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Insulin Dependent Diabetes Trust

July 2006 Newsletter

Why Are People So Passionate About Animal Insulin?

The answer is simple - they are passionate about having a future. For people who have experienced the adverse effects of synthetic insulins, and for their relatives, this is not a dramatic, emotional response but one that is based on their experiences.

As the editor of this Newsletter, I freely admit to being passionate about animal insulin. At the age of only 18 my daughter was very ill and deteriorated to the stage that she could hardly walk but within days of changing to animal insulin, she improved beyond belief and has had 17 health and happy years using animal insulin. As a mother, I expected to worry about her future and the risks of long term complications but in a developed country with a health system, I did not expect to have to worry about the possibility of the insulin she needs not being available to her. We share these experiences with many other people and yes, we are entitled to be passionate about animal insulin, it holds the key to a healthy life for so many people.

The looming discontinuation of pork insulin by Novo Nordisk has raised emotions amongst people - fear for their future and anger because their health is being put in jeopardy by ‘rationalisation of a product range’, or put more simply, by the desire of pharmaceutical companies for even greater profits.

We understand that the general public believes that insulin is insulin per se, but surely everyone involved with the treatment of diabetes knows that insulins are different, people are different and what suits one will not necessarily suit another, or do they? That the question in the title is being asked at all shows a lack of understanding of

people with diabetes and indeed, of diabetes itself. ‘Why are people so passionate about animal insulin?’ The answer to this lies in a letter received a few weeks ago from an IDDT member:

‘I have been diabetic since the age of six; I am now forty five years old. I was always healthy and fit until the early 90s when I began feeling lethargic and generally run-down. I now know this was due to a change of insulin - from pork to synthetic with no reason and without my knowledge or consent.

At first there seemed to be no difference, but over time, the side effects became increasingly worse and over a number of years built up to include the following symptoms:

Loss of hypo warnings
Extreme tiredness
Unstable blood sugars
Non-stop bad dreams
Fits with hypos
Paranoia
Extreme fatigue
Mood swings
Aching bones [similar to arthritis]
Muscle cramps
Panic attacks
Depression
Hair loss / poor hair condition
Generally unwell
Extreme perspiration

In 2001, when at death’s door, I insisted on being put back on pork insulin because everything the doctors and diabetes nurses had attempted to relieve the side effects had failed [apart from changing the one thing it had to be]. Within three days, every side effect had reduced to such a level that I felt like a new person. Within a three-month period, I was 100% improved, although I have never regained my hypo warning signs, a condition that I attribute wholly to the long-term use of synthetic insulin.

I have received your Newsletters since 2001 and compliment you on your professional and accurate portrayal of information. I also think it is important that you are not funded in anyway by the very pharmaceutical company that is ceasing production of a valid and proven insulin that some of us need. So I thank you once again for a life-changing Newsletter.’

Even Tighter Targets For Diabetes Control - Can We Do It?

A report by the Joint British Societies, ‘Guidelines on the Prevention of Cardiovascular disease in Clinical Practice’ was published in December 2005 and sets even tighter targets for people with diabetes [and the general population].

The targets are as follows:

- pre-prandial [before a meal] blood glucose levels of 4-6mmols/l
- HbA1cs of 6.5% or below. [long-term test showing average blood sugars over lat 6-8 weeks]
- blood pressure target - 130/80mmHG
- total blood cholesterol target - less than 4.00mm/l or a 25% reduction; LDL cholesterol [the bad stuff] lower than 2.00mmol/l or a 30% reduction

Looking at these targets, one wonders how many patients were present when they were made and if those setting these targets look at any other aspects of living with diabetes, in other words ‘real life’.

Raising the targets raises a whole load of questions and practical issues for people who actually have diabetes. Here’s a few:

- What extra help and support is going to be given to people to help them to try to achieve them? Are there going to be more frequent clinic visits? We have known since 1991 and the Diabetes Complications and Control Trial [DCCT] that tight control reduces the risk of complications, but the follow up study also showed that once the study had finished, people could not maintain the same level of tight control. So simply raising targets without the extra help needed to achieve them, may not be effective for many people.
- What about the trebling of the increased risks of severe hypos that we know occurs with tight control if the targets are 4-6mmols/l and HbA1cs of 6.5%? [Again results from DCCT 1991] Tight control increases the risks of hypo risks per se, so what about the increased risks of loss of hypo warnings, a cause of which can be frequent hypos?
- What about driving with a pre-meal blood glucose level of 4? With the known inaccuracies of meters, a level of 4 could actually be less than 3.9 which is hypoglycaemia and is known to impair judgements, could cause traffic accidents and ultimately loss of driving licence and loss of job.

Diabetes UK 'welcomes the challenging targets because more than 25,000 people with diabetes die from cardiovascular disease every year' and states that 'though not everyone will achieve the targets straight off, any progress towards them will help reduce the risks.' [Diabetes Update, Spring 2006] This is undoubtedly true and the medical thinking is understandable - to help people reduce the risk of long-term complications. However, people with diabetes may have a different perspective and a different set of priorities that are more to do with the quality of their everyday life and that of their families. It is all about choice, so set the standards but at the same time understand that people may have other priorities and should not be made to feel failures for not achieving the targets.

The avoidance of complications is vital and no one would dispute this but to people with diabetes, the quality of life is also important.

Frequent hypos and/or hypos that require the assistance of partners or parents, reduce the quality of life for everyone. It is well recognised that people avoid hypoglycaemia by keeping their blood sugars a bit higher than recommended, but this gives rise to conflicts - do I do what the doctor says and achieve the targets or do I run the risk of hypos at work etc.

For some people constantly trying to achieve targets by increased blood glucose testing, increased injections and increased numbers of medications is seen as a reduction in their quality of life. All this and then perhaps failing to achieve the targets can give rise to a hold load of other emotions - feelings of failure, of low self-esteem, depression and wanting to give up altogether.

Setting higher targets places additional pressures upon both people with diabetes and their families.

An article by Marie Clark [Pract Diab Int, March 2006 Vol 23 No.2] says of more intensified treatment and increased self-management that the advances in medicine have increased the demands on the individual. How well those living with diabetes are able to self-manage diabetes depends on many factors and there is increasing evidence that emotional and psychological well-being play a major role in this. This is why the National Service Framework [NSF] for Diabetes includes a section 'Empowering People with Diabetes' which recommends that psychological support is part of the treatment for diabetes. Marie Clark's article says that 'psychological and emotional well-being is the foundation upon which all other aspects of the treatment regimen should rest.'

So if targets are to be tighter, greater help and support is needed f or people to achieve them or to help people cope with not achieving them!

Dispelling The Myths

My diabetes nurse has told me that I can't use pork insulin because I am on such large doses of 'human' insulin, is this true? NO and in fact quite a lot of people find that they need less insulin when they change to pork insulin.

My diabetes specialist nurse has told me that pork insulin is not available in cartridges for use with a pen, is this true? NO, Wockhardt supplies pork insulins in both vials and cartridges.

My diabetes nurse has told me that I can't use pork insulin because I am not insulin dependent but have Type 2 diabetes so have to be treated with 'human' insulin, is this true? Insulin dependent diabetes was the commonly used name for what is now called Type 1 diabetes. However, whether or not you have Type 1 or Type 2 diabetes treated with insulin, you can still use pork or beef insulin.

Northwick Park - New Rules On Drug Trials

April 6th 2006 - the interim report on the drug trials at Northwick Park hospital that resulted in 6 men being in intensive care, found no evidence of human error, contamination or failure to follow protocols but stricter rules are to be introduced for drug tests on people. The report suggested that the drug TGN1412 caused an unprecedented and unexpected reaction that did not occur in tests on animals. Medicines and Healthcare products Regulatory Agency (MHRA) chief executive, Kent Woods, said that future trial applications for biological agents would be subject to new levels of scrutiny:

- such agents will now be seen by the Commission on Human Medicines as well as the MHRA, with further external experts brought in ad hoc should any doubts remain.
- a working group is also being set up by the government to examine the transition from animal to human testing involving biological agents with novel actions.

