impaired inflammatory responses.

At the same time, poor circulation leads to peripheral vascular disease, often in the arteries of the lower leg, causing lack of oxygen [ischaemia] to the tissues. If the blood flow is completely obstructed, the surrounding tissues will eventually die, becoming gangrenous and leading to amputation of the limb.

Simple wounds that ulcerate are the common starting point of the vast majority of such amputation in people with diabetes. However, regular foot care could go a long way towards reducing ulceration, infection and limb loss. Diabetic patients are strongly advised to check their feet daily for variations in skin colour, excessive dryness, cracks, corns, blister and bleeding. It is vital that they wash, file and moisturise their feet and carefully cut toe nails because long curved nails can damage adjacent toes. Appropriate footwear is critical and well-cushioned, well-fitted shoes may help to relieve pressure on the soles of feet and reduce further damage to fissures or ulcers.

Despite these precautions, if a foot ulcer still develops, using the right dressing on that wound makes a great deal of difference to the healing process. In 1999, the International Consensus on the Diabetic Foot [see http://www.iwgdf.org/home.htm] outlined a number of characteristics for the ideal dressing. In particular, the dressing should create and maintain a moist wound environment, without adhering to the wound. It should conform well to the body's contours and should be easy to remove, without causing pain or firther trauma to healthy skin surrounding the wound.

Dressings have been developed specifically to meet these criteria for leg and foot ulcers, for example, the recently developed Mepilex Lite, which contains Safetac technology, has a soft silicone wound contact layer which adheres gently to surrounding skin and not the wound bed. It seals around the edges of the wound, preventing exudate from leaking on to surrounding healthy skin. The development of such atraumatic dressings is an important move towards helping diabetic patients to look after their feet and reduce the risk of further complications.

Chris Lane, Marketing Manager, Molnlycke Health Care.

Lantus [Glargine] new Information

The medical profession and patients have been warned via the prescribing information, SPC and Patient Information Leaflet about the adverse impact of insulin glargine [Lantus] on medications for schizophrenia and HIV following a review of spontaneous adverse reaction reports.

Patients Can Now Report Adverse Drug Reactions!

Yes, it's still a pilot but you can now report your own suspected adverse drug reactions. Here's how to do it!
The Yellow Card Scheme is the UK collection of reports of suspected adverse drug reactions, held up as the cornerstone of drug safety monitoring but it has always been in the hands of doctors and more recently pharmacists and some nurses. Their enthusiasm or time limitations have resulted in an estimated under-reporting of 90% which raises questions about the efficiency and effectiveness of the system!

The information is collected by the MHRA and the Committee on Safety of Medicines

In January 2005, it was announced by Lord Warner, and we must congratulate him on this one, that patients can now report their own suspected adverse drug reactions! So when doctors have ignored your reports of adverse reactions to a particular type of insulin or you doubt that they have actually sent in your reports, you can do it yourself. The information reminds us that you don't have to prove that a drug or insulin has caused the adverse effects, it is enough to only have a suspicion that it has. ALL medicines may cause side effects or reactions.

Here's how to report any adverse reactions:

- **If you have access to the internet:**

Go to www.yellowcard.gov.uk and CLICK on submit a Yellow Card report

- **If you prefer to use a paper Yellow Card reporting form:**

telephone the MHRA on 0207 084 2000 or e-mail patientreporting@mhra.gsi.gov.uk and ask for a form to be sent through the post.

What happens next?
On receiving your Yellow Card report, the MHRA will put the details of your suspected reaction on the drug reaction database. The personal information you give them will remain confidential. Your contact details are only asked for so that you can be contacted if further information about the reaction is needed.

This is something that you can do to help - report any adverse reactions that you or your son/daughter/partner have experienced with any of the insulins. This way there be a much better picture of their effects. If this could have taken place in the 1980s, the situation now would be very different - perhaps the UK would have been like the US with 'human' insulin reaching the dizzy heights of the top 10 drugs with the most reported adverse reactions.

IDDT has written [twice] to the MHRA to ask if the same weight will be given to reports from patients as are given to the reports from doctors and health professionals. So far no response but I will ask again because it is an important question!

Freedom Of information [FOI] Has Arrived

You too can look at the adverse reactions of drugs - no longer just doctors!

The Yellow Card reports of adverse reactions to drugs, and insulins, are recorded on what are known as Drug Analysis Prints. It is the information on these Prints that help to identify possible medicines safety issues but they do not present a complete overview of the risks associated with specific medicines and conclusions on the safety of medicines cannot be made on this information alone.

Prior to the arrival of FOI patients had no access to this information but now you can visit the MHRA website and take a look. Go to www.yellowcard.gov.uk and CLICK on Patient Information on Adverse Drug Reactions.

It makes interesting reading and shows many of the adverse reactions that people have reported to us, especially with the analogues! But of course, we mustn't draw any conclusions from this! The prints are to January 2004 not January 1005 because a time lag has been built in to enable the MHRA to investigate any safety concerns that arise from the reports and take any action. Not sure I understand why we can't look at the full number of reports while they're doing this but never mind, information 12 months out of date is better than no information at all! The Prints that go to doctors when they report an adverse reaction to a drug are up to date.

Gastroparesis

Neuropathy means damage to the nerves supplying any part of the body and it can be divided into two categories:

- Peripheral neuropathy that affects the nerves supplying the skin and muscles
- Autonomic neuropathy that affects the nerves supplying the organs such as the bladder, kidneys or heart.

Gastroparesis is a stomach condition caused by neuropathy or nerve damage, affecting the nerves of the stomach so that the stomach muscles do not work properly and the food remains in the digestive system for a long time. It is thought to affect 25% of people with diabetes to a greater or lesser extent.

The symptoms of gastroparesis include:

- nausea
- vomiting
- abdominal bloating, discomfort or pain
- feeling full soon after eating
- indigestion or heartburn

Gastroparesis can also affect blood glucose control because the food remains in the stomach for longer than it should and this can lead to erratic blood sugars.

Device for treatment of symptoms of gastroparesis
Medtronic, a US company, have developed an implantable device that has been shown to improve the symptoms of gastroparesis. The device delivers mild electrical pulses to the nerves in the stomach and this stimulates digestion. The treatment is called Enterra therapy and has been available in the US since March 2000.

IDDT Goes To Westminster

We are continuing to meet MPs and members of the House of Lords and so are many of you. I have to thank you all for your continued and unstinting support. I know it looks as if we have come to a brick wall but we have to knock it down or climb over!

It's not easy but nobody ever said it would be! It is a matter of staying focussed and for me, maybe this is easy - I look at my healthy daughter and I remember just how ill she was when using GM insulin and that keeps me focussed. I read the letters and e-mails from people who have benefited from a change to animal insulin - that keeps me focussed. I look at the reasons for the discontinuations of animal insulins and they are not for patients' benefits but profits - that keeps me focussed. I look at the lack of evidence of long-term safety with insulin analogues - that keeps me focussed. I look at the lack of evidence of superiority of GM insulins over animal insulins - that

keeps me focussed.

I look at all the people, the MPs and MEPs and many others who are supporting us, who see our case to maintain animal insulins as understandable and reasonable, not neurotic, not old-fashioned, just 30,000 people who can't tolerate any other insulin and that keeps me focussed. Finally I look at the people who don't support us and wonder why - that keeps me even more focussed! A touch of controlled anger does a lot to concentrate the mind and the pen! So don't give up, we are not finished yet!

