Insulin Dependent Diabetes Trust

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The Carbohydrate Question!

In 1986, the UK government issued dietary guidelines for the general population recommending high carbohydrate/low fat diet to reduce the risks of heart disease. Diabetes experts followed suit in recommending this diet for people with diabetes. Yet after nearly twenty years, we have a population that is more obese, more overweight and with a higher rate of Type 2 diabetes than ever before. People with Type 2 diabetes are using more combinations of anti-diabetic drugs, many are also taking anti-obesity, anti-cholesterol and anti-hypertensive drugs. People with Type 1 diabetes are having more daily injections, larger daily intake of insulin to cope with higher carbohydrates plus many of the drugs described above.

So is the low fat, high carb diet actually working?
Clearly not very well has to be the answer! We are well aware that people are taking less exercise than ever but this alone cannot be responsible for this huge rise in obesity and overweight. The alternative explanation could be that no one has taken any notice of the dietary recommendations, but this seems unlikely. So were these recommendations based on evidence that they would actually improve the health of the nation and people with diabetes? Such evidence is hard to find.

In the US, where obesity levels are the highest in the world, authors of a recent study [ref 1] maintain that the US population are eating less fat but they are not losing weight or improving their cardiovascular health. This research [ref 1] brought a flood of media debate about the popular Adkins diet which is low carbohydrate, high protein and not worrying about saturated fats such as butter and cream. But as ever,

there was confusion with implications that all low carbohydrate diets are the same as the Adkins diet. We had vitriolic health professionals telling us that low carbohydrate diets are bad because of the high fat content but without mentioning that it is possible to eat a low carb diet without increasing 'bad' fats - by increasing 'good' fats, such as omega-3 fatty acids in oily fish. So were health professionals just a shade too defensive of the high carb diet and a little too critical of the low carb approach?

So why did the research bring about such a reaction?
The research participants were severely obese people, some with diabetes, and were divided into two groups. One group followed a low carb diet limited to 30grams per day, with counselling on healthy types of fat, such as omega-3 fatty acids, but there was no limit on total fat intake. The other group followed a low fat diet and a calorie-restricted diet with no more than 30% of total calorific intake from fat.

The results showed:

- the low carb diet group lost an average of about 13pounds but the low fat group only lost 4pounds.
- The low carb group reduced their triglycerides, blood fats like cholesterol, by an average of 20% compared to 4% in the low fat group.
- In the non-diabetic participants, insulin sensitivity improved in the low carb group but worsened in the low fat group which could increase their risk of Type 2 diabetes.
- In diabetic participants, the low carb group reduced their fasting blood sugars by about 9% versus only 2% in the low fat group. During the 6 months of the study, 7 people in the low carb group were able to reduce their insulin dose or other medication but in the low fat group only one lowered his insulin dose and one had to begin insulin therapy.

The authors of the study make three important comments:

- even though all the study participants remained extremely overweight, those on the low carb diet significantly reduced their risk factors for diabetes and heart disease, their triglycerides dropped to normal range and their blood sugar levels approached normal.
- more attention needs to be paid to the harmful effects on the body chemistry of carbohydrate rich foods
- diabetics in particular did very well on the low-carb diet, so 'we might have to broaden our horizons on what we are recommending".

So are the dietary recommendations of the low fat, high carb diet actually working? To find answers we first have to look at what happens in non-diabetic people.
When they eat carbohydrates the body produces insulin to cope with the intake of carbohydrate. If they adopt a high carb diet, then the body has to produce greater amounts of insulin, resulting in constant greater peaks of insulin that in turn lead to greater blood sugar fluctuations. It is these frequent insulin peaks that lead to insulin resistance which can lead to Type 2 diabetes. But if they adopt a low or restricted carb diet, then they produce lower amounts of insulin, with less peaks and therefore less fluctuating blood sugars.

What happens in people with diabetes?
In type 2 diabetes, the body either does not produce enough insulin or the insulin that is produced cannot be used properly. So a high carb diet can only make this situation worse - their own insulin is even less effective.

In Type 1 diabetes the body produces no insulin and the amount of insulin that is injected has to 'match' the amount of carbohydrate that is eaten. So with a high carb diet, greater amounts of insulin are needed to control the blood sugars. While this process is complicated by the type of carbohydrate consumed - high fibre foods being more slowly absorbed so blood sugars fluctuate less, the principles still hold true - higher carbohydrate meals require larger doses of insulin. Higher doses of insulin mean that the blood sugars dip and peak much more.

Counting carbohydrate - a thing of the past or not?
Prior to the introduction of the 1986 high carb/low fat recommendations for people with diabetes, the recommended diet was 'carbohydrate controlled' - a specific amount of carbohydrate allocation for each meal and the insulin dose was worked out to matched this. A wonderful book, Carbohydrate Countdown, often called the diabetic bible, listed the carbohydrate contents of all the foods one could think of - a Jaffa cake was 8 grams of carb! The drawback to this diet was that it did not restrict fats, because it was not then known that fats increased the risk of heart disease.