Professor Woods said that the interim report raised questions about the potential risk involved in human trials, particularly the new class of drugs which work by stimulating action affecting cells in the immune system. He also said that this is a complex scientific issue which raises important scientific and medical questions about the potential risks associated with this type of drug and how to make the transition from pre-clinical testing to trials in humans.

Call for independent inquiry

There are calls for an independent inquiry, as it is being suggested that the Health Select Committee Report on the influence of the pharmaceutical industry [April 2005] casts doubt on the MHRA's suitability to carry out an investigation. The Committee's report said 'The organisation, process and techniques of the MHRA are focused on bringing drugs to the market fast. The organisation has been too close to industry, a closeness underpinned by common policy objectives, agreed processes, frequent contact, consultation and interchange of staff. We recommend that more research be undertaken into the adverse effects of drugs, both during drug development and medicines licensing.' So maybe in independent inquiry is the correct way forward.

The rush to licence drugs

One of the delays in bringing new drugs to the market is that many companies were already struggling to find people prepared to enter trials. A recent report published by market intelligence firm Cutting Edge Information showed that 30% of clinical trial time is spent finding and enrolling study participants - the cause of almost half of all trial delays. In many cases trials are being delayed by over six months costing drug companies over half a million dollars in lost sales for specialty products and more than $8m (?6.7m) for blockbuster brands.

Pressure on people to take part in trials

It is important that new drugs [and new insulins] are developed but

this is almost bound to involve trials in people. The first trials take place in healthy men [men because they are not likely to be pregnant!] and then in people with the disease/condition for whom the drug is designed.

Taking part in trials is or should be entirely voluntary but some people feel obliged to take part especially if their doctor is running the trials - they want to please their doctor or they feel pressurised to do so. Other people want to take part in trials, especially if there is a 50/50 chance that the new treatment may be better and in the case of trials related to diabetes, the care received is usually significantly better than 'normal care'.

So before agreeing to participate in a trial here are a few things to think about:

- It is important to know that the effects of older chemical drugs are likely to be more predictable than with the newer biotech drugs and so the risks with them are greater.
- Do not feel you have to take part in trials because your doctor or clinic has asked you
- Take the details of the trial home with you and read them carefully and see what is involved
- Always ask questions about anything you don't understand
- Ask if the trial is to be published as it is important that your effort in participating in the trial forms part of the evidence on which the drug/treatment can be judged
- Ask if the trial is being sponsored by a pharmaceutical company or is an independent study as this may affect your decision
- If you decide to enter the trial, you should be given a consent form, and again read carefully and if there is anything you don't understand, ask the questions
- Do not be rushed into a decision, take your time.

Changes to improve improve the safety of drugs

March 28th - the Dept of Trade and Industry [DTI] has set up an £8million fund to stimulate research into safety biomarkers. Biomarkers are an emerging science which will help assess and predict toxicology and adverse side effects of potential medicines in pre-clinical research. The use of these techniques will help drug companies identify compounds for elimination at an earlier stage which is expected to save costs on research, speed up medicine development and contribute to a reduction in animal research. In the long-tem it is also expected to contribute to patient safety.

May 22nd - in the wake of Northwick Park, the World Health Organisation is calling for greater transparency in clinical trials by announcing new registration standards for all medical research involving humans.

Just To Remind You

Date for your diary - IDDT's Annual Conference entitled 'Make your Voice Count' is on October 14th 2006 at the Paragon Hotel in Birmingham. Please do come and join us - the programme and further details are available by contacting Bev Freeman at IDDT on 01604 622837, e-mail enquiries@international.org or write to IDDT, PO Box 294, Northampton NN1 4XS

If you are a parent of a child or teenager with diabetes - in May 2006 IDDT published it's first Parents Bulletin, If you would to receive this and future copies, just get in touch with Bev as above.

IDDT Goes To Westminster

Report from Jenny Hirst

Thanks to you - our members

I would like to thank all our members who have written to their MPs about the discontinuation of Novo Nordisk pork insulin and the supply problems there have been with Wockhardt's animal insulins. The key points that you have made are the vulnerability of people who need pork insulin when the UK is left with only one supplier and the misinformation that is being given by health professionals about future availability. Your letters have supported us when meeting MPs and asking them to table Parliamentary Questions and of course, they have resulted in the Minister of Health and the Dept of Health being made well aware of our concerns!

Working with our advisers, the following has been achieved:

- The Earl Howe and John Baron MP had a meeting with the Minister, Jane Kennedy MP to put our concerns to her.
- A meeting with the officials from the Dept of Health, Novo Nordisk [NN], Wockhardt, Diabetes UK and the JDRF to discuss the confusion amongst healthcare professionals and patients about the Novo Nordisk discontinuation of pork insulins, made worse by the misinformation about temporary shortages of Wockhardt insulins. It was agreed that all steps possible will be taken to ensure that everyone using NN pork insulin would be informed that they can continue to use pork insulin from Wockhardt including a warning seal on every NN pork insulin pack and letters to GPs. Wockhardt is building up their stocks to take into account the increased demand from the NN withdrawal and to have 3-6 months contingency stocks.
- Over 30 Parliamentary Questions have been asked along with follow up Questions to the Minister's response, if appropriate.

The aim of the Parliamentary Questions is:
Secure supplies - to ensure that supplies of animal insulins are secure when there is only one supplier and to encourage the Dept of Health to have back up supplies in place.

NICE appraisal of all insulins - asking the Minister to refer all insulins to the National Institute of Clinical Excellence [NICE] for an appraisal of their clinical effectiveness and their cost effectiveness. As diabetes affects so many people and is such a high cost to the NHS it seems only reasonable that NICE should do this, as it does for many other drugs but it is particularly important because [i] choice is being reduced by the Novo Nordisk discontinuation of pork insulins and some human insulins so we need an assessment of the all the alternatives [ii] there are concerns about the long-term safety of analogue insulins [iii] Canada has not approved Lantus for funding and Germany has not approved NovoRapid for funding for Type 2 diabetes, so surely NICE should carry out an appraisal of all insulins in the UK.

Adverse reaction reports - the information on these on the Yellow Card Reports available to the public has not been updated since it was first available in January 2004. With the increasingly widespread use of analogue insulins with only scant evidence of benefit for some people, it is important that patients have access to up-to-date information on suspected adverse effects to enable them to make informed treatment choices. As IDDT has received a lot of complaints about long-acting insulins and Lantus in particular, the Minister was asked how many adverse reaction reports there have been and how many deaths. The answer is: "A total of 373 reports of suspected ADRs have been received in association with insulin glargine [Lantus] since January 2002 and of these 15 had a fatal outcome. Where cause of death was reported there is no particular pattern."

NOTE WELL - The reporting of a suspected adverse reaction does not necessarily mean it was caused by the drug as it may relate to other factors such as underlying illness or other medicines taken concurrently. It is not valid to compare the number of reports of suspected adverse reactions between products as a number of different factors affect the level of reporting of adverse reactions including the level of usage of the product, how long the product has been on the market and any publicity surrounding the product.

Future actions - again I would like to thank all our members and their Members of Parliament for their support. I assure you all that we will continue to do all that we can to make sure that animal insulin users

are not forgotten and that all insulins are demonstrated to be safe and effective.

Pharmaceutical Industry News

New Code of practice for industry - in January 2006 the Association of the British Pharmaceutical Industry [ABPI] introduced a tighter Code of Practice to govern relationships between the pharmaceutical industry, health professionals and patient/carer groups ie acceptance of gifts etc or in the case of charities, funds. A survey by the ABPI showed that only 52% of all doctors are aware of the ABPI Code of Practice with 65% of GPs being aware compared to only 40% of hospital doctors.

Damages awarded in the latest Vioxx lawsuit - law suits have followed the withdrawal of arthritis drug Vioxx by manufacturers Merck, on evidence that it increased heart problems. A recent case in the US awarded $13.5million of damages when the jurors concluded that Merck delayed notifying patients of the risks once they were aware of the drug's dangers. This case was the first to involve people who used the drug for more than 18months and is important because the study that resulted in the withdrawal of Vioxx found that its risk doubled after 18months' use. Merck faces 10,000 Vioxx related lawsuits in the US.