Update

Report of meeting with the Minister of Health, Rosie Winterton.
This meeting took place on December 7th as a result of the help and support of David Hinchliffe MP, Chairman of the Health Select Committee. He accompanied us to the meeting with the Minister and several of her civil servants, including representatives from the NHS Supplies Dept and the MHRA [Medicines Health products Regulatory Authority]. We have to thank the Minister for spending nearly an hour with us and for listening. The discussions can be summarised as follows:

The type of insulin is a clinical decision
The Minister confirmed that the type of insulin a patient receives should be a clinical decision and certainly should not be controlled by commercial considerations or issues of availability.

Very important - gives plenty of room to have the animal insulin that you, and many people like you, want. It supports patient choice and patient need so what more do we need? Perhaps just an open-minded doctor and diabetes team who will prescribe animal insulin, but then the first duty of all doctors is to 'First, do not harm'. So if you have adverse effects from GM insulins, what doctor would make a clinical decision to deliberately prescribe GM insulin for you with the obvious risk of 'doing harm'?

Animal insulin availability
We were told that the supply problems at CP were over! We said that they were not and she agreed to take this up with Lord Warner [we'll deal with this separately!]. Most importantly, we pointed out that this situation highlights what could happen if we are left with one supplier for the whole of the UK and asked that the Dept of Health look to other sources of animal insulin outside the UK.

Action: I can confirm that this is happening because the Dept of Health phoned me for further information. I can also confirm that within days of this meeting CP announced yet further delays and I immediately faxed the Minister and wrote to Lord Warner.

Good news on choice
We emphasised to the Minister the lack of informed choice for patients about insulins and the inaccurate information often provided by the range of health professionals. In a subsequent letter, we were delighted that the Minister stated that she is "keen to ensure that the choice between animal and synthetic insulin remains available to patients

Action: She suggested that we meet with members of the National Diabetes Support Team [NDST] to use the DoH's website and other DoH communications with doctors and health professionals to increase their awareness of these issues. We thought this was a real step forward but the NDST representatives told us that what the Minister thought could be done, can't be. I didn't understand why not then and don't now but it appears that the role of the NDST is to 'facilitate and inform diabetes service development rather than directing the activities and policies of NHS organisations'. Anyway, we eventually agreed that the next Diabetes NSF Briefing would include the following:

The Insulin Dependent Diabetes Trust promotes informed patient choice in insulin prescribing. It campaigns for animal as well as human insulin to be available to people with diabetes. More information can be found at www.iddtinternational.org

One thing that I did find interesting in the course of the discussions was that the diabetes NSF targets were referred to as 'soft targets'. Strange because the NSF lays down specific dates by which standards have to be in place ie 'hard targets'. So when did the targets become 'soft', who decided that they are 'soft' and is anyone going to tell patients and planners that the targets are now 'soft'?

The safety of insulin analogues

We raised our concerns with the Minister of the issue of the potential for carcinogenic effects from insulin analogues and their lack of long-term safety data:

1. Analogues are being prescribed without any apparent caution but patients are not being told that there is a lack of long-term safety data and that they have a greater potential for causing tumours in rats than human or animal insulin.
2. Novo Nordisk are suggesting that analogues are an alternative for people who cannot use 'human' insulins. They are not an alternative - animal insulins have a 75year history of safety and efficacy.

I have to add a comment that there is always discomfort when we discuss these issues and I don't understand why. If we are wrong, then just tell us so and provide us with the evidence of long-term safety.

Action: A subsequent letter from the Minister states *"We are not aware of any evidence to suggest that diabetic patients who receive either human, insulin analogues or animal insulins are at an increased risk of developing cancer. The European regulatory guidelines provides guidance to industry on the general approach to the assessment of new insulin analogues, and these points need to be addressed before a licence would be granted."*

This avoids the issues - of course there isn't any evidence because these are long-term risks but in 2001 the European Medicines Evaluation Agency were sufficiently concerned to call for better pre-clinical testing of insulin analogues in order to definitely rule out relevant carcinogenicity of these compounds. IDDT is asking government to ensure if this hasn't taken place, it does and if it has, to let us know the findings. We are following this up through Parliamentary Questions and other means.

Parliamentary Questions asked by supportive MPs
A number of PQs have been asked on our behalf covering a variety of aspects related to our case. One of the most recent and particularly interesting questions was:

Will the Minister ensure that Patient Information Leaflets include the full range of side effects experienced by those taking human insulin as reported to the Committee on Safety of Medicines.

Answer: Current authorised product information provides details on both common and less common side effects associated with human insulin. The most common ADRs reported are decreases or increases in blood sugar, headache, injection site reaction and pruritis [itching]. Less common adverse reactions include allergic reactions, muscle pain, depression, rash, diarrhoea, fatigue, palpitations and vomiting.

Spot the error! 'Current authorised product information' refers to the Summary of Product Characteristics [SPCs] or datasheets and this is NOT the same as the Patient Information Leaflets [PILs]. All these adverse reactions are NOT listed in the PILs so patients will NOT be aware of them unless they know where to find the SPCs or that SPCs even exist! We shall be following this up!

NOTE: If you have access to the internet and you want to look at the Patient Information Leaflets and perhaps more importantly the Summary of Product Characteristics you can find them at www.medicines.org.uk

European Parliament
We are grateful for the continued help and support of MEPs who are

pursuing our issues in the EU in the following ways:

1. ask MEPs from other countries about availability of animal insulin in their countries
2. to write to the EMEA [European Medicines Evaluation Agency] about the long-term safety issues associated with analogues raised by them in 2001 and
3. to ask Lord Warner what warnings have been issued to the medical professions and to affected patients about the adverse impact of glargine on medications for HIV and Schizophrenia.

We are awaiting responses to the first two questions. To the final question Lord Warner has stated that the medical profession and patients have been warned via the prescribing information, SPC and Patient Information Leaflet about the adverse impact of insulin glargine [Lantus] on medications for schizophrenia and HIV following a review of spontaneous reports.

The House of Lords
We have had a further meeting with Earl Howe, Shadow Spokesman for Health in the Lords and he has asked Lord Warner to meet with us in a face to face meeting and we are awaiting the result of this request.

An election is looming and undoubtedly this will affect our lobbying activities but only temporarily. Governments and their Ministers may come and go but we don't and nor does our need for animal insulin to remain available. We will keep you informed. Again thanks to all of you for your hard work and determination and thanks to all the politicians who are helping us.

Parliamentry Update

Parliamentary Question - Eye screening
20th January 2005 Dr Evan Harris MP asked what progress had been made in each Strategic Health Authority towards the target of 80% of diabetics being offered retinopathy screening by 2006. The answer from Minister Rosie Winterton was that the information has been placed in the Library. IDDT's comment is that we know that many areas are not geared up for this to happen and in many cases this is due to local decisions involving the funding.

Report of the Health Select Committee Inquiry into the influence of pharmaceutical industry on health.
At the time of writing, publication of the above Report is expected in April. The Committee has listened to evidence from a very wide-ranging group of people from equally very wide ranging organisations - even IDDT! Among other things the Committee is expected to make recommendations about the relationship between the pharmaceutical industry and voluntary organisations. Even before the report is published, the Long-term Medical Conditions Alliance [LMCA], an umbrella organisation for charities concerned with chronic conditions, is recommending that member organisations should consider whether they need to review their arrangements for working with, or accepting funds from, the pharmaceutical industry.

This is not something that IDDT needs to review as our policy is simple - we don't take any money from the pharma industry as we are firmly committed to maintaining, and being seen to maintain, our independence.