Then the carb controlled diet went out of the window - people were no longer taught to carb count and were told to eat a high carbohydrate with plenty of fibre, low fat diet and they could even eat foods containing sugar! Without any knowledge of the carbohydrate content of food, it was [and still is] difficult to understand how people could actually work out their insulin dose.

It is interesting that the DAFNE courses [Dose Adjustment for Normal Eating] teach people to estimate the carbohydrate content of their meals in order to adjust their insulin doses accordingly. This method has been used in Germany for over 23 years and there are great similarities to the carb controlled diet. It is equally interesting that

people using insulin pumps are now being advised to count their carbohydrates. We know that pump therapy requires fine manipulation of control, but it is hard to see that this situation is a great deal different from people on multi-dose regimes aiming for near normal blood glucose levels. So will the time come when there will be a return to a carb controlled diet? While this is not the same as a low carb diet, at least it will be a reduction in carbohydrate intake and a reduction in insulin intake.

So what about low carbohydrate diets, are they good or bad?
On April 9 2003, the Journal of the American Medical Association published a review that analysed scores of studies comparing diets over the last 30 years. The review concluded that there was not enough evidence to make recommendations for or against low carb diets, so little evidence on which to base any recommendations! This latest study has really thrown the whole debate wide open and shown that low carb diets may offer some advantages over the low fat diets and while the participants in this study were severely obese, there have been other studies in healthy volunteers that have shown similar results.

Lowering fat intake to reduce the risks of heart disease is logical for people with or without diabetes, although it has not been stressed sufficiently that 'good fats' are OK. But the high carbohydrate diet has always seemed somewhat illogical.

For people without diabetes, it is bound to lead to greater peaks of insulin production and greater fluctuations in blood glucose levels, with increased risks of Type 2 diabetes. But for people with diabetes, especially Type 1 diabetes, it really does seem illogical. The one thing their bodies cannot deal with is carbohydrate and the one thing they are aiming to control is blood glucose levels. Yet a diet that is high carbohydrate will push blood sugars higher which then require higher doses of insulin to bring them down. This results in greater peaks and troughs in blood sugars which is not good control. Higher insulin doses also increase the risk of hypoglycaemia and more severe hypoglycaemia and of course, increase weight.

How low is a low carbohydrate diet?
Many people with diabetes have chosen to not follow the high carb/low fat dietary recommendations, especially those with long-standing diabetes who have continued with a carbohydrate controlled diet with reduced fat intake. But increasingly people who were diagnosed more recently and advised to use the high carb/low fat diet have started to look into the benefits of low carb diets and given them a try.

But how low is low? This varies in different people with some choosing to eat extremely low carbohydrate diets while others reduce their carbohydrate intake to what is acceptable to them. But it is important to recognise that lowering carbohydrates should be a gradual process,

with a gradual reduction in insulin dose and plenty of blood glucose monitoring while the changes are being made. It is also important to ensure that if reducing carbohydrate intake, the diet does contain the essential nutrients, vitamins and minerals.

Anecdotal reports from people on low carb diets

- *Lowering my carb intake has meant that I take a lot less insulin and my blood sugars don't dip and peak anything like as much as they did. Taking less insulin has meant that my hypos are very mild and easily dealt with.*
- *I have lost weight and maintained this loss*
- *I had early gastroparesis, but this is no longer a problem since changing to a low carb diet.*
- *I had muscle and joint pains and 'diabetic prayer' and tried the low carb diet and a reduction in my daily insulin intake and this has considerably reduced these problems. I don't know whether this is the diet or taking less insulin or both.*
- *I have felt to have much more energy on the low carb diet and have felt so much healthier.*
- *I did feel hungry when I first started the low carb diet but not any more and I have read that eating fewer carbohydrates and more protein and good fats makes people feel fuller and so not want to eat as many calories.*

GM 'human' and analogues, a factor or not?

GM 'human' insulins are more aggressive than animal insulins with a higher peak of insulin immediately after injecting, so this does raise the question of whether the reported increased hypos with GM insulin could be related to some people not using the high carb diet approach. It certainly was not the recommended diet when people were changed to GM insulin in the 1980s.

Over the last few years we have seen the development of fast-acting analogues and it is easy to see why. If people are consuming high carbohydrate meals, then their blood sugars are going to rise sharply after a meal and a fast acting analogue [Humalog and NovoRapid] will act immediately and aggressively to lower these post meal high sugars. However, these insulins also have a very short duration with some people finding their insulin 'runs out' before the next meal, leading to highs before meals. Overall this results in greater blood sugar fluctuations. If the high carbohydrate diet had never been recommended, would fast-acting analogues have ever have been necessary?