A new drug to treat neuropathic pain - Lyrica made by Pfizer. The doctor who ran pre-marketing trials has said that it provided rapid and sustained pain relief among the participants. However, the common adverse effects are dizziness, sleepiness, dry mouth, swelling of hands and feet, blurred vision, weight gain and trouble concentrating. Finally patients with a history of drug or alcohol abuse may have a higher chance of misuse or abuse of Lyrica. It is available on an NHS prescription.

Shopping Around For Doctors!

Thanks to the actions of the pharmaceutical industry, in most countries there are NO animal insulins but most countries do have a system for personal importation of drugs that are not licensed in their own country. This is the case in the US so in theory people who cannot tolerate human and analogues insulins, should be able to import beef or pork insulin from the UK for their personal use. But this is proving difficult and in some cases, impossible. The reason? Doctors are refusing to write the necessary letter for importation which has to say [i] animal insulin is medically necessary and not available in the US and [ii] that he/she will report any adverse reactions.

Not too difficult one would think but many doctors are not prepared to prescribe animal insulins as they are classing them as 'unapproved drugs' when pork insulin was approved and available until just a few weeks ago! This is illogical nonsense that is harming people with diabetes and causing great distress:

Nonsense - before their discontinuation, both beef and pork insulins were available over-the-counter [no prescription needed at all], and this was classed as safe.

Nonsense - doctors won't prescribe animal insulins that have been used safely for many years and yet they are happy to prescribe new insulin analogues where the long-term safety is unknown!

Nonsense - the reason for the refusal to write the letter could be doctors' fear of litigation, perhaps understandable in the US, but don't they fear litigation if harm comes to their patient as a result of adverse effects from using synthetic insulins because they have refused to supply animal insulin?

What's the answer? IDDT receives desperate calls, letters and e-mails from people in the US who need animal insulin and the only answer we have is to advise them to shop around for a doctor who understands the needs and indeed, understands the first ethical

principle of medicine - first do not harm.

Canada - Wockhardt Pork Insulin Is There, But?

For our Canadian members, the good news is that following Lilly's discontinuation of Iletin II [pork] insulins in April 2006, Wockhardt Hypurin porcine insulins are now available in vials. The details are:

Hypurin NPH Insulin, Pork [DIN 02275864] - short-acting
Hypurin Regular Insulin, Pork [DIN 02275872] - intermediate-acting

Your pharmacist can access this insulin by contacting:
Nucro-Technics, Tel: 416 438 6727 Fax: 416 438 3463 or
info@nucro-technics.com

At the time of writing, Wockhardt is applying to the provinces to have this insulin included in their formularies which is required for patients' costs to be covered.

However, the bad news is that the cost is just under $100 per vial [£50] which gives it the very dubious honour being about the most expensive in the world! One of the major concerns is that at this price, will the provinces fund it? Even if they do, under the Canadian health system the cost is not covered for everyone. So for people requiring 4 vials a month, the cost could be $400 dollars = £200 a month! No matter how much people need pork insulin, for some, it will simply be unaffordable.

It was actually slightly cheaper to import directly from the UK but this option is now no longer open because Wockhardt pork insulin now has a licence in Canada. Needless to say, people in Canada feel very let down - the promise that they would not be denied the pork insulin they need but when it arrives, it is at a price that is unaffordable for many people. IDDT-Canada and the Society for Diabetic Rights are working together to try to help this unfair situation.

What's New

- **Autopen Special and the Autopen Junior discontinued** - from June 1st only the Autopen Classic will be available from Owen Mumford. This is now the only pen available for users of pork and beef insulins. It is a pity that they have not kept the Autopen Junior because the colours of the markings, black on yellow, are easier to see for people who are visually impaired.
- **Updated version of the needle free injector, mhi-500** - called the SQ pen, still made by the Medical House and available on prescription. There has been a medical device alert issued to warn people using the mhi-500 devices made before June 2005 - it could break and become unsafe either when it is dismantled to add or remove the comfort rings or if it is fired without insulin in the nozzle. New instructions have been issued by the manufacturers and are also being given out with the purchase of mhi-500 consumables. The mhi-500 devices made after June 2005 have the comfort rings fitted by the manufacturers and therefore do not need to be dismantled. Further help can be obtained from the Medical House on 0800 917 7326.
- **New blood glucose meters** - Glucomen Visio by Menarini Diagnostics which doesn't need calibrating and has an adjustable lancing device to reduce the pain. Then there is another new meter from Roche, Accu-Chek Compact plus, which is a combination device of meter, test strips on a drum and detachable finger pricker so theoretically tests could be done with one hand. More details are available from Roche's website www.accu-chek.co.uk

Inhaled Insulin - We Can't Avoid Talking About It!

The interim recommendation from the National Institute for Clinical Excellence [NICE] that inhaled insulin, Exubera, is not funded by the

NHS has caused quite a fuss, hitting headlines in the newspapers. It was even raised in Prime Minister's Question Time when the Chairman of the All Party Diabetes Group asked the Prime Minister to look again at the NICE decision and on this occasion, Tony Blair's answer seemed sensible. While agreeing to pass the remarks to NICE, he said: 'It is important to remember that that body ends up making clinical decisions. I am not qualified to do that and neither is he.'

The Times made political mischief on their front page by linking the NICE decision to shortages of funds within the NHS. Sadly in the Letters column the next day, an angry father wrote to ask members of NICE if they had tried chasing a 4year old around struggling to inject him. While sympathies are with the father, it is sad because he has been so misled by all the hype about inhaled insulin - no trials have taken place in children and Exubera was NOT licensed for use in children. For months newspapers have raised people's hopes for inhaled insulin, no doubt fuelled by press releases from manufacturers but the newspapers gave a very one-sided story in making their claims that inhaled insulin is the greatest breakthrough since insulin was discovered. But is it?

It could lead to better and more reliable alternatives to injections, so in this sense it is a great breakthrough but we should not lose sight of other great breakthroughs that have had a truly dramatic effect on the lives of people with diabetes. The development of long-acting insulins in the 1940s made a huge difference - can you imagine life without them? Home blood glucose monitoring was probably the greatest breakthrough since 1922 - it has resulted in better diabetes control and knowing what their blood sugars are at any given time provides people with a better quality of life. Can similar claims be made for inhaled insulin? Based on the evidence so far, the simple answer is, no.

Let us look at some facts:

1. Inhaled insulin is licensed for use in adults only, not children. The trials have been carried out in adults with Type 1 and Type 2 diabetes but no benefits in diabetic control have been shown.
2. Injections of long-acting insulin are still necessary so people who are needle phobic will still have to inject. Trials have only been carried out with 'human' insulin as the long-acting insulin and NOT with analogue insulins which are now widely prescribed, so again the safety is unknown if Lantus or Levemir are used.
3. The long-term safety is unknown with concerns about possible lung damage and the effects on the development of insulin antibodies. It is not suitable for people with underlying lung disease, those with asthma or smokers.
4. The amount to be inhaled is in 3 units, so people who make small dose adjustments of 1 or 2units will not be able to do so with Exubera.
5. The inhaler is not small like an asthma inhaler, but opens up to about 9 or 10inches, there are 5 steps to prime it. There is no way that it could be used discreetly in public, as is the case with injections! Women would need a fair sized handbag to carry it around and men could not fit it into a jacket pocket as they do with pens or syringes.

So what are the benefits?

The benefits appear to be patient preference and quality of life, but NICE considered the information on this was insufficient. Some of the evidence on quality of life was gathered from people with Type 2 diabetes who don't use insulin, so could they make a fair comparison between inhaling and injecting insulin?

It is argued that people with Type 2 diabetes are put off going on to insulin because they have to inject and if inhaled insulin was available to them, they would start insulin treatment sooner, so reducing the risk of complications. The logic of this argument does not stack up as they would still have to inject long-acting insulin. There is also evidence that one of the reasons people are put off going on to insulin treatment is that they think this means their diabetes has got worse - this would still apply if they used inhaled insulin. So the evidence suggests that the people who could benefit would be those with Type

2 diabetes who have yet to go on insulin.

Then there is the cost!
It will cost an extra £500 per patient per year. NICE made this interim decision by looking at inhaled insulin on its own merits. We should do this too but we can also look at it on a broader level - at a time when people are being refused essential blood glucose testing strips to save NHS money, should NHS money be spent on inhaled insulin when the evidence shows little benefit and unknown long-term safety?