And the European Commission steps up pressure on the food industry
The European Commission is stepping up pressure on the food industry to phase out junk food adverts targeted at children as part of the plan to reduce obesity. The Commission and industry have been consulting for 6months on the best way to bring in some form of self-regulation. However, the new European Health Commissioner, Markos Kyrianou has warned that he will not hesitate to use legislation if talks

fail. He has given the food industry a clear timetable to introduce self-regulation - a year and stated *'If there is not discernible progress I will look at other options.'*

Around 14million children in the EU are overweight and of these 3 million are obese.

The Unwelcome Stranger

Part I: the effects of chronic illness on body and soul

by Anne St Aubin Roberts

Like many IDDT members, my journey with Type 1 diabetes and 'human' insulin has been a rocky road. I became so unwell I was medically retired at age 46. At the time my diabetes was diagnosed, a friend, Jean, was struggling to come to terms with severe hypertension and her experience of having to take medication to manage it. Jean and I met regularly to support one another and to try to make sense of what was happening to us. We used the concept of chronic illness as 'The Unwelcome Stranger', the uninvited guest in our bodies, with whom we now had to live.

Jean and I both have a background in psychosynthesis1, a model for understanding the wholeness of being human. We look back on our meetings as a creative form of co-counselling. We've come to realise that this framework can be used by anyone - one person putting aside time to focus; someone thinking with their partner or a friend; or by all members of a family being affected by an illness like diabetes. It could also be used by anyone wanting to move through the stages of adaption to illness described by Dr Ahmed in his article in a recent IDDT Newsletter2. In Part I of this article I cover understanding the effects of illness, and in Part II (in a later newsletter), managing illness in a unique and personal way.

We all grow up with a somewhat indefinable sense of 'self'- we know who we are, we know what feels right to us. Illness, treatment, and our reaction to those things, can make us feel different, or strange. Thus the Unwelcome Stranger is a symbol for everything that has changed. Jean and I discovered that we could meet our Strangers, get to know them, live with them, and even learn from them. To do this we used a series of simple self-help techniques.

Continuing to ask ourselves questions enabled us to ***think reflectively.*** This was a way of not feeling stuck in an emotional quagmire and being able to expand the way we looked at our experience of illness. When we were 'lost for words', we found greater understanding by sitting quietly and asking for a symbol or an ***image***. Children (or adults who like to play) can draw a picture, make a model from clay, or enact their story with figures. Some people hear words of a song, or feel a sensation in their body, rather than finding a picture. Next, we learned to spend time on a daily basis tuning into our physical state, ***listening to our bodies***, and beginning to trust that our bodily intuition would tell us what we really needed. Finally we learned to ***monitor dreams*** which can tell us in an instant what we need to know.

We posed a series of questions, the first two of which I describe in this article (the later questions will be discussed in Part II):

1. Who is the Stranger? How did we get to know one another? How has the Stranger changed my life?
2. How did the Stranger appear in my life and how did I react?

We met for about 1½ hours, a couple of times per month. In each meeting we spent 20 minutes alone, quietly reflecting on one set of questions. We then discussed our answers, and deepened our understanding. We wrote up each other's comments, plus our reflections on listening to the other person, and sent this to each other before the next meeting. In this way it was a continually shared and supportive experience. We learned from each other's Strangers. To show how this works I'll use my illustrations about diabetes.

The Stranger
Here's one way of getting to know your Unwelcome Stranger. Focus on wanting to understand your illness and how it's changed your life. Write 'Diabetes' in the middle of a large piece of paper. Use a coloured pen to write any words, thoughts, feelings, or images that come to you. Look over the paper. Pause. Take a different coloured pen and repeat the process. Pause. Do this a third time. Often the things you feel most deeply and strongly about come up this last time, or you'll find you've written an important thought more than once. Reflect on what your inner self is telling you.

18 months after diagnosis, I learned from this exercise that I had done everything I could to deal wholesomely with being diabetic - but at that time to no avail. I had a different relationship to food. I had seen myself as steady as a rock, but now felt adrift on a sea of emotions. I felt huge grief at how much I'd lost - my roles in life had gone. My body image had altered. Yet despite all of this, I recognised the steady and unchanging nature of one part of me - this inner self that could observe it, and know it was wrong.

Next we sat quietly and asked for an image for our Strangers and their impact. My stranger was a tree-feller, or lumberjack. I used to be like a strong tree: grounded, yet reaching to heaven; connected to other living beings; but now I felt like a telegraph pole. I felt detached, un-alive, rigid, and stuck. However, all images contain the whole picture, and I also began to see my diabetes like the tree-feller. Diabetes is a part of the living world too. It just does what it does - by chance I had the genes and the environment to be felled by it.

When did your Stranger come to call?
This phase may feel more relevant to people who are recently diagnosed. However, it's also really useful for someone monitoring the effects of a new treatment, or dealing with a complication (such as failing sight). We can also learn a lot from our habitual pattern of dealing with illness.

The Time-Line. Draw a line across a sheet of paper and mark an X along it to represent the present, so the past is behind the X, and the future stretches out in front of it. Look back with hindsight to when the Stranger first began to call. Did you hear his or her messages, in the form of symptoms or instincts you ignored? Look back further: what was it like to be ill as a child? Is there a family pattern? How healthy has your life been? Write down any thoughts. In your own time, focus again on the present, then pause. If it feels right, move into the future. Is there anything you fear? Is there anything you're really determined to do? Write down your thoughts for reflection. This exercise can also be done by imagining the line stretching along the floor, and physically moving along it. I have found this enables my body to tell me more.

To be brief, I'll just give one small example from this exercise. I realised that the Stranger rang my bell when I had a bizarre dream telling me to dipstick my urine, despite being unaware of any symptoms. Sure enough, that's how my diagnosis got made. Like most people, I would have said I didn't dream very often. I started to write my dreams down every morning (excuse for a lie-in!) and soon discovered I dreamt every night - and the dreams often had something empowering to tell me.

In Part II, I'll move on to the questions and techniques which proved useful in diagnosing the adverse reaction I had to my first insulin regimes, and in adapting to life with diabetes.

References

For more information about psychosynthesis, try the following:
What We May Be. Pierro Ferrucci. Mandala, 1990
A Psychology with a Soul. Jean Hardy. Woodgrange Press, 1996

Is there an emotional reaction to the diagnosis of diabetes mellitus?
Dr Almoutaz Alkhier Ahmed. IDDT Newsletter, July 2004

Hypurin Insulin - Supply Update

As many of you are aware, there have been supply problems with animal insulins from CP Pharmaceuticals / Wockhardt UK since last September. The company has been issuing monthly statements with the expected in-stock positions but these are inaccurate as soon as they are issued, if not before!

To add to the confusion, both Lord Warner and Minister of Health, Rosie Winterton, have been stating since before Christmas saying that the problems at CP are now resolved and stocks are back to normal. Clearly they are not, so someone, somewhere is misinformed!

Rather than publish inaccurate information in the Newsletter, we are including a flier with the latest position as we know it.

Future availability of CP animal insulins
Tim Loughton MP has been very supportive of our case and wrote to the head of CP/Wockhardt UK in India, Mr Habil Khorakiwala in January 2005. And received the following information:

Wockhardt UK is committed to the continued supply of animal insulins and definitely for the next 2 to 3 years. They have negotiated the availability of animal insulin crystals [the raw material for production] and do not see any issues for the next few years.