Can we come to any conclusions?

One conclusion is obvious - there is now a very real need for more research into carbohydrate and fat intake. It is very surprising that in the recent research, cholesterol levels were significantly higher in the low fat diet than the low carb diet - the opposite of what one would expect. Could it be that there has been an overzealous reduction in all fats, not just the reduction of 'bad' fats? Fats are necessary in our diets because the body does not produce fats and they are an essential source of energy for insulation and for the absorption of the fat-soluble vitamins A, D, E and K?

The research showed that the low carbohydrate diet had very real benefits for people with diabetes which itself warrants further research but it would also be interesting to find out if these benefits are due to the low carb diet, the accompanying lower insulin intake or both?

CAUTION: We must remember that whatever the diet, exercise is a very important part of staying healthy. If you are considering changing to a low carb diet or just a reduction in your carb intake, the advice must be that this should be done with the help and advice of a dietitian. However as we know, most dietitians favour the high carb approach, so seeking their help may be hard to achieve.

Diabetes Solution is a good book to read, written by Dr Richard Bernstein, M.D., who has diabetes. It is published by Little Brown & Co, ISBN 0316093440 but large sections of it are available on his website http://www.diabetes-normalsugars.com

Ref 1 New England Journal of Medicine 22.5.03, F F Samaha, L Stern

Aspartame - We'd Like To Hear From You...

One of our members, let's call him John, has been having problems with fatigue and joint and muscle pains. These have increased to pains throughout his whole body making walking difficult. He has changed his insulin, his regime and seen various specialists but after two years he has still had no diagnosis, no treatment and no help.

With a certain amount of desperation, he searched the internet and found that the sweetener, aspartame, causes adverse reactions in some people that mirrored his problems. Aspartame, also known as NutraSweet, is used to sweeten 'sugar-free', 'low-sugar' and 'light' drinks as well as many foods. So John decided to completely remove all aspartame from his diet.

Within 14 days, there was a remarkable improvement in his condition and he described himself as having returned to the state of health that he was in 2 years previously! This happened just before going to print, so we will keep you posted about what happens to John.

Aspartame and its possible adverse effects have been a source of debate for many years. In America the FDA has set a recommended maximum safe level for the daily intake of aspartame, although not based on research. The Scientific Committee on Food [SCF] that advises the EU has reviewed the safety of aspartame and still says it presents no health hazard to consumers. But Dr Erik Millstone from Sussex University told Health Which? that 'the most crucial issues have been ignored or discounted by the SCF'.

It is worth commenting that as a group, people with diabetes possible consume more sugar-free drinks and foods containing aspartame than any other group.

If you have had any similar experiences to John or any comments, then contact Jenny at IDDT, PO Box 294, Northampton, NN1 4XS, tel 01604 622837 or e-mail jenny@iddtinternational.org

Young People Sponsor IDDT

Readers will remember that in the July issue we thanked two young people for running the London marathon for IDDT. This time we have to thank two more people for their energetic efforts and for raising sponsorship money for IDDT. We are really grateful for their help and support and above all it is great to see young people supporting our cause.

Thank you to Emma Davies who as part of the University of Manchester team completed the British University Sports Association triathlon. This consisted of a 400m swim, 22m bike ride and 5km run. This was Emma's first triathlon and in her own words 'probably the only one!' Emma raised the money in memory of her brother Jonathon.

Our thanks also go to Charlie Upton who completed the Marathon des Sables 2003 and raised a wonderful £4500 for various charities. IDDT received £1530 as a result of his efforts. We are very grateful to Charlie for helping IDDT in this way - and it wasn't easy for him! If you have never heard of the Marathon des Sables, it is known as the toughest footrace on earth. He was part of a team walking 150miles in five stages but in the desert with temperatures rising to 49degrees! Not only did he complete this task but he finished in an overall position of 277 from a starting field of 677. So to Charlie we not only want to say a big thank you but also 'Well done'!

Foody Facts - A Mixed Bag of Information

WHO new guidelines on nutrition and exercise

April 2003
The World Health Organisation [WHO] and the Food and Agriculture Organisation have issued new guidelines on diet, nutrition, exercise and prevention of chronic diseases based on a study from 30

independent experts. It recommends:

- a fat intake of 15-30% of total daily energy intake
- saturated fats at less than 10%
- carbohydrates at 55-75%
- free sugars at below 10%
- 10%protein intake 10-15%
- iodised salt intake less than 5gms a day
- fruit and vegetable intake should be greater than 400gms a day
- 1 hour of moderate exercise, such as walking, everyday.