Note: The NICE recommendation is only interim and the final decision will be made later this year. On May 15th Pfizer told Pharma Technologist.com that they vow to fight the decision and are confident of having it overturned in light of 'new evidence.' We shall see????

May 4th 2006, Germany takes a similar stance - the Institute for Quality and Efficiency in Health Care (IQWiG) in Germany has published a report showing that there is no additional therapeutic benefits to replacing insulin injections with inhaled insulin; no evidence that Exubera shows advantages over injected short-acting human or insulin analogues; no evidence that it would improve the quality of life or treatment satisfaction of diabetes patients in Germany. However, they state that there are indications of disadvantages of Exubera therapy eg an increase in severe hypoglycaemia rates. IQWiG recommends further evaluations and an adequately designed randomised study before Exubera is widely prescribed in Germany.

The significance of Exubera to the pharmaceutical industry - "The groundbreaking approval of Exubera signals that exciting times are ahead for the pulmonary route of drug delivery in many disease areas.' [In-PharmaTechnologist.com 21.4.06] In other words, Exubera approval opens the door for this method to be used for other drugs. So just as human insulin was the first GM drug to be approved and opened the market for all other GM drugs, inhaled insulin is set to do the same for inhaled drugs!

More News On Driving

Driving restrictions for people with Type 2 diabetes reassessed
As a result of new research, the Dept of Transport is to consider easing the driving restrictions on people with Type 2 diabetes taking insulin. At present they are banned from holding a Group 2 licence, which includes lorries and buses, because of the risk of hypoglycaemia which can cause blurry vision and delayed reactions.

New government research using self-reported hypoglycaemia and continuous glucose monitoring over 9-12months has shown:

- people with Type 2 in the early stages of insulin treatment are at no greater risk of hypoglycaemia than people treated with sulphonylureas [tablet treatment that can cause hypos]
- people with Type 2 in the early stages of insulin treatment may be prone to less severe or less frequent periods of hypoglycaemia compared to people with Type 1 diabetes.
- once insulin injections are used over a longer period in people with Type 2 diabetes, the rate of hypoglycaemic events begins to increase and by 5 years the risk is similar to that in people with Type 1 diabetes.

So it appears that some people with Type 2 may be less of a risk on the roads than previously thought. Road Safety Minister Stephen Ladyman has said the government will review the research to check the validity of the findings as there are potentially serious implications for driving licence entitlement. The research will be considered by Medical Advisory Panel on Diabetes and Driving to assess whether any changes to licence restrictions may be necessary. A European Commission medical expert group has been considering the minimum medical standards for diabetes and driving and is due to report shortly. The UK expert group is likely to wait for the results of this investigation before making any recommendation.

Campaign update - the DVLA, driving and visual fields
By Jackie Banks

I am pleased to report that after 7 years of campaigning on behalf of drivers with diabetic retinopathy, I was invited to attend the Dept of Transport Lay Interest Meeting on this subject [1.2.06]. The meeting was also attended by the At Work Partnership: Mr Peter Hamilton, retinopathy consultant: Mr Simon O'Neill, Diabetes UK: four lay members of the Secretary of State's Honorary Advisory Panel [DVLA]: Dr Liz McNeil Grist, independent medical writer and Dr Liliana Read, Dept of Transport.

The purpose of the meeting was to thrash out concerns and misunderstandings being experienced by drivers with retinopathy when they have lost their driving because they have failed to teach the current criteria for visual fields.

One of the concerns has been that testing is carried out on machines we find extremely difficult to use. The reason for this is that following retinal laser treatment you learn to adapt to any field loss by scanning with the eyes [which is required anyway in order to pass a basic driving test] whereas testing equipment requires central fixation of the eyes. The results are therefore known to be misrepresentative of what you actually see. In addition, the test machines have never been tested in controlled trials and were never intended to use for licensing purposes. However, results from them have been viewed by the DVLA as an accurate portrayal of what is seen.

Another concern has been an obvious lack of knowledge of retinopathy on the part of the visual disorders panel, leading to its insistence that retinopathy automatically leads to eventual blindness even after laser treatment, and therefore can never be stable.

These and many other related issues were discussed at length and all relevant points carried forward to the experts' workshop on retinopathy on March 2nd 2006. Following these meetings, I am now confident that the DVLA is now in full possession of all the medical facts relating to retinopathy. The experts are to meet at 2 yearly intervals, which has to be encouraging.

At the lay meeting, it was recommended that:

- a fairer approach to testing be adopted by the DVLA with on-road assessment being an option rather than licence removal in cases where field test results are borderline to requirements for as long as current test machines are still in use,
- if no further laser treatment has been given since the previous renewal, that field testing is unnecessary at renewal once the required criteria are reached.

I am hopeful that all these recommendations will be implemented.

Note: A consensus report agreed by the experts will be published for the public in about 6 months.

Dietitians Lack Training In Carb Counting

A report published in Diabetes Update [March 2006] of a survey of dieticians shows that 50% of dieticians feel that they need more training in carbohydrate estimation. One third of dietitians did not consider themselves confident to teach people on insulin about the quantity of carbohydrate in food. Dieticians who have had additional training or are treating patients on insulin pump therapy are more likely to teach carbohydrate estimation to their patients.

Diabetes UK who carried out the survey says: 'There are huge gaps in patient care and dietician's education and it is crucial that all people with diabetes have equal access to education. At the moment this is clearly not happening and people with diabetes may well be suffering as a result.'

Those of us that have lived with diabetes for many years must find the results of this survey amazing as we were automatically trained in carb counting as part of the standard education package - and by

dietitians! Much as we may joke about 10grams of potato being the size of a hen's egg and having little scales to weigh food, it provided us with sound knowledge of carbohydrate values that have stayed with us throughout life. Clearly this has been lost over the years and dietitians have not received the necessary training to treat people with diabetes appropriately.

As the three cornerstones of diabetes management of Type 1 diabetes are insulin, diet and exercise, this situation is a very worrying. How are people supposed to manage their diabetes if half of dieticians admit to not feeling able to teach people about carbohydrates? How can people be expected to meet the target blood glucose levels, if they are not adequately trained in carb counting? How can something as basic and essential to diabetes management as carb counting be omitted from the training of dietitians?

Has diabetes care become so wrapped up in National Service Frameworks, meeting targets, so called technological advances, post prandial and pre-prandial blood sugar levels etc etc, that the very basic facts about the treatment of diabetes, insulin, diet and exercise, have been forgotten?

Planning To Lose Weight?

By Katharine Morrison - a GP with a son who has Type 1 diabetes
Becoming and keeping slim is of even greater benefit to people who have diabetes than the general population. Abdominal obesity promotes insulin resistance and insulin resistance promotes abdominal obesity. Worsening of blood sugar control and the insidious death of overworked pancreatic beta cells results.

Most people know what to eat and what not to eat to stay thin. They just don't follow their plan consistently enough says weight loss doctor Stephen Gullo. He asks his patients, 'Do you really love this food so much that you want to wear it?'
He has many tips and strategies to help people succeed and these are published in his best selling book, 'The Thin Commandments.'

Keeping a written record of all the food you consume is a good starting point. Instead of grazing throughout the day or alternatively delaying and missing meals he recommends planned eating about every four hours. The food of course cannot be any old thing that is around. You must plan ahead. A simple and obvious thing to do, isn't it?

Yet, many things seem to get in the way of such a straightforward action plan. Emotional eating, food cravings, distractions, huge portions, just plain boredom. Every meal is a weight losing, gaining or maintaining opportunity. You have the choice.

It can be difficult to deal with carbohydrate and other cravings especially if you are sleep deprived or stressed. A high protein or high fibre breakfast can help. Protein shakes are portable and can blunt that sweet tooth. It is much easier not to buy food that you overeat rather than attempt to resist it once it is in your cupboard. High sugar or fructose plus fat seems to be the worst combinations for craving which stimulates fat storage. This combination is widely available in processed and fast foods.

Many people are quite frugal eaters till they get home at night. By then they are starving and then there is no holding back. An afternoon snack around 4 pm can help especially if it is of the filling high protein/ high fibre type. Following this with an evening meal with high fibre vegetables, salad, and an adequate amount of protein will keep you going till morning without over doing the calories.