If there are lessons to be learnt from all this they are:

- It was only by chance that they had 1.5ml cartridges left in stock from the change to 3ml cartridges. If a similar situation arises again, then it may be that people would have to use a vial and syringe and for the first time, so perhaps it is worth asking your Diabetes Specialist Nurse to show you.
- This shortage has clearly demonstrated that we cannot be left with one supplier of animal insulin, if Novo Nordisk decide to discontinue their animal insulins.

Just a note about diamorphine
Before Christmas the government announced that stocks of diamorphine, the most common drug for severe pain relief were running low and doctors were asked to conserve stocks of diamorphine for people who were dying until more supplies could be assured. The reason for this was that Chiron, the main manufacturer had its licence suspended because of manufacturing problems. The only other UK manufacturer, CP/Wockhardt UK, was asked to increase their production. Conservative Health Spokesman, Simon Burns described this situation as ‘a fiasco that the Government could have prevented with better forward planning’.

Here is an example of having only two suppliers of a much-needed drug and what happens with no forward planning - all we are asking Government to do before Novo Nordisk discontinue their pork insulin!

Disability Living Allowance

Loss of hypo warnings is sufficient to make a successful claim
Disability Living Allowance [DLA] is a benefit given to people who require care/help from others and the amount of the benefit depends on the extent of the problem and the time spent giving care. Basically it is made up of two components - mobility and care. If you have needed help for 3 months and you are likely to need it for at least another 6 months, are aged 5 or over and under 65, then you are entitled to claim DLA. It can also be claimed for children aged 3 months and over and generally need extra help and looking after - more than other children of the same age.

Attendance Allowance is very similar to DLA but applies to people who became ill or disabled and needed help after your 65th birthday.

Just recently one of our adult members made a claim for DLA on the basis that he has lost his hypo warnings and has severe hypos in the

night that his wife has to treat. He has been successful in his claim for DLA and been awarded the lower amount and he felt that other members may wish to consider applying.

Note: For full details of these benefits are easily available in your local Post Office, Benefits Office or Citizens Advice Bureau.

In Memory

It is with sadness that I have to report the death of Helena Croft. Helena was 79 years old and died peacefully in hospital. She had diabetes for 65 years, since the age of eleven and her philosophy was: ***"Diabetes must live with me rather than me with it."*** She was very interested in sport and played and umpired hockey until 1982.

Helena and her late husband, Ted, were founding members of IDDT and their support was unstinting. Many people will remember Helena attending IDDT Annual Meetings. Her words were that she was forced to be treated with 'human' insulin in the 1980s but she wrote to her consultant about the problems she was having and he agreed to her reverting to animal insulin. She was looked after by Luton and Dunstable Hospital and was very happy with their care. In latter years she tried 'human' insulin again but it still didn't suit her, so she remained on pork insulin. Her daughter's words are, "She was a very brave lady, she did what she wanted and would not be told what to do." Helena's approach served her well for her 65years of living with diabetes and we shall miss her.

Bringing A New Madicine To The Market

A useful medicine may treat many thousands or millions of people and for any medicine to be allowed to be prescribed it has to be shown to be:

Effective - it must prevent or cure the illness or relieve the symptoms.

Safe - it has to treat the illness/condition without causing unacceptable side effects.

High quality - a medicine must be able to be manufactured to a high standard every time and it needs to remain stable so it can be stored without deteriorating for a given period of time.

Research into new medicines has to ensure that all these requirements are met and this can take up to 12 years and only a small number of possible new medicines get through this process.

Clinical trials - testing new drugs in human beings usually begins in healthy volunteers who are given very small doses of the new medicine over short periods. The information on the new medicine is then compared to the information from animal studies and if all is well, then the dose is increased to realistic levels and trials take place in small numbers of people who the medicine is meant to help. Later the studies broaden until there is enough information to decide if the medicine should be licensed, for what type of patient and in what dosage.

Consent - before trials can take place in people, researchers must have the permission of the Dept of Health and MHRA, Ethics Committee approval and the consent of the people taking part.

Adverse reactions - can occur at any time after a drug is administered, minutes, weeks, months or years later. Pre-licensing drug trials are usually carried out on a limited number of selected people and the information about benefits may be easily accessible but the information on harms may be much more limited. The participants in the trials may not be typical of the wider population, so unexpected adverse reactions may well occur after a drug is used in the wider population.

One UK study has suggested that 1 in 15 hospital admissions are due to adverse drug reactions and a US study estimated that 106,000 patients die and 2.2million are injured each year by adverse reactions to prescribed drugs. [BMJ 2000;320:987-990, April 8]

Post marketing surveillance - is the term used to describe the collection of information about a drug once it has reached the market and used on the wider population.

Do we understand 'risk' when looking at adverse reactions and making choices?
As part of making an informed choice about which drug or insulin we are going to use, we have to look at the benefits and harm and whether the benefits outweigh the risks of harm. Making this decision is difficult enough but understanding risks just adds to the difficulties!

Research shows that people looking at information about risks of side effects to drugs often overestimate the risks and underestimate the benefits. Risks can be expressed in words or in numbers and that greater overestimation occurs with words rather than numbers.

For example:

In words ?.*statin is associated with some side effects. It can cause constipation. This is a common side effect of the medicine.*

Or in numbers ?..*statin is associated with some side effects. It can cause constipation. This side effect occurs in 2.5% [that is 4 in 100] people who take the medication.*

Patient Information Leaflets inside the insulin or other drugs we receive describe the risks of adverse effects and often these are categorised as very common, common, uncommon or rare. So it is hardly surprising that these can be misunderstood or misinterpreted but the EU has described these categories as follows:

Verbal	**Frequency**	**Probability**
Very common	Over 10%	More than 1 in 10
Common	1-10%	1 in 100 to 1 in 10
Uncommon	0.1 - 1%	1 in 1,000 to 1 in 100
Rare	0.01 - 0.1%	1 in 10,000 to 1 in 1,000

In other words, if the Leaflet says that a side effect is common, then between 1% and10% of people taking the drug are likely to experience it or 1 in 10 to 1 in 100 of people taking the drug are likely to have the side effect. Still complicated but this may make things a little clearer!

To bring this closer to home, the adverts for Levemir, Novo Nordisk's new long-acting analogue describe the 'Undesirable effects' as follows:

Common: hypoglycaemia, injection site reactions, usually transitory

Uncommon: lipodystrophy, oedema [fluid retention], refraction anomalies on instituting therapy [blurring of vision so that glasses may need changing], allergic reactions, generalised hypersensitivity reactions which are potentially life threatening

Rare: acute painful neuropathy may be associated with rapid improvement in blood glucose control, usually reversible.

When a medicine is licensed, what type of patient is it for and what dose should be used?
Looking at Patient Information Leaflets for drugs, including insulins, we often see statements such as *'not to be used in children under 13' or 'if you are pregnant you should inform your doctor'*. The statements are included because trials in these groups of patients have not been carried out so there is no proof of safety or what dose should be used in particular groups of patients.

Concerns have been expressed in the press and in medical journals about the lack of testing of medicines on children despite them being

prescribed for them. Often this results in doctors having to guess the dose for children from the adult dose - far from ideal and possibly unsafe. All this was highlighted in the much publicised case of Saroxat followed by Panorama on BBC1.