Guess what?
The Sugar Association in the US, a coalition of major food companies including Coca Cola, asked Congress to cut all funding to the WHO unless it revises the new rules for healthy eating and asked for the WHO report to be withdrawn. Sounds like blackmail! Once again we are witnessing the interests of big business and their profits conflicting with the best interests of people's health!

Food labelling

European Commission proposes evidence-based nutrition
EU draft legislation could ban many health and nutritional claims on food products such as 'low fat' and 'promotes wellbeing'. The European Commission believes that these claims confuse and mislead consumers. The new proposal includes the setting up of a new European Food Safety Agency that would have an independent panel to approve such claims.

The EU is particularly concerned about foods that are targeted at children and slimmers and the draft law would ban slogans that could not be verified eg 'boosts your immune system' and 'halves your calorie intake'. The terms 'low fat', 'high fibre' and 'low sugar' would all be strictly regulated and phrases such as '80% fat free' for a product that actually contains 20% fat would also be banned. In addition, endorsements of foods by medical associations would not be allowed. The endorsements by medical charities on some foods has recently been criticised in the UK.

In future food manufacturers are going to have to provide evidence to support the claims they make about their products. This has to be a step in the right direction, although in ten years time, one wonders if we shall be questioning the quality of the evidence and the independence of the evidence as we now do with drugs!

Present food labelling
In the UK the Food Standards Agency [FSA] was set up in 2000 to ensure that food is safe and to make sure that we are provided with unbiased and full information about the food we eat. The Food Labelling Forum is currently looking at labelling and how to standardise it to make it more understandable. At present food labels can be confusing, especially if you can't or don't want to eat certain things.

Labels contain the following information:

- **List of ingredients** - this list says what is in the food including water, colouring, flavouring and preservatives. The largest amount of ingredient by weight is listed first and so on in order but the actual weight of each is not given.
- **Nutritional information** - some products give food values per 100g and/or per serving and some just give it by content. As well as calorie content the labels say how much protein, fat, carbohydrate, sugar, fibre and salt there is in a product.
- **Storage instructions** - covers keeping in the fridge and/or freezer.
- **Best before and use by dates** - this is often confusing. Best before dates are used on products that will keep for a while and mean that while the food will not go bad immediately after that date, it should be thrown away as it may be stale. Use by dates are important because they mean that the food will go off. Food with a use by date should be eaten or frozen before the date or thrown away to avoid stomach upsets.

Note - don't be fooled by fats!
Labelling of fats can be misleading as many foods are sold with a 'light'

claim but it doesn't necessarily that they are low fats as designated by the FSA. For instance, Philadelphia Light contains 16g of fat per 100g and the 'extra light' version contains 5g per 100g. However, the Food Standards Agency define low fat as less than 3g per 100g so even Philadelphia Light is not actually low fat! Some other foods also have 'per cent fat free' labels, although these are not recommended by the FSA. It is well worth remembering that a label saying 90% fat free actually means that the food still contains 10g fat per 100g!

Some foods have logos:

- **Organic produce** - this means that the food is produced without using artificial fertilisers and pesticides and meat is from animals raised without routine use of drugs and antibiotics. It also means that the food contains no genetically modified organisms [GMOs]. The Soil Association also has a logo that is an organic standard mark that certifies that the food is organic and meets the legal definition of 'organic'.
- **Vegetarian** - this guarantees that the food is free of any animal products, GMOs and that there is no cross-contamination between vegetarian and non-vegetarian items during production.
- **Freedom Food** - these logos were set up by the RSPCA to improve animal welfare. They are attached to meat, eggs and dairy products from animals raised, transported and slaughtered according to the RSPCA's welfare standards.
- **New '5 A Day' logo** - the Dept of Health has developed this logo to appear on foods that count towards your daily intake of 5 portions of fruit and veg a day and put in place strict criteria for its use. However, it is only a voluntary scheme and some manufacturers and retailers already have their own. More information at www.doh.gov.uk/fiveaday

Labelling of GM Foods

In October 1998 the EU stopped approving new GM foods after safety concerns were expressed but in July 2003 the European Parliament approved two proposals to ensure that there is a strict system to trace and label food and feed products made with genetically modified [GM] ingredients. It will then be possible for GM foods to be traced throughout the human food chain.

The new legislation is expected to receive final approval in Autumn 2003 and will require supermarkets in the EU to label all foods containing more than 0.90% of ingredients, although this is higher than some would have liked. This legislation will also allow EU member countries to set their own rules to prevent GM seeds contaminating non-GM crops and an amendment will require farmers to label the exact ingredients used in GM foods.

So it does seems that the EU has taken on board the concerns of consumers and environmental groups about the lack of evidence about the long-term safety of GM foods.

More 'Foody Facts' in the next Newsletter!