Hunger outside with meal times usually means you have underdone the protein or overdone the rapidly acting carbohydrate at the previous meal. Your daily protein requirement can be worked out by dividing your ideal weight in kilograms by six. If a woman weighs 60kg for instance she will need 10 oz of lean protein a day split between meals

and snacks as a minimum. One egg is around one ounce of protein if this makes size estimation more meaningful.

When you shop for food go on a full stomach and don't buy naughty things for 'someone else'. Make a list and stick to it. For many people internet grocery shopping can help. What things do you find difficult to resist?

Apart from not actually buying and eating the stuff what else can you do to take your focus away from food? Social activiies, exercise, self soothing activities and house and garden work are all possibilities. 'Why are they so unattractive compared to eating a tube of Pringles in front of the telly?' I can't help but ask myself.

Dr Gullo insists that your lifelong success at weight control depends on how well you handle the foods that tempt you the most. For each food you have any sort of problem with you need to decide whether you can truly limit your consumption to special occasions or whether you need to eliminate that food entirely. This may seem rather harsh, but for virtually everyone a complete ban is actually easier than a plan to moderate consumption. It is an addiction after all.

Here are three tips to control cravings.

- Is it hunger? Eat cold meat or a boiled egg.
- Desperate for something sweet? Rinse your mouth out with dry wine, lemon juice or vinegar.
- Desperate for something salty? Eat something sweet like a square of high cocoa chocolate or suck an artificial sweetener tablet.

If you do go ahead and guiltily get tucked into your personal equivalent of my Pringles problem, what do you do next? Many people will do the manana, manana thing. I've done it now, so I may as well have toasted cheese, the kids' smarties, the leftover quiche and start again tomorrow. No. No. No. Says Dr Gullo. You must get back on the wagon right away. You are not on death row. This is not your last meal. There are lifetime consequences on your health you know. You need to eat foods that you like and are nutritious and that fill you up. And you must do this consistently.

The best foods to fill you up are white meat, fish and seafood, high fibre low starch vegetables and eggs. High calcium dairy foods, grapefruit and cinnamon can also enhance weight loss. Removing unnecessary fat from you meals by attention to cooking methods. Removing dressings and sauces also helps. Be careful to avoid alternatives such as 'lite' dressings that are bulked out with sugar. Just cut them down.

Drinking water, eating meals that contain a fixed amount of calories and exercise are all strategies that help weight loss.

As we know the first and last three minutes of our lives are the most dangerous. And it's a bit like this when you go into a restaurant. In the first ten minutes you are choosing what to eat and drink and are possibly getting stuck into the bread and butter. In the last ten minutes you have the desserts and cheese and biscuits and the bill to contend with.

Once you are a weight you are happy with it can be just as hard to keep it off. To do this you need to keep to your good habits and not go back to your self defeating ways. Remember that it will be the same old stuff that is likely to trip you up. You may have lost a lot of weight but you will never lose your vulnerability to the old habits.

As a society we do tend to reward ourselves with food as we celebrate life events and relieve our misery over daily events. How can you reward yourself differently? How can you promote healthy eating habits to get the best out of your life?

Test Your Knowledge

Ring your answers - the correct answers are at the end.

1. Who is responsible for your diabetes management?

A. You
B. The Consultant
C. The Diabetes Nurse
D. Your family

2. Which three of these parts of the body is affected by long term high blood sugars?

A. Heart
B. Eyes
C. Bones
D. Feet

3. Damage to nerves starts at blood sugars over which level?

A. 4
B. 8
C.12
D.16

4. For insulin users it is safe to go straight onto a low carbohydrate diet as long as you have..

A. Thrown out all your crisps, cereals and biscuits.
B. Bought a good low carb book to help you.
C. Bought in plenty of meat, vegetables and olive oil.
D. Planned out a gradual reduction in carbohydrates and appropriate reduction in your insulin with a knowledgeable heath professional.

5. What foods cause a rapidly high blood sugar level?

A. Starch such as bread and potatoes.
B. Meat such as fish and burgers.
C. Vegetables such as cauliflower or broccoli.
D. Fat such as butter and cheese.

6. Your HbA1c test is?.

A. A test of whether you are anaemic or not.
B. A test of your blood sugar control over the last week.
C. A test of your blood sugar control over the last two months.
D. A test of your blood sugar over the last year.

7. Useful strategies to control your weight are to?.

A. Write down everything you eat.
B. Write down how miserable you feel about being fat.
C. Write your will.
D. Write to Santa Claus.

8. You should eat?.

A. Only when you are hungry.
B. Regularly every 4-6 hours throughout the day.
C. Everything that is on your plate.
D. Everything that is in your fridge.

9. A useful strategy to help you eat less includes?.

A. Miss out breakfast when you are not hungry anyway.
B. Divert yourself by reading or watching television to take your mind off the food.
C. Stop cravings by eating a little of the food so it has less power over you.
D. Measuring out your portions.

Answers

Question 1 - answer A Although many people with different areas of expertise can help you with your diabetes the eventual responsibility for the things you do and the decisions you take is YOU.

Question 2 - answer C. There is practically no tissue in the body that is not affected to some extent by ongoing [chronically] high blood sugars but bones don't seem to be affected.

Question 3 - answer B. Chronic blood sugars over 7.8 (UK) or 140 (US) cause irreversible nerve damage.

Question 4 - answer D. It is essential that you plan the start of a low carb diet with care when you take insulin and indeed any drugs that lower blood sugar to prevent hypoglycaemia.

Question 5 - answer A. Bread and potatoes can break down about as rapidly as sucrose.

Question 6 - answer C. The HbA1c corresponds to the amount of sugar in the blood over the last 2-3 months.

Question 7 - answer A. Keeping an accurate food diary helps.

Question 8 - answer B. Regular meals help prevent unnecessary snacking or loss of control due to hunger when you do eat.

Question 9 - answer D. Measuring out your portions helps. Satisfy your craving just a little bit? You have got to be kidding.

NHS News

Investigations into the profits pharmaceutical companies make from the sale of drugs to the NHS - the Office of Fair Trading [OFT] is holding an inquiry to check whether safe and effective branded prescription medicines are being provided at reasonable prices to the NHS. The current Pharmaceutical Price Regulation Scheme [PPRS] is a voluntary agreement negotiated every 5 years between the Dept of Health and the Association of British Pharmaceutical Industry [ABPI] and the current agreement is due to run out in 2010. The PPRS sets a cap on the profits that each drug company can earn on its annual sales of branded medicines to the NHS. The inquiry is expected to take until the end of 2006. The results could be interesting?

NHS to merge local services
The government has announced that the number of primary care trusts [PCTs] are to be reduced from 303 to 152 and all the new organisations will be established by October 1 2006. The population covered by each PCT will rise from an average of about 165,000 to an average of just below 330,000. NHS ambulance trusts will also be merged from 29 into 12.

Out-of-ours service - the National Audit Office's [NAO] report on the handing over of out-of-hours health services [nights and weekends] from GPs to primary care trusts [5.5.06] showed the switch cost £70m, 22% more than the government allocated. Only 15% of PCTs met the requirement to provide emergency consultation at the healthcentre within an hour or urgent consultation within 2 hours. Only 2% managed to answer phone calls within a minute and only 8% began a clinical assessment of urgent calls within 20 minutes. The head of the NAO commented that PCTs are getting better but expressed disappointment that so few providers of the service are meeting their targets for the time it takes to respond to patients.

GPs to address obesity problems - Tony Blair and health minister Caroline Flint have announced that every GP will have to tell overweight

patients that they should lose weight, with children and young people being particularly targeted. [4.5.06] GPs will have to treat obesity as if it is a medical condition and advise overweight people to slim and obese people, regardless of age, to eat less, improve their diets and take exercise. They are also expected to encourage people to join leisure centres and children to have 60minutes exercise a day. [Our sympathies probably have to go to GPs - as this can't work in isolation!]