Pregnant women can also be prescribed drugs for which trials have not been carried out to demonstrate their safety for both mother and the developing foetus. A recent study showed that among a group of 152,531 pregnant women between 1996 and 2000, 64% of them had been prescribed a medication other than a vitamin or mineral supplement. Of these women, 40% had been prescribed a drug for which human safety during pregnancy had not been established and even worse, 5% had been prescribed a drug that was known to cause risk to the developing foetus. [Am.Jour Obstet Gynecol 2004;191:398-407]

So once again the message must be to READ THE PATIENT INFORMATION LEAFLET.

When an insulin is licensed, what about children and pregnant women?

The trials for insulin to be licensed are no different from other drugs - they are carried out on a limited number people - usually about 1500. However these people are usually highly selected and not necessarily typical of the wider population who will be using the new drug. So in the case of a new insulin, the people involved probably have no complications, probably youngish, not pregnant and not children or adolescents. So it is not until the insulin is on the market that it will be tried on all these, and more, categories of people. For instance, does a new insulin affect people with retinopthy or kidney problems differently from people without these complications? Does it affect children differently? We don't know.

It is not difficult to see that carrying out trials in children has its problems - one of which is, do parents want to give consent to putting their children through trials and what are the risks involved for their children? Nevertheless, if drugs are to be used on our children, then we should know that they are safe, effective and what dose should be used. Similar concerns can be expressed for drugs used on pregnant women and their unborn children.

What about the use of new insulins in children and pregnant women?

This information we should have as part of our choice of treatment so that we know what trials have been carried out and the evidence of benefit from using any particular insulin.

There are two documents that give this information:

- the Patient Information Leaflets [PILs] which are inside the packs of insulin
- the Summary of Product Characteristics [SPC] documents which provide a lot more information and are contained in the Medicines Compendium. This is a huge book about all drugs which is available in libraries or on line by visiting www.medicines.org.uk

We have therefore looked at the SPCs documents and PILs for the new insulin analogues to see what they say about their use in children and in pregnant women. Here is a table of the insulin analogues but first perhaps we all need a translation of the terminology!

- ***"The efficacy and safety have not been studied in children and adolescents"*** - no trials have been carries out in children and adolescents to test whether it is safe and effective in these groups.
- ***"No studies have been performed"*** or "No studies performed in children under 6 years"- no trials have been carried out at all or in the age band stated. Therefore there is no evidence of safety or effectiveness if it is prescribed and this is called 'off-label' prescribing which means that if damage is done through its use, then the drug company would not be liable.
- ***"Should only be used in children in preference to soluble insulin when a fast action of insulin might be beneficial"*** - implies that it should not be prescribed automatically for children so does it mean that adequate trials have not been done?

- ***"There is limited clinical experience in pregnancy"*** - this means just what it says, the use of the insulin in pregnancy has been limited to a few people.
- ***"No clinical data on exposed pregnancies are available"*** and **"There is no clinical experience during pregnancy"** - no trials have been carried out to show that it is safe and effective.

Hopefully this information will help you to understand more about the new insulins

Type of Insulin	Children	Pregnancy
Humalog [Lispro]	Should only be used in children in preference to soluble insulin when a fast action of insulin might be beneficial eg timing of injection in relation to meals. But PIL says suitable for use in adults and children	Information on large numbers of exposed pregnancies do not indicate any adverse effect on pregnancy or the health of the foetus/newborn
Humalog Mix 25 [Lispro]	Administration to children below 12 years of age should be considered only in case of an expected benefit when compared to soluble insulin.	Same as for Humalog
NovoRapid [Aspart]	No studies have been performed in children under the age of 6 years.	NovoRapid should only be used in children [NOTE: NO AGE LIMIT] in preference to soluble human insulin when a rapid onset of action might be beneficial. PIL says the same.
NovoMix 30 [Aspart]	No studies have been performed with NovoMix 30 in children and adolescents under the age of 18 years.	As for NovoRapid
Lantus [Glargine]	Safety and efficacy has been established in adolescents and children of 6 years and above. But PIL says there is limited experience with the use in children and the DTB [vol 42 No 10 10/04] says that its efficacy and safety has only been assessed when given in the evening.	No clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal or foetal development, parturition or postnatal development.
Levemir [Determir]	The efficacy and safety have not been studied in children and adolescents.	There is no clinical experience during pregnancy. Animal reproduction studies have not revealed any differences between NovoRapid and human insulin regarding embryotoxicity or teratogenicity.

Transplant News

First successful transplant in the UK announced on March 9, 2005
Researchers at King's College Hospital in the UK have successfully transplanted islet cells in a 61-year-old man who has had type 1 diabetes for over 30 years. He now no longer requires insulin injections after islet cell transplants from three separate donors over a six-month period. The transplantation is the third to take place in the UK, the other two procedures having achieved partial success. As a result of donor shortage, islet cell transplantation is currently limited to people with diabetes who have serious problems managing

their condition with conventional insulin therapy. It is hoped, however, that many more people will be able to benefit from this procedure in the future. Apart from King's College Hospital, eight other centres in the country are currently researching islet cell transplantation and the people who are candidates for the transplant research programme are those most at risk of disabling hypoglycaemia.

We have to remember that there are still drawbacks, especially having to rely on anti-rejection drugs for the rest of life and their adverse effects. There are also severe shortage of pancreases - only about 800 are donated annually in the UK.

Living donor transplant
Doctors in Japan have successfully transplanted insulin-producing, islet cells from a mother to her 27year old diabetic daughter.

Previously islet cells have been taken from dead organ donors which have the risk of being damaged. Dr Shapiro who was the first to successfully transplant islet cells in Canada was one of the surgeons who led the transplant team in Japan and he reported that the islet cells began to produce insulin minutes after being transplanted into the daughter. He also commented that living donor transplants could allow many more desperate people with Type 1 diabetes to have successful transplants as the expectation is that islet cells from these near-perfect organs will work better.

Some Islet transplant progress
Stem cells are the primitive cells that have the capability to become any cell in the body including islet cells that will produce insulin. One of the major problems with islet cell transplantation is that a large number of cells is required and there are not enough donors. US scientists believe that they may have discovered a way to solve this problem by using a serum derived from cows to help in the production.

The researchers removed islet cells from pancreases of people who had died and exposed them to a substance containing foetal bovine serum. The serum appeared to encourage the islet cells to change into more primitive cells that were the predecessors of islet cells. Although these cells do not produce insulin themselves, they are able to multiply easily. They are more developed than stem cells and can only go on to produce islet-like cells capable of producing small amounts of insulin. The researchers hope that this could lead to advances in islet transplants for people with Type 1 diabetes but they stress that their work is in the early stages and there are still problems to be overcome.

New anti-inflammatory compound for islet transplants in mice - researchers in the US have found a new anti-inflammatory compound, lisofylline, that can prevent the recurrence of diabetes in mice which have had islet-cell transplantation. Diabetic mice were given islet-cell transplants and were then injected daily with lisofylline for 3 weeks. The treated mice had healthy glucose levels for 65 days without the need for insulin or immunosuppressants but those treated with saline only maintained healthy glucose levels for 6 days. [Transplantation 2004;77:55-60]

New Zealand to consult on pig cell transplant
In the 1990s in New Zealand transplantation of insulin producing cells from pigs into human beings took place and the people in one of the groups receiving pig cells no longer have to inject insulin. However, the trials were stopped by the New Zealand Government because of fears of cross species infections that may bring new diseases to man. Cross species transplantation is known as xenotransplantation and perhaps has particular relevance in New Zealand where the population is small and too small to find donors for all the organ transplants that are needed. The government has now requested a 4month full public debate into xenotransplantation and hope that a final decision will be made by the end of the year.