Avandia And Actors - NICE Updates Guidance

By Jenny Hirst

I could be accused of having something of a bee in my bonnet about the group of drugs known as glitazones for Type 2 diabetes - insulin sensitisers to enable the body's insulin to work more effectively. This is probably true because the history of this family of drugs makes me wary. The first glitazone, troglitazone [Rezulin], had to be withdrawn from the market when it was suspected of causing 400 deaths from liver failure, but not until 2 years after the reports were first received after scandal and the threats of whistle-blowing.

Avandia and Actos, from the same family of drugs, were introduced about a year before troglitazone was withdrawn. It was claimed that these drugs did not cause the same problems, later proved not to be entirely correct when warnings of serious liver and cardiac complications appeared.

August 2003 NICE change their guidance
NICE, the National Institute for Clinical Excellence, first issued guidance on glitazones in March 2001. It recommended that glitazones were effective at reducing blood glucose when added to ***either*** metformin ***or*** a sulphonylurea but only in people whose blood glucose could not be adequately controlled by one of these drugs on their own [monotherapy]. Now NICE have reviewed and changed this guidance as a result of new research.

In ordinary language NICE recommends:

- The combination of metformin and a sulphonylurea should remain the first treatment choice where treatment with one of them on their own has failed to achieve adequate blood glucose control.
- A glitazone should be used in combination with metformin or a sulphonylurea **ONLY** in people with Type 2 diabetes for whom monotherapy hasn't worked to control blood glucose and cannot take the combination of metformin and a sulphonylurea because it is not suitable for them or they cannot tolerate its side effects.
- The licences for glitazones do not permit the use glitazones as triple therapy ie with the combination of metformin and a sulphonylurea or with insulin.

NICE recommends that if you or someone you care for has Type 2 diabetes, you should discuss this guidance with your doctor.

Further information can be obtained from the NICE website www.nice.org.uk and the full guidance can also be requested by telephoning 0870 1555 455

Background
Avandia - the manufacturer, GlaxoSmithKline [GSK], is facing legal action in the US by 32 people, some of whom claim that they needed liver transplants within weeks of starting the drug. They claim that the company failed to adequately warn patients that Avandia could cause serious cardiac and liver complications and was slow in reacting appropriately with additional warnings once these reports were made known to them. GlaxoSmithKline deny these claims - to be expected when Avandia, used by 3 million people, had sales rising last year by 19% to £809 million!

Legal actions continue with troglitazone - in April 2003, a New York jury ordered the manufacturer, Pfizer, to pay $2million damages compensation to a woman who was injured after taking troglitazone. Pfizer is appealing against similar verdicts in other States. Recently a federal appeals court reinstated a $1.4billion [£834million!!!] lawsuit against Pfizer brought by health insurers to recover the amounts they paid for drug and subsequent liver testing between Feb 1997 and April 2001.

AND Trials stopped in two new diabetes drugs of the same family
In October 2002, we reported that trials of Novo Nordisk's new insulin sensitiser drug were stopped because bladder tumours were found in mice and rats. In January 2003 Novartis, halted development of their new dual sensitiser drug for the same reason – tumours in mice and rats.

Ask The Doctor

QUESTION *'I have had Type 1 diabetes for 28 years and have just been told that I have developed hypothyroidism [underactive thyroid]. I understand that this is quite common in people with diabetes although I had never heard of this risk. Are there are any long-term effects of the combination Type 1 diabetes and an underactive thyroid that is treated with thyroxine tablets?'*

Doctor's answer: They are both auto-immune conditions and sometimes occur together. Hypothyroidism is very easy to control compared with diabetes and normally there is no additional complication. Over treating the thyroid condition can lead to weight loss and under treating it can cause high cholesterol levels.

Facts:

- The thyroid gland is situated at the base of the neck in front of the throat.
- It produces the hormone, thyroxine, an iodine containing substance that influences growth and maturation by regulating the rate of metabolism.
- Sometimes the body's autoimmune system targets the thyroid gland itself eventually destroying it and shutting down the hormone production. It may take many months or several years for the level of hormone production to be sufficiently low to need treatment with thyroxine tablets.

Foot Care - Heel Fissures

The Isle of Wight Diabetes Monitoring Group, have kindly given permission for IDDT to reprint an article from their magazine, *Sweet Pea by Oliver Davies*, Senior Diabetes Chiropodist.

What are heel fissures?
Heel fissures are a common occurrence in all the population, but in diabetes they can cause serious problems if they are not dealt with effectively. They are essentially cracks or splits in the skin often extending through to the dermis [the inner layers of the skin] and are often painful when pressure is applied to the heel on standing. They can frequently bleed and once the fissure opens it is often difficult to get the two edges of the split to knit back together.