Dignity nurses to protect elderly patients - are to be appointed in every hospital to tackle age discrimination and ensure the elderly are treated with respect after evidence has emerged of the mistreatment of elderly people in hospitals. [20.4.06] [Treating older people with respect and dignity used to be common courtesy!] It is expected that national hospital ratings by the Healthcare Commission will now cover dignity issues with guilty hospitals downgraded. However, it was admitted there is no new money to fund this proposal!

Scottish Parliament keeps prescription charges - MSPs voted to keep prescription charges following a debate in the Scottish Parliament in January. However ministers have promised to reform the system and introduce more exemptions for chronic conditions, students and those on low incomes

Private Research News

Stress can delay healing
Researchers at Ohio State University team focused on 42 married couples and found wounds on hostile couples healed at 60% of the healing rate for non-hostile couples. Levels of interleukin-6 (IL-6), a key immune system chemical that controls wound healing, were found to be particularly raised in the hostile couples. Published in the Archives of General Psychiatry the findings showed that hospitals should try to minimise stress for patients ahead of surgery, as this could lead to shorter hospital stays and save money. Professor Steve Bloom, an expert in stress at Imperial College London, said "these findings are interesting, and illustrate yet again the control that the mind has over the body." As wound healing can be a problem for people with diabetes, this research may be of interest!

New developments in targeting kidney treatment
One of the long-term complications of diabetes can be kidney disease, called nephropathy. Initially the kidney becomes leaky so protein [albumin] appears in the urine and at later stages it may affect the functioning of the kidney. Researchers at Glasgow University have developed a new method for targeting treatment of kidney problems. They knew that the kidney was a difficult organ to treat because it is difficult to access with traditional drugs so they developed a new technology to allow drugs to target the kidney directly whilst still being administered through the rest of the body. They believe that this technology reduces the toxicity of the drug and increases its effectiveness. These are positive results and so a further grant from Kidney Research UK has been awarded to carry on with the research.

Dental care may help manage diabetes
Diabetes increases the risk of periodontal disease as a result of bacteria feeding on the excess glucose present in the saliva in people with diabetes. A study [April 2006 Journal of Periodontology] investigated whether common non-surgical gum treatment, scaling and root planing, would improve the blood glucose control of people with Type 2 diabetes and gum disease. They found that the treatment improved their HbA1cs [measure of average blood glucose levels over the last 6 to 8 weeks] from 7.2 to 5.7. The researchers made the point that reductions of this level could reduce the risks of diabetic complications and they recommended that further research is carried out involving more patients and comparing the effect of this treatment in people with diabetes and those without.

Diabetes and erectile dysfunction - erectile dysfunction is common in men with diabetes but a study carried out in Israel suggests that there are ways of cutting the risk. [Diabetes Care July 2005] The

study of 1040 men with diabetes with an average age of 57 involved participants answering questionnaires about their lifestyle and their doctors then filled in another questionnaire about their diabetes, treatment, complications and general health. The information from both questionnaires was combined and the showed that only 13.5% had 'normal' erectile dysfunction and in the remaining 86.5% it was mild to severe.

The study showed several things that increased the risk of erectile dysfunction:

- the older the man and the longer he has had diabetes
- poor diabetes control
- the presence of complications - heart disease, nerve, kidney and eye damage
- water tablets to treat high blood pressure.

The risks can be cut by better diabetes control and switching to a different type of drug to treat high blood pressure. The research also showed that men who were physically active at work or leisure had a lower risk of erectile dysfunction and so did men who had one alcoholic drink a day.

Cocktail of drugs offers hope for reversing diabetes - doctors have developed a mixture of two drugs that could reverse Type 1 diabetes. The cocktail combines a monoclonal antibody which calms the immune system with a peptide that acts like a vaccine to protect the insulin-producing cells. The approach focuses on teaching the immune system to tolerate rather than attack the insulin-producing cells. The adverse effects of suppressing the immune system is that it makes it increases the risks of cancers and viral infections but by combining these two drugs this risk is reduced because a lower dose of the immuno-suppressant antibody is needed. Trials of the monoclonal antibody in humans have already shown it can reverse Type 1 diabetes but the diabetes returned after a year. The results suggest that when combined with the peptide, the two drugs act together to produce a greater effect than either one individually. The combination has only been tested in animals but each of them individually is already being tested in human clinical trials. The researchers hope to begin human trials later this year but is waiting approval from drug safety regulators.

This Is One Time That You Don't Believe The Healthcare Professionals!

We are receiving lots of calls from people who have been told by pharmacists, nurses and doctors that animal insulins are no longer available in the UK. It is often said with great authority but it is simply not true. Here is the truth:

Novo Nordisk are discontinuing all their pork insulins - Pork Actrapid, Pork Insulatard and Pork Mixtard but they expect stocks to last until the end of 2007.

Wockhardt [formerly CP Pharmaceuticals] are continuing to supply pork and beef insulins in both vials and cartridges for pens.

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

Unlike Novo Nordisk, Wockhardt supply the above pork insulins in 3ml cartridges are for use with a pen and this has to be the Autopen Classic made by Owen Mumford - dosages are 1-21units and 2-42 units, available on a GP prescription.

Wockhardt also supply a range of beef insulins:

- Hypurin Bovine Neutral [short-acting] in vials and cartridges
- Hypurin Bovine Isophane [intermediate acting] in vials and cartridges
- Hypurin Lente [24hours] in vials only
- Hypurin Bovine PZI [30hours] in vials only

From Our Own Correspondents

Newly diagnosed
Dear Jenny

I received your information pack today. Excellent!!!!! The information is just what I am looking for it answers the questions we really have. Clearly you are dedicated to the cause so well done you must be very proud of your achievements. Have only read the January Newsletter so far and many of my questions have been topics of discussion so I'm off to bed to read the October one.

Thank you again!
Mrs J.S. by e-mail

I was diagnosed with Type diabetes in 1941
Dear Jenny,

As a newcomer to your mailing list, may I say how much I enjoy reading your Newsletters and all the information they contain.

I am 70 and became an insulin dependent diabetic in 1941, when I was 5years old. In 1987 the diabetic consultant decided that human insulin was for me, and over the following 5 years I went through hell. I asked him on numerous occasions to put me back on to pork insulin, but he refused. I had hypos three or 4 times a week at night and lost all the recognition signs of a hypo approaching. I also had neuropathy in my legs and even morphine could not suppress the pain.

My wife finally took me to our GP and thankfully he agreed to put me back on pork insulin and I started to feel better in 48 hours.

Mt present consultant tried me on Lantus which gave me excellent control for 3 years and then the hypos started again.

I now use Hypurin Porcine Neutral and Hypurin Porcine Isophane from Wockhardt which suits me very well.

Mr S.W.
South East

Remove prejudice
Dear Jenny,

I think in the Newsletters should stress that "ALL nursing and support staff should be educated NOT to be prejudiced against animal insulins," which is my experience locally.

Mr T.R.
S. East

Absolute disgust
Hi Jenny,

It is with absolute disgust I read in the April 2006 Newsletter that Novo Nordisk are discontinuing their pork insulins in 2007. We knew it was going to happen but now that they have confirmed this fact it just shows the integrity of these pharmaceutical companies. I wrote a letter last year to the New Zealand Minister of Health who confirmed that we would be getting a continuous supply of Porcine Insulin. Like a lot of people I cannot afford to import the "Wockhardt" insulins to New Zealand without a lot of financial distress. I will now have to decide do I go broke to keep my wellbeing or do I literally die a painfilled, mentally disturbed, drug distressed death because that is what it will amount to for me.

I dragged myself off GM insulins after being refused pork insulin for over 15 years with every excuse and reason under the sun being used and professionals messing around trying to stabilise me. I only succeeded in changing to pork insulin by slamming 42 pages of information(a lot from IDDT) down in front of my Diabetic Specialist and demanding a prescription for pork insulin.

I still suffer some of the after effects of those insulins but at least I am that much better mentally and physically. I can now put up with these effects a lot better and have been going to the gymn on a regular basis for two years now. I had my eyes looked at this week and my Eye Specialist couldn't believe that they were in such good condition for a type one diabetic of just on 50 years standing. My wife and I did a 4 week long trip around South America and the Galapagos Islands two years ago quite successfully. Something I never could have attempted while on Genetically Modified insulin that is for sure. I am even starting to get back some recognition of a hypo now which is saving a few blood sugar tests now and sore fingers.