Genetically modified pigs
Kidneys from genetically modified pigs and unaltered pigs have been transplanted into baboons. The 8 baboons receiving the kidneys from the modified pigs survived for up to 81 days but those receiving kidneys from unaltered pigs survived for only 30 days. The molecules

on the surface of the transplanted cells of the organ are modified so that the baboon's immune system does not recognise them as foreign and therefore does not reject them. It is hoped that eventually the use of genetically modified pigs may be a source of organs for animal to human transplantation that could help with the shortage of human organs for transplantation.

Research supported by the Juvenile Diabetes Research Foundation

NHS to increase the numbers of pancreas transplants
The NHS aims to triple the number of pancreas transplants from 50 to 150 a year from April 1st 2004 so the national need for the operation will be met by 2009. Health Minister, Rosie Winterton, said that the national commissioning for pancreas transplants will ensure a high quality, expert service and equal opportunity of access for patients no matter where they live in England and Wales. The operation is only recommended for people between the ages of 20 and 50 who have poorly controlled diabetes or at least two complications. According to the Minister, whole pancreas transplants have become a realistic option for a small minority of people and are usually combined with kidney transplants in people with kidney failure.

Note: a recent study [JAMA 2003;290:2817-23] people who have a pancreas transplant without a kidney transplant appear to have worse survival rates than people on the waiting list just receiving conventional treatment. The 4year survival rate for people who had a pancreas transplant alone was 85% compared with 92% for people who had no transplant. In other words, survival rates for people who have combined pancreas and kidney transplants are better than pancreas alone transplants and this also removes the need for dialysis and insulin injections.

From ou own Correspondents

Enlightened staff is the answer.
Dear Jenny,

I would like to respond to the article in the October Newsletter about being in hospital with diabetes. I have had diabetes for 25 years and on insulin for about 10years and I am able to maintain very reasonable control over my blood sugars. I have been in hospital for six operations in the last five years and five of these required a general anaesthetic, three of which were carried out at one hospital and two at a different hospital.

For my first three ops I was allowed to keep my own insulin, check my own blood sugar levels with my own meter and was consulted about my injections. I got the feeling that this was not quite the norm so it was probably because I was very firm with the nursing staff and the consultant that this was what I wanted. For the operations where I needed a drip, there were discussions before and after and blood glucose levels were corrected again fairly quickly.

My next operation was carried out at a different hospital and this was a totally different story - I was not allowed to keep my insulin or my blood meter!! There were no discussions with me before the operation and after the operation blood sugars went haywire. After 24hours of failing to correct this situation, I was a little annoyed and insisted that they let me control my insulin and my own blood glucose testing. This I did and within 24hours the sugar levels were back within reason and it was only then that it was admitted they did not really understand what they were doing.

My last op in July 2004 was in the same hospital but things had changed - for the better! It is now normal to take people with diabetes into hospital the day before the operation when my diabetes control was discussed and I was told that I was probably the best person to control my diabetes. There was a choice of food and it was hot or cold as it should be, well presented and tasted good! All this made my

sugar control easier so I was able to keep very reasonable control for the length of my stay.

I now realise that I was lucky to be in a hospital with enlightened staff as well as good food. To others I say, try hard to keep your own control, be firm with the staff and you should succeed.

Mr H.B
South West

Is this a good enough reason for prescribing Lantus?
Dear Jenny

I am a member of IDDT and have had diabetes for 45years and I work as an occupational therapist. Many of my clients are elderly people in care and recently I noted that most of those with diabetes were being given Lantus [glargine], the 24hour-acting insulin. I questioned whether this was the best insulin for everyone and the answer was 'one injection a day saves nurse time'! I found this incredible and I have to ask what has happened to treatment decisions being based on what is the most appropriate treatment for the individual person with diabetes? Surely this is still important and 'nurse time' should have nothing to do with this decision. Or do I have unrealistic expectations by today's standards?

[Name supplied]

Where's patient choice?
Dear Jenny,

After living a healthy lifestyle with plenty of exercise, I had severe leg ulcers for several years until eventually a medical expert said they were 'diabetic ulcers'. I was then treated with tablets for 10years and the ulcers cleared up. The same hospital then started me on 'human' insulin and not only did the leg ulcers break out again but my trunk was covered in dry blisters and very itchy skin. A massive swelling in my left breast caused more amusement than sympathy from the medical staff. I asked for a change to animal insulin and even had a private consultation but I was still refused the chance to try animal insulin. I have now been on 'human' insulin for 15 years and during the last 3 years I have deteriorated greatly and now virtually cannot walk. I consider that medical negligence has ruined my enjoyment of life and I have written to the Hansard Consultation on diabetes to let them know.

Mr P.C.
North West

I don't have coeliac disease after all!
Dear Jenny,

After many years of having Type 1 diabetes, I was diagnosed by my doctor as having coeliac disease and found getting to grips with the gluten-free diet really quite difficult. I was unhappy and decided to see a consultant privately. After biopsey, I was told that I didn't have coeliac disease at all and feel angry that I could have gone through the rest of my life struggling with both coeliac disease as well as diabetes.

Mrs P.C
Midlands

Information from Jenny: Coeliac UK [Crossed Grain Magazine Spring 2005] says that many patients who have tested positive for antibodies are not offered a duodenal biopsy, despite recommendations by the British Society of Gastroenterology. A biopsy is still the gold standard method for diagnosis.

Thanks to IDDT
Dear IDDT members,

I was delighted to become an IDDT supporter when my oldest friend got back her life thanks to the charity. Having been really ill, she switched to pork insulin from genetically engineered yeast insulin. I know many IDDT members are indebted to either pork or beef insulin,

and might like to keep the good energy flowing, by supporting one or both of the following organisations:

Compassion in World Farming, Freepost (G1/2198), Petersfield, Hants, GU32 3BR

Viva! 8 York Court, Wilder Street, Bristol, BS2 1OW. This organisation is supported by Martin Shaw, Sir Paul McCartney and Joanna Lumley and is currently campaigning against farrowing crates for pigs (where sows are forced to give birth and nurse in crates which are so small they cannot even move).

Thank you!
Sherri Brodie, Fife

Silver Linings

Another in the series by Sue Marshall who has had insulin dependent diabetes since she was five years old. In this article she talks about carbohydrates.

I love counting carbs, and that's just as well as I do it all day, every day. I have just been trained that way. Like somebody who has broken their back and literally has had to learn to walk again, getting diabetes means you have to use your conscious brain to count the value of the food and drink that you consume.
Like a sportsman or dietician, you can literally 'read' a plate of food according to whether it contains carbohydrate, protein, fat, or (more likely) a combination of all of them. Once you get the hang of it, you can judge if the carbs will be slow-release, fast-release, and how they react in terms of release once they have come in contact with the other foods on your plate.

I get it wrong a lot. My HBA1C, giving my average blood sugar levels over the last three months, could be better. It is meant to be under 7, mine hovers just over 8. But I do blood test a lot, so I do tend to pick up quickly if I have misjudged my insulin dose against the food I have eaten, or activity undertaken (or not!).

There is definitely a formula containing four factors that need to be considered.

1. The amount of insulin you inject is based on
2. The amount of carbs you calculate that you have eaten in combination with
3. Your latest blood test result, as well as
4. Your expected activity levels.

These factors rotate through my day. I tend to do a blood test when my food appears in front of me. Then based on what is on the plate and what the blood test result shows, I then give myself my insulin. I then do another test about an hour and half after eating.