With so many people with diabetes suffering from neuropathic damage [causing loss of feeling, commonly in the feet] these fissures often go unnoticed until they have become quite severe. Frequently they can become infected, and where many people with diabetes can suffer with ischaemia [a reduced blood supply] they are subsequently difficult to heal and may ulcerate.

What causes heel fissures?
Invariably heel fissures are symptomatic of dry skin conditions. Loss of innervation [nerve supply] to the sweat glands in the feet can result in people with diabetes having drier skin than the rest of the population. Hot weather, wearing of sandals, inadequate skin care, abrasive hosiery, poor circulation and possibly some forms of medication can all contribute to the drying of skin.

How can I prevent heel fissures?
Generally, after washing or a short soak of the feet, the application of a good moisturing cream should be sufficient to keep skin more supple and hence prevent their formation. The cream should be applied EVERY DAY, particularly if you have been instructed to do so by your chiropody/podiatry clinic. The Podiatry Department often recommend Aqueous Cream B.P. which is a water based cream that helps to rehydrate the skin [and not just in the feet!] Basically, you can use any moisturising cream providing it is done on a regular basis!

How do I deal with a heel fissure already present?
If, on your DAILY FOOT INSPECTION, you discover a crack in the heel, keep a close eye on the area and initiate the daily moisturising routine maybe 2 or 3 times a day. If there is no improvement after a week it is advisable to contact your local Chiropody/Podiatry Clinic and let them assess it and advise you. At the clinic they will be able to apply suitable dressings to heal the fissure and suitable padding materials to prevent the inevitable shoe rubbing that might prevent them healing.

- **Remember if in doubt about any foot problems, always contact your local chiropody/podiatry clinic for advice.**

Advertising Of Drugs - Europe Has Decided No!

Regular readers will be aware that IDDT joined other international

patient/consumer groups to lobby against the EU proposal to lift the ban on the direct advertising of prescription drugs to consumers [DTCA]. This was particularly important for us because diabetes had been proposed as one of the three conditions to be used in a five-year 'pilot' project to allow advertising of drugs to consumers ie patients.

In June the European Health Council rejected Article 88 of the Directive on the Community Code relating to Medicinal Products for Human Use, so preventing Direct To Consumer Advertising of drugs - a great success for the lobbying campaign!

In August 2003, the Association of the British Pharmaceutical Industry [ABPI] in their edition of SCAN, maintains that the proposal was never intended to mean 'advertising' but that there was an error in the French translation and the proposals actually meant 'information'. They are also critical of those who have continued to refer to it as advertising, labelling them as misinformed or knowingly misleading the public - not too nice! Advertising or disease information giving, our view is that neither should be provided by the pharmaceutical industry - it should be from an independent source that has no financial gain.

New Zealand and the US have second thoughts too!
These are the only two countries that allow direct to consumer advertising. In New Zealand, doctors are now campaigning to have this reversed and ban all advertising of drugs to consumers. In the US the sales of drugs have gone up hugely as a result of advertising but even in the US the tide is turning as the medical community start to express their concerns. At a meeting of the Senate Special Committee on July 22 the American Medical Association speaker said that TV ads may lead to an over-medicated society. Dr Janet Woodcock [FDA] quoted a survey of 500 doctors, 25% of doctors felt pressurised by patients to prescribe a TV advertised drug and 75% thought that TV ads made patients believe that a drug was more effective than it actually was. Dr Arnold Relman, [Harvard Medical School] pointed out that most drug ads last 30 to 60 seconds adding "There simply isn't time to provide any useful information about the side effects, to call this education strains the meaning of the word."

But…
The ban on advertising prescription only drugs remains, but now the UK Dept of Health has decided to remove the restrictions on advertising of over-the-counter [OTC] drugs to the public for a wide range of conditions - happily this does not apply to diabetes and other metabolic diseases. These changes will not come into force until guidelines for advertisers and information and training for pharmacy staff have been developed, to be overseen by the Medicines and Healthcare Products Regulatory Agency [MHRA]. So we are likely to see more OTC drugs advertised some of which have previously been prescription only drugs.

Health Minister, Lord Norman Warner maintains that *'Removing the restrictions on promoting non-prescription medicines to the public has the potential to bring real public health benefits by giving more power and information direct to patients. The government intends to increase the number and range of medicines over the counter as quickly as possible, commensurate with public safety.'*

But advertising drugs, or to quote the Minister 'promoting medicines', only truly increases patient information if the ads provide full information about adverse reactions as well as the good aspects the industry will want to highlight. We will see, but no doubt this change will be very lucrative for the pharmaceutical industry.

CP Pharmaceuticals Acquired By Wockhardt Ltd

July 8th 2003
CP Pharmaceuticals announced that it has been acquired by Wockhardt Ltd, a leading Indian pharmaceutical company, making CP a subsidiary of Wockhardt.