Mr B.W.
New Zealand

DVLA - do not be bullied
Dear Jenny

Just a note on the subject of the DVLA and field vision test as I know just how the people in your latest newsletter feel. My husband and I have had 2 battles with the DVLA with regard to them trying to take his licence off him - the last one 2 years ago and one 3 years before that. There seems to be a pattern as the DVLA says sorry you can't have you licence back, the optician and hospital consultant say they see no problem. MANY e-mails, letters and phone calls later (the last time dragged on for 6 months) we threatened them with legal action and within days the licence was returned. We expect a new battle to commence in October this year.

I would like to tell all your readers to fight and not be bullied by these people as I think that they are counting on people backing down.

T. D.
By e-mail

BMA Report - Doctors Must Report Adverse Drug Reactions

The British Medical Association [BMA] has issued a new report *"Reporting Adverse Drug Reactions: A guide for healthcare professionals"* [11.5.06] calling on health care professionals to report to the regulatory agency when a medication has an 'unwanted effect', ie an adverse drug reaction [ADR]. The report suggests that at least a quarter of a million people each year are admitted to hospital with an ADR at a cost of around £466 million a year.

An ADR is an unwanted or harmful reaction experienced following the use of a drug or combination of drugs, and is suspected to be related to the drug. The reaction may be an already known side effect of the drug or it may be new and previously unrecognised. A spokesperson for the BMA pointed out that ***"When a drug is first marketed, its effectiveness may be well understood but relatively little may be known about its safety in the population at large."***

The report says:

- Healthcare professionals should consider it their professional duty to report suspected ADRs.
- All healthcare professionals should be vigilant about the status of medicines, particularly those labelled as black triangle medications which are those under intensive monitoring eg new insulins arriving on the market
- When prescribing drugs, doctors [and now presumably prescribing nurses] should tell patients that if they suffer any reaction to a

drug, they should inform the prescribing doctor [or nurse] and/or complete a patient Yellow Card as available on the MHRA website.
- Healthcare professionals should ask patients which medications they are taking, including any over the counter or herbal remedies to avoid interactions which can cause ADRs.
- The importance of reporting ADRs, known as pharmacovigilance, should be taught more thoroughly to medical undergraduates.

From January 2005 patients have also been able to report adverse reactions and IDDT recommends that people should be as vigilant in doing this as healthcare professionals. These reports can show a pattern to warrant further investigations into a drug or even signal its removal.

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. On this site you can also check the adverse reactions reports already made.

If you prefer to use a paper Yellow Card reporting form: GP surgeries should have them or ask for a form from the MHRA telephone 0207 084 2000 or e-mail patientreporting@mhra.gsi.gov.uk

It Worries Me When I Read

"A major concern about all newer insulin analogues is their altered mitogenic properties and resultant risk of carcinogenicity on long term use." [Indian Journal of Medical Science 2006 Mar;60(3):117-23]

Statements like this are appearing with greater frequency and yet insulin analogues are being increasingly prescribed, all too often without patients being aware of these risks. The risks may be very small but we don't know and we should. Do the benefits of insulin analogues outweigh their risks? We don't know.

And as if to prove this: at a Symposium of the German Diabetes Society in 2004 when asked about the carcinogenic risks of insulin analoges Dr. P.Kurtzhals, Vice President of insulin manufacturer, Novo Nordisk, said "We don't know".

Title of the Symposium 'Physiologische Therapiekonzepte mit langfristiger Perspektive', and the statement was published in "Diabetes-Journal" 2004 No. 7 page 12, "Arzneitelegramm" August 20,2004.

Changes In Benefits

Some people with diabetes need to claim Incapacity Benefit - government proposals to get a million people to return to work

In January 2006, the Dept of Works and Pensions [DWP] published proposals for reforming the Incapacity Benefit system. Quite rightly people with long-term conditions who are unable to work have been angered by the use of expressions such as 'the sick-note culture' which imply that they are choosing not to work. However, the green paper itself does not propose to cut or put a time limit on Incapacity Benefit but the high rate will be conditional on people taking steps to return to work.

Some people with diabetes need to claim Incapacity Benefit and are concerned about the proposed changes which are:

- Incapacity Benefit will be replaced by a new Employment and Support Allowance.
- The Pathways to Work Programme will be rolled out nationally by 2008. At present claimants have to attend one work-focused interview but this Programme means that people are compelled to attend five further interviews and draw up mandatory action plans.
- The number of conditions will be increased for sick and disabled

claimants with ‘manageable conditions’ but people with the most severe conditions will be exempt from these.
- The personal capacity assessment through which capacity for work is decided is to be reformed.

The green paper also announced a range of measures involving employers and GPs such as:

- Improved occupational health services for small and medium sized employers
- Better sickness management by employers
- Pilot schemes of employment advice services in GP surgeries
- Incentives to improve rehabilitation and occupational health provision in primary care.

The green paper can be found at www.dwp.gov.uk/aboutus/welfarereform

Note: Attendance Allowance - adults receiving Attendance Allowance may have noticed a change. In the past this allowance has been given for a specific period of time and then people had to go through the whole application process when in reality their condition may have remained the same or deteriorated. Now if the Attendance Allowance is granted there is no time limit but a statement that it could be reviewed at any time.

The Use Of Metformin In Type 1 Diabetes

A question that IDDT is frequently asked by people with Type 1 diabetes is why they are being prescribed metformin [Glucophage] when it is a tablet used in the treatment if Type 2 diabetes. There is very little research evidence about its use in Type 1 diabetes and the Specific Product Characteristics information produced by the manufacturers states: *“In Type 1 diabetes the combination of metformin and insulin has been used in selected patients but the clinical benefit of this combination has not been formally established.”*

In other words, formal clinical trials have not been carried out but it has been tried in some people and been found to be beneficial, although which people remains unclear. Gastric problems are a common adverse effect of metformin and this is why people ask us the question - do they really have to put up with frequent visits to lavatory?

Note: Generex is trying to develop a new metformin chewing gum that aims to avoid the significant adverse gastrointestinal side-effects that often accompany the use of metformin tablets.

Another use for metformin

Cochrane Review: The insulin-sensitising drug metformin increases ovulation in women with polycystic ovary syndrome.
Polycystic ovary syndrome [PCOS] affects menstruation, prevents ovulation and causes excessive body hair, hirsutism. PCOS involves resistance to insulin that may increase the risk of heart disease and diabetes. Usual treatments are hormonal. Metformin sensitises the body to insulin and this review found that metformin alone or in combination with clomifene, increases ovulation in women with PCOS and may reduce the effect of abnormal levels of male hormones. Adverse effects included nausea and vomiting and there is no information about the safety of this treatment in long-term use in young women. They conclude that metformin may reduce health risks from insulin resistance in women with PCOS but more research on long-term safety and effectiveness is needed.

Hospitals - You Can Help To Make Improvements

The article in the April 2006 Newsletter about problems people with diabetes experience in hospital raised some important issues and the one thing that people tell IDDT when they report bad experiences in hospital is that they don't want other people to go through similar difficulties. Making a complaint may mean that an apology and/or explanation may be received but it does not necessarily mean that changes in the hospital system or approach to people with diabetes will be made.

One way that this may be achieved is by reporting your experiences to the National Patient Safety Agency [NPSA] as one of its roles is to help the NHS learn from its mistakes so that patient safety can be improved. The NPSA does not investigate individual complaints but collects errors in healthcare so that they can identify trends and introduce practical ways of preventing similar problems in the future. Many of the problems people with diabetes experience in hospital are similar - removing insulin and pens, not giving injections and/or food at the right time, wrong insulin being given, not listening to or respecting the patients' knowledge of their own diabetes and mismanaging diabetes control. So it would seem that the NPSA would not find it difficult to pick up the trends and errors that occur in the treatment of people with diabetes!