A blood test is always only ever a 'snap shot'. It does not indicate if your blood sugar is going up or down, it just tells you what it is right now. If you are worried that it's heading either north or south, then a follow-up test is a good idea.

Counting carbs is becoming easier and easier, and right now whole tracts of society is getting better educated about our relationship with carbs -- and I mean humans not just diabetics. Dr Atkins did a lot to enlighten people about the value of understanding how carbs work on in your metabolism. His now-famous diet was not written for people with diabetes, but it has educated the public as to the effects on your body of fast food, what complex carbohydrates are, and why adding fat to carbohydrates is going to make them absorb more slowly, then leave you feeling hungry. While Atkins used to make me want to spit tacks, I appreciate that he did a lot to promote conversation that has helped more people become aware of what they are eating.

The fact of the matter is that as a diabetic you can count the carbs to

help gain better control. But you have to have carbs. Everyone else is just playing catch-up!

Sue Marshall has had insulin dependent diabetes for 30 years and has started a company that designs kitbags and organisers for people with diabetes to use to carry all their tools with them as they go about their normal daily lives. For more information visit www.desang.net or call 01483-825690

Tsunami Appeal

"Thank you very much for the massive support from your organisation towards our cause."

These are the words of one of the doctors co-ordinating the distribution of insulin and other diabetes supplies in Sri Lanka. The support for our Appeal for unwanted, in-date insulin and other supplies has been tremendous and we have been regularly sending insulin and other supplies to Sri Lanka.

Supplies from Australia, Germany and IDDT in the UK were sent within a week of the tsunami. Working with Insulin for Life in Australia, IDDT despatched supplies to the President of the Diabetes Association of Sri Lanka who had quickly organised a system for the supplies to reach the areas of need. He estimated that at least 10,000 people who require insulin could have problems obtaining it through normal channels as a result of the disruptions due to the tsunami. The unwanted and in-date supplies sent through your efforts have helped to bridge the gap over the weeks and months since the tsunami.

IDDT will continue to send supplies to Sri Lanka as they are needed. In the meantime we must not forget the ongoing needs of children and adults in poor countries that we helped prior to the tsunami - sadly, their need is always there and we shall continue to send to them. So please keep your supplies coming. Just put them in a jiffy bag and post to: IDDT, PO Box 294, Northampton NN1 4XS

Hoildays Are On The Way!!!

Going on holiday if you have diabetes means that you have to take a few extra precautions, especially if you are travelling overseas. Here are some tips to help you - ones that we have learnt by experience.

Looking after your insulin

- Travelling overseas probably means that your insulin will not be kept in a refrigerator for days or even weeks. Exposing insulin to high temperatures makes the insulin weaker and so it does not act as efficiently.
- If a refrigerator is not available try to store the insulin in a cool dark place.
- Carry your insulin in a polystyrene container or a small wide necked vacuum flask.

Precautions when travelling by air

- Always obtain a letter from your doctor explaining that you have diabetes and need to carry syringes or pens on the aircraft otherwise you may not be allowed on to the aircraft.
- Make sure that your insulin is in your hand luggage in the cabin with you. The hold of the aircraft may go below freezing because of the high altitude and this will destroy or damage your insulin.
- Carry two lots of insulin, testing equipment and syringes/pens and distribute them between two different hand luggage bags. You could give one set to your travelling companion. Luggage does frequently get lost and it could prove difficult to replace your insulin or syringes/pens.
- Remember to always take sufficient insulin with you because you

may not be able to obtain your type of insulin in the country that you are visiting. This is particularly important for people using beef or pork insulins that have been withdrawn from many countries.
- When you come home it is sensible to throw away any unused insulin that has travelled with you because it has not only been exposed to heat and bright light but also to vibrations, all of which can damage insulin and make it less effective.
- If you are overseas for long periods and cannot obtain your usual insulin in that country, John Bell and Croyden, Pharmacists, Wigmore Street, London will courier insulin [and other drugs] to you. They require a doctor's prescription, either NHS or private, payment by credit card and they will properly pack the insulin and courier it to you.

United Airlines catering for people with coeliac disease - from the beginning of 2005 all United Airlines flights will provide gluten-free meals.

Keeping healthy on aeroplanes - avoiding the drinking water on aeroplanes may save people from drinking harmful contaminants in it. It is difficult to pinpoint the exact source of contamination as airlines can take on water numerous times a day in different cities, the procedures for filling could be incorrect or it could be the passengers themselves. One way to avoid all risks is to drink canned or bottled drinks, to avoid tea and coffee made with tap water and avoid brushing your teeth with airline bathroom water.

Diabetes holiday foot syndrome - research [ref 1] has shown that there is a greater risk of foot ulceration that can lead to serious complications during holidays, especially those taken in hot countries, hence the name 'Diabetes holiday foot syndrome'. Among 435 people studied 17 experienced foot lesions during foreign holidays, 10 of whom reported a foot lesion for the first time. The people with holiday foot damage were a younger age, mainly male and their diabetes was of shorter duration than foot lesions from other causes.

The causes of diabetic foot syndrome were:

- direct injury
- unaccustomed exercise
- burns from walking barefoot on hot pavements
- wearing inappropriate inflexible bathing shoes

If you need any further warnings, nine out of the 17 people had to be hospitalised for infections as a result of the foot damage and the average stay in hospital was 11 days!

Ref 1 Prac Diab Int March 2001 Vol 18 No2

US Sets Up Independent Monitoring Board To Check Drugs

The US is to set up a special independent monitoring board to keep checking on medicines once they are on the market. This was announced in February 2005 after complaints that officials reacted to slowly to reports linking prescription painkillers [Vioxx and Celebrex] to heart attack and stoke. In making the announcement, it was said that it has become clear that people want more oversight and openness from the FDA.

The sales for this class of drugs had risen to a massive $5billion a year before the potential side effects became publicly known. Vioxx was withdrawn from the market in September 2004 after a study showed that up to 140,000 people developed heart disease after taking Vioxx. There was also an increase in heart attack and strokes and other studies have raised questions of heart problems with drugs in the same class, Celebrex and Bextra.

Dr James Le Fanu Follows Up His Telegraph Article About GM Insulin

In the January 2005 Newsletter, we reported an article published in the Sunday Telegraph [31.10.04] by Dr James Le Fanu in which he described the adverse effects experienced by a member of the medical profession diagnosed with Type 1 diabetes two years ago. She had chronic ill-health, erratic blood sugars and psychological impairment. A change to pork insulin resulted in her 'feeling me again'! He concludes that 'it is scarcely revolutionary to propose that some of those with diabetes might do better with animal based insulins.'

The article resulted in many people contacting IDDT but obviously many people must have also contacted Dr Le Fanu as he continued to report other people's experiences.

Sunday Telegraph [29.11.04] - he reported that David Sibley had written to him. His specialist had switched him to the 'exciting new' and much more expensive GM insulin in the 1980s and 'promptly his life went downhill'. His consultant told him he would get used to it but in despair, he asked his GP for help who happily switched him back to beef insulin on which he has remained. Dr le Fanu goes on to say "Loss of hypo warnings is clearly hazardous and recurrent hypos can also adversely affect the functioning of the brain, resulting in poor concentration and loss of memory."

Sunday Telegraph [26.12.04] - he reported that Mrs T.J. was at her weekly Welsh class when a friend thrust into her hand the copy of his first article 'the hazards of human insulin'. The friend said 'That's you.'