Extracts from the press announcement July 8, 2003
About Wockhardt:

With the acquisition of CP Pharmaceuticals, Wockhardt's annual sales in the UK alone touches 50million sterling pounds, making it one of the top 10 generic companies in the UK. Wockhardt is one of India's leading pharmaceutical companies with sales of 105million sterling pounds. It has 11 manufacturing facilities, three of which are approved by the FDA in the US and its products are exported to over 90 countries.

About CP
CP has four key businesses consisting of hospital drugs, generics, contract manufacturing and exports. Some of CP products have significant market shares in the UK, including Hypurin Bovine insulin [100%], Hypurin Porcine insulin [34%].

The future of natural animal insulins assured
Naturally concerns have been expressed about the future of the range of Hypurin animal insulins and on July 14th a press release was issued stating the following:

"CP and Wockhardt would like to confirm that the supply of Hypurin porcine and Hypurin bovine insulin continues unchanged.

CP has been dedicated to the production of natural porcine and bovine insulins for over 30 years and has further invested in the product range with the recent launch of Hypurin 3ml cartridges. CP's investment has demonstrated a clear commitment to ensure continued supply of Hypurin insulin for the foreseeable future."

IDDT's position:
We welcome the reassurances from Wockhardt and CP that supplies of natural pork and beef insulins will continue but it is understandable that there are concerns about future availability, a worry that people should not have to face on top of having to live with diabetes itself. It is sad that we now no longer have a UK manufacturer of animal insulin, in fact insulin of any type. But there is always the possibility that Wockhardt might look to expanding the animal insulin business so that more people are aware of its availability and advantages - they now do have a niche market!

Our thanks and good wishes to Charles Savage
As part of the acquisition Mr Charles Savage will be stepping down as Chief Executive of CP, although he will remain in a consultancy capacity for two years. IDDT would like to express our most sincere gratitude to Charles for CP's commitment to the ongoing supplies of natural insulins. However, we would also like to thank him for his personal commitment to helping and understanding the people who need animal insulins, a commitment that has often extended far beyond the call of duty and is appreciated by people in many different countries.

Further information can be obtained by visiting: www.wockhardt.com and www.cppharma.co.uk

Later news August 5th 2003

Wockhardt launches first locally produced 'human' insulin in India
Wockhardt announced that they are launching a synthetic 'human' insulin in India derived from yeast, called Wosulin. It is the first synthetic insulin to be manufactured in India - the large multi-national companies have only assembled and packaged there. Until now 90% of the Indian insulin market has been pork and beef insulin prescribed for the Muslim and Hindu communities respectively.

The report by the BBC Correspondent in Bombay says:

"But medical experts believe that selling the new product to an existing patient will not be easy because switching over to the new insulin might lead to complications."

We must be thankful that the diabetic community in India is being warned by their diabetes experts that there may be complications with the changeover - something that the experts in developed

countries failed to do. Perhaps the experts in India have gained from our experiences.

Wockhardt are pricing a 10ml vial of Wosulin at 129Rs [nearly $3] and will be the cheapest insulin on the market. They will also be marketing the insulin globally and let us hope that this could have positive implications for people in developing countries who cannot afford the high costs of the insulins produced by Lilly, Novo Nordisk and Aventis.

Worth a note: the BBC headline describes the rDNA insulin as 'vegetarian insulin'. That's a new one but in India almost as good a sales line as 'human' insulin was in 1982!

Inaccurate Reporting By The NCVO Could Damage IDDT

As a result of Charity Commission investigations, in June 2003 two fundraisers were convicted in separate cases. One person was Arthur Bennett, described in the National Council for Voluntary Organisation's [NCVO] July magazine as being from the 'Diabetes Trust'. In fact the organisation with which he was involved was called 'Diabetes Help' and any such press reports do NOT refer to IDDT, the Insulin Dependent Diabetes Trust. IDDT is often referred to as the Diabetes Trust so we have treated this inaccuracy very seriously as it could damage IDDT's reputation and even income - the NCVO has apologised and a correction will be printed in the next edition.

The Safety Of Our Medicines

HRT research raises questions about the whole system for monitoring the safety of medicines

For the last year or so evidence has been gradually creeping out of the woodwork that has cast doubt on the safe use of HRT, suggesting that HRT should only be used as originally intended - for short-term treatment of menopausal symptoms. Whether to use HRT has been a dilemma for women with diabetes because there has never been any clear evidence but on August 9th 2003, the Lancet [ref 1] published the results of the Million Women Study turning previous HRT beliefs on their head. Equally importantly, it raises wider questions about the safety and monitoring of medicines we take and the protection of public health, questions that are very similar to the unanswered questions that many of us have about the safety and monitoring of GM synthetic insulin.