So one practical thing that you could do if you experience problems in hospitals, or indeed within the NHS, is to tell the National Patient Safety Agency. Their contact details are as follows:

Call free on 0800 015 2536 or enquiries@npsa.nhs.uk or write to The Public Enquiry Manager, National Patient Safety Agency, 4- 8 Maple Street, London. W1T 5HD

Visit their website www.npsa.nhs.uk/pleaseask

Cost To The NHS and Taxpayer Of Test Strips

Readers may have seen an article in The Times in May suggesting that people with diabetes could be denied their test strips due to cost. This article was very misleading because the only people who should lose out are the manufacturers of test strips as the Dept of Health is proposing to reduce the reimbursement to them and so the cost to the NHS of test strips by 15% in August 2006. After an analysis, the Dept of Health has concluded that 'the NHS and taxpayer may not be obtaining value-for-money at the current rates.' It appears that there is a difference of up to 35% between costs in primary care and costs in secondary care [supplies to hospitals] and they do not believe that this difference can be reasonably explained. They put the proposal out to consultation with industry but have not received any convincing reasons not to reduce the reimbursement by 15%. Seems very sensible as the numbers of people using strips just goes up and up and yet the costs do not come down and down as they would do in the retail industry! Hopefully this will encourage GPs and Primary Care Trusts not to restrict the numbers of strips to people who need them.

IDDT is still receiving reports from members who are either being refused blood testing strips by their GP surgery or are having the numbers strips supplied restricted.

IDDT wrote to the Minister of Health and we were assured hat there is no national decision to restrict blood testing strips and restriction or refusal to supply is local level decision and it can only be a cost cutting exercise.

A lady with Type 1 diabetes was only allowed one box of test strips and at a time when she had a virus infection and wrote to IDDT:

"I rang the doctors to ask why I could not have more than one box and was told that they would only supply one box at a time because

some patients were hoarding them! I was then told that I could make an appointment with the doctor to ask if I could have another box. I found this totally insulting - a condition I have managed for 24 years and been told at regular clinic visits that blood tests were the most accurate and best way to control your diabetes, is now being rationed.

Blood monitoring has given me so much better quality of life so that I can live an active life, driving, walking helping elderly parents etc with the knowledge that I am not going to go hypo. I am not begging for something that I am entitled to. But it has made me feel, why do I bother trying so hard to do everything I can, when the one thing that would always be there for you was the medical profession but I am sorry to say that we are now up against accountants not doctors and they deal in figures not people. What a cold world we are living in!"

Another person has had Type 2 diabetes for 5 years and takes tablets of the type where hypos can occur. He lives alone and takes a lot of exercise so relies on testing his blood glucose levels for safety and was very angry at being totally refused any strips and wants his area named and shamed - Huddersfield.

If this happens to you, IDDT's advice is:
Complain to the GP practice manager and if this fails, then complain to your Primary Care Trust. Prepare your case before making the complaint:

1. Explain why you need test strips and why the number you need cannot be reduced - this is the way you manage your diabetes and you are more secure knowing what your blood glucose levels. If you have been advised to keep tight control, this cannot be done safely without blood glucose testing eg DAFNE courses recommend testing at least 4 times a day.
2. Point out that if you are ill, eg a tummy bug or 'flu, you need to use extra strips. If you end up in hospital because of not being able to test enough, this will cost an awful lot more than the annual cost of your test strips!
3. Point out that it was a doctor that prescribed them for you in the first place, so ask why he has suddenly decided you don't need them. Make your GP practice aware that you know that this is not a decision made by the Dept of Health and that test strips are available on an NHS prescription.

Our member with Type 2 diabetes followed this procedure and complained to the Practice Manager who said that the decision not to supply test strips could be reviewed on an individual basis, so he insisted on a review and his prescription for strips was issued immediately.

Did you know?
In the UK there were 10,447 pharmacies in England and Wales at March 31st 2005, a decrease of 15 from the same time in 2004. And every last one of them needs to know that pork insulin will continue to be available after Novo Nordisk stops supplying.

IDDT Have Stickers For Medical Notes

The problems of ensuring that the correct insulin is given in hospital can be helped by having stickers attached to your medical GP and hospital notes.

This patient does not give consent for 'human' or analogue insulins to be administered.

If you become a hospital inpatient and this sticker is on your notes, then the hospital are acting against your expressed wishes if they give you any other type of insulin, something that they very much should not do!

If you would like some of the stickers, just call IDDT on 01604 622837, e-mail enquiries@international.org or write to IDDT, PO Box 294, Northampton NN1 4XS

Summer's Here - Warning About Sun Lotion Labels

The EU Commission has warned that unclear sun lotion labels may lead to skin cancer risk. According to the warning, some labels are confusing or inaccurate and the main concern is the widespread confusion over the two types of dangerous ultra-violet radiation from which people need protection. The Commission stated that the labelling guidelines should be reviewed and called on manufacturers of sun lotions to avoid misleading or vague advice or face the prospect of new legally binding rules.

EU health commissioner Markos Kyprianou stated that consumers must be made fully aware that no sunscreen product can provide 100 per cent protection against hazardous UV-radiation and that there are serious health risks such as skin cancer linked to insufficient protection from the sun.

Exercise

High blood sugars afterwards are not what you would expect, so why?

Some people get high blood glucose levels after exercise and this does not seem logical because exercise tends to lower them and the advice is to eat extra carbohydrates before or during exercise or to lower your insulin dose. So what are the possible explanations for why blood glucose levels go up after exercise?

1. Insufficient insulin. During exercise your body needs energy but if insulin levels are too low or if there is no insulin present, the body will be unable to use glucose for energy. So the blood sugars will rise and if this persists, the liver will convert fatty acids to ketones.
2. Short burst of strenuous exercise. With this type of exercise [weight lifting, sprinting] stress hormones are produced such as adrenaline and they work to increase the blood glucose levels by causing the liver to release stored glucose, just as it does in a hypo or when the body is under threat.
3. Low sugars during exercise. High blood sugars after exercise can also occur if there was a low during the exercise but it was not recognised and treated. If this happens then the stress hormones are released again and cause the liver to release stored glucose to prevent a serious hypo.

The best way too deal with this is to learn what happens to your blood glucose levels with different types of exercise so that you can make adjustments to your food intake or insulin dose. The only way to do this is by testing before, during and after exercise and work out what is happening to your blood glucose levels.

Snippets...

Hospital staff count chocolates to assess satisfaction

The Royal Cornwall Hospital Trust has told staff to count boxes of chocolate left by patients. The 'chocolate audit' was suggested as an informal way of gauging patient satisfaction, but the measure has provoked a backlash with critics saying that this is a waste of precious time and "Surely the measure of satisfied patients is that they have been successfully treated, not how generous they are?" Figures for the Royal Cornwall Trust indicate that last year there were 8,000 gestures of gratitude and 316 letters of complaint.

Roast Vegetables could be bad for teeth

Researchers at Dundee University have tested different ways of cooking the vegetable dish ratatouille for levels of acidity. They found that oven cooking the vegetables produced acid levels similar to

those found in many fizzy drinks, already known to cause serious dental erosion in children when consumed excessively. Red peppers, tomatoes and onions were not more acidic when roasted but courgettes, aubergines and green peppers were found to be the most acidic when roasted, although they were still acidic when cooked using other methods. [NetDoctor.co.uk] 5/5/06

Too much or too little sleep

A study published in the Archives of Internal Medicine [25.4.05] concluded that sleeping for less than six hours or more than nine hours a night was associated with a higher risk of risk of developing Type 2 diabetes and impaired glucose tolerance (IGT). People who slept for five hours or less had double the risk of developing diabetes compared to those who slept for seven to eight hours. It is suggested that restricting sleep may hamper the regulation of glucose in the body.

BUT?

A study tracking the sleeping habits of 70,000 women for 16years [American Thoracic Society in May 2006] showed that women who slept for five or fewer hours a night were a third more likely to put on weight than sound sleepers during that time. It also found that light sleepers were 15% more likely to become obese compared with women who slept for 7hours a night. The research also showed that the increase in weight had nothing to do with light sleepers eating too much or taking too little exercise - in fact the women who slept less, ate less suggesting that appetite and diet are not accounting for the weight gain. It could be that having less sleep alters the balance of hormones which control the rate at which we burn off calories.

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

IDDT
PO Box 294
Northampton
NN1 4XS

Name: _____

Address: _____

_____

Postcode: _____

Tel No: _____

From Your Editor – Jenny Hirst

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