Earlier in the year Mrs T.J.'s doctor had changed her from animal insulin to GM insulin and almost immediately her blood sugars became erratic and she noticed a deterioration in her concentration and memory. In addition her joints became painful, she was depressed and lost her self-confidence. She gave her doctor a copy of the article and he switched her back to animal insulin and she says: *"I feel so much happier, my joints began to free up, my brain got back into gear, and I find myself tackling my Welsh class and crossword puzzles with renewed gusto."*

Dr Le Fanu writes ***"Another woman, from Keighley, Yorkshire, has an almost identical story, which makes me wonder just how many other diabetics there are out there who could do so much better if they too switched back to animal insulin."***

What Is The HbA1c Test?

The HbA1c test is the one that doctors rely on to gauge blood glucose control over the previous couple of months. It is quite different from the finger prick blood glucose tests which give a reading of glucose in the blood at the time of the test and it is not the average of your finger-prick test results.

How does the test work?
Glucose in the blood stream attaches itself to haemoglobin, a protein inside the red blood cells that carries oxygen to the cells. Normal haemoglobin with glucose attached is called A1c. The more glucose there is in the blood, the higher the person's A1c result. The red cells live for about 120 days but this is not a true average of blood glucose control during the whole of this time, so doctors consider it to be an indicator of control over the past 2 to 3 months.

Different methods of measuring
There are more than 30 different methods of measuring HbA1cs and they don't always produce comparable results. The only way to compare your results is to always have the test done at the same lab. So for instance, if you change hospitals or move districts, then your new hospital may use a different method or you cannot compare your HbA1c result with that of a friend who lives at the other end of the country.

Measurements
The general recommendations are that HbA1cs should be below 7.0% in people with diabetes. [In people without diabetes HbA1cs are between 4 and 6%.] Your doctor should discuss your target HbA1c for you. Your HbA1cs should be measured twice a year and if this is not happening you should ask why not.

Factors affecting HbA1cs

- The test detects glucose attached to normal haemoglobin but scientists have discovered 850 variants of haemoglobin and these could result in abnormal results.
- glucose is not the only molecule that attaches itself to haemoglobin - people taking high doses of aspirin can have abnormally high HbA1c results as can people with kidney disease.
- genes also influence HbA1c levels so that the same average blood glucose level may result in different HbA1cs in different people.
- The day to day things of life can affect your HbA1c. For instance if you have been ill recently resulting in diabetes control being difficult, then a test taken immediately after would give higher results and this does not necessarily means that your control has been adrift for the whole 2-3 months.
- If you have had a period of a lot of hypos, then you may be told that your HbA1c is good and so is your control. But actually a lot of hypos is not good control - the test result means that because you have not had high sugars, less glucose has attached itself to the haemoglobin.

Generally speaking your HbA1c results should be consistent with your daily blood glucose tests - if you control is good on a day to day basis, then your HbA1c should be low but there is no advantage in having so-called 'good' HbA1cs if you are having frequent hypos! If your HbA1cs do not tally with your home blood glucose tests, your meter may not be working properly or you may need more training in using it.

Both tests have their place!

Daily self-monitoring of blood glucose has the advantage of telling you what your glucose levels are at that moment in time. It gives you reassurance and also enables you to take any action necessary as a result of the test - eat if your sugars are low, take exercise, eat less or increase insulin dose if they are high.

NHS News

Prescription charges to rise by 10p - from April 2005, the cost of an NHS prescription in England is to rise by 10p to £6.50 which is expected to produce more than £400m for the health service. The cost of a 4month prescription prepayment certificate will go up by 50p to £33.90 and for a year's certificate by £1.40 to £93.20. People with diabetes are exempt from prescription charges, except those on diet-only treatment. NHS dentistry charges will also go up with the maximum cost for a single course of treatment being £384.

Patient choice and cataract surgery - as part of the government's initiative to give patients choice, from January 2005 people requiring cataract surgery, including those referred by an optometrist, are to be offered a choice of hospital at the time they are referred. The NHS Guidance says that this choice should be between two alternate providers in January 2005 rising to a choice of 4 or 5 by December 2005 and these choices include NHS or private hospitals.

Government and drugs industry do a deal - over the next 5 years the NHS is to save 7% on branded drugs bill. In return the pharmaceutical industry has been given a 5% increase in its allowance for research and development. According to a BBC report, the government has claimed that the money will be invested into frontline primary care services but the NHS Alliance that represents Primary Care Trusts [PCTs] maintained that it is not clear that the money would be handed to Trusts.

Many patients will soon be able to make an appointment to see a GP over the internet - EMIS, a Leeds based firm provides software to 55% of GPs in England that will enable patients to make or cancel GP appointments online. It also allows patients to ask their GP confidential questions online and to update their own contact details. The software has been tested by 150 GP practices and is now available across the country. The company maintain that this system could save the NHS millions of pounds. One of the drawbacks of the system is that it only appeals to certain groups of patients - those who use computers.

NHS ban on top rate phone lines - from April 2005 NHS organisations will be banned from setting up new premium and national rate telephone numbers for patients contacting local services. GP practices currently using national rate phone lines will be expected to switch to low rate numbers. These numbers are used in 290 GP practices to take appointments and for requesting prescriptions. This ban will also apply to NHS dentists, NHS opticians and out of hours service providers although dentists will have until the summer to comply. National rate numbers start with 0870, premium rate numbers start with 09. In future the only special service numbers the NHS will be able to use are freephone numbers or low rate calls that include 0845 and 0844 numbers.

Snippets...

Fatter Americans cost the airlines and the environment - researchers in the US estimate that in 2000 American airlines spent an additional 275million US dollars on fuel to carry the additional weight of passengers. In the 1990s the average weight of Americans increased by 4.5kg. The amount of extra fuel now burnt is about 1.4billion litres and burning this puts an extra 3.8million tonnes of carbon dioxide into the atmosphere.

Brazil's biggest baby - was born in January weighing 17pounds, more than double the average UK birth weight. It is likely that the mother's diabetes was the cause of the large baby - the higher the mother's blood sugars, the more insulin her baby produces and insulin is a potent growth stimulant. The world record of big babies is held by a 32ppund baby born in France in 2001. Needless to say both babies were born by Caesarean Section!

Downhill Exercise May Be a Good Thing - an unusual study of hikers in the Alps found that different types of exercise had different effects on fats and sugars in the blood. Going uphill cleared fats from the blood faster, going downhill reduced blood glucose more, and hiking either way lowered bad cholesterol. Dr. Heinz Drexel of the Academic Teaching Hospital of Feldkirch, Austria reported the research to the American Heart Association Conference in New Orleans, and said that both types of hiking are beneficial, but one may help people with diabetes more than the other.

McDonald's growing faster in China than the United States - according to a survey of more than 14000 adults in 28 countries, researchers found that 41% of those surveyed who live in China eat in a fast food restaurant once a week compared to 35% of people in the US and 30% of people in Australia. When the first McDonald's opened in Beijing 12 years ago, 40,000 people lined up to observe a Big Mac and have their picture taken with Ronald McDonald! Now McDonald's operates 600 stores across 105 cities across China and plans to open another 100 a year in the coming years. [Business Wire, 21.12.04]

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

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From Your Editor – Jenny Hirst

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Insulin Dependent Diabetes Trust
PO Box 294
Northampton
NN1 4XS

tel: 01604 622837
fax: 01604 622838
e-mail: support@iddtinternational.org
website: www.iddtinternational.org