The HRT study showed that women using HRT are at significantly greater risks of breast cancer, and fatal breast cancer, than women who don't take it but it has taken nearly 30 years from the introduction of HRT for this evidence to come to light. We are led to believe that the UK has one of the best regulatory systems for the safety of medicines, so how can we have reached a situation where so many women's lives have been put at such risks?

The Committee on Safety of Medicines [CSM] was set up in 1968 in the wake of the thalidomide tragedy to protect the public from damage caused by medicines and its own definition to IDDT of ***'safety'*** is ***'an absence of harm'***. But here we are again - the lives of scores of women have been harmed and some sadly lost, as a result of using a medicine that they were led to believe offered greater benefits than harm.

At best, we can say that the necessary large-scale long-term study has eventually been carried out and the risks are now known. But with many drugs including GM insulin no such studies have ever been done. Unfortunately no one in the diabetes world has had sufficient interest, or received funding, to carry out similar long-term monitoring to compare the safety of GM insulin to natural animal insulin. As a result it is being prescribed to millions of people without any good evidence of benefit over its tried and tested predecessors and without

any research to compare the development of complications, mortality rates and quality of life issues [ref 2]. We don't know what the outcome of such a study would be but we deserve to know as our health, our quality of life and even our lives depend on them.

Surely the Million Women Study is a wake up call for everyone, including patients who need greater reassurances that all medicines are being closely and independently monitored to provide reliable evidence about risks and benefits.

Let us take a closer look at the Million Women Study…
Between 1996 and 2001, this recent HRT study recruited over a million women aged between 50 and 64 who provided information about their use of HRT and other personal details. They were followed up for cancer incidence and death. While the detailed results are a little complicated, the interpretation is not! In the UK the use of HRT in this age group of women over the past 10 years, has resulted in an estimated 20,000 extra breast cancers of which 15,000 were associated with oestrogen-progestagen, more commonly used because oestrogen alone has been shown to increase the risk of endometrial cancer. As yet the extra deaths cannot be reliably estimated but 517 women who died from breast cancer, had no history of it at the start of the study. It also showed that the risk of breast cancer is significantly increased after one or two years and increases with duration of use of HRT although this risk decreases within a few years in women who have stopped using HRT.

While the researchers make no recommendation for action, Dutch commentators in the Lancet [ref 3] are much more specific:

- HRT use should be discouraged in women going to the doctor for the first time with menopausal symptoms and doctors should seek alternative solutions. If it is necessary to prescribe HRT, then it should be for no longer that 3 to 6 months. New guidelines need to be written to discourage the use of HRT.
- For women already using HRT, estimated to be between 20% and 50% of all women between 45 and 70 years old, HRT use should be discontinued as soon as possible but without panic and in a controlled way by discussion between doctor and patient.
- There should be an information campaign, led by the medical profession, stating the clear evidence in unsensational language that encourages women to consult their GP.

Broader issues relating to the safety of medicines must be addressed sooner rather than later, if our health is to be protected.
We are supposed to have a good drug regulatory system, yet we now have a situation where 30 years after its introduction it is discovered that HRT is found to be posing a significantly greater risk to women who take it than women who don't. Of equal concern is that although approved as a short-term treatment for menopausal symptoms, it became used as long-term treatment for postmenopausal women. We now know that HRT increases the risks of breast cancer and the risk of heart disease and stroke [see panel] and this must cast doubt on the system for monitoring the safety and effectiveness of our medicines:

- Why did it take so long for the recent research to be carried out, putting so many women at risk?
- We were lead to believe that HRT prevented heart disease and stroke, was this based on assumptions or evidence from research? If research based, how could it have been so wrong and why was this not picked up by the CSM? Was it poor quality, was it independent or funded by the manufacturers of HRT?
- According to the Lancet [ref 3], it was known from the outset that HRT increased the risks of breast and endometrial cancer, so why has then been downplayed compared to the apparent health benefits?
- Was there any formal post marketing surveillance, independent or otherwise?

So the comparisons with the GM synthetic insulin become obvious:

- it was known before the introduction of GM insulin, that there were unexpected problems with hypoglycaemia [ref 4] but we were not

told until years later. In our case the risks were not just downplayed, they were not mentioned! Would anyone have really changed to synthetic insulin, if they had been told that there was a greater risk of hypoglycaemia and/or loss of warnings?

- GM insulin was 'sold' and prescribed on assumptions of benefit, not evidence of benefit. The research that was carried out, much of it only after pressure from people with diabetes, was poor [ref 2] and did not investigate many of the important issues for patients.
- No large-scale, long-term studies [post marketing surveillance] were ever done.

Post-marketing surveillance is vital to protect public health

Trials for a new drug are only carried out on a relatively small number of selected people, so post marketing surveillance is essential to find out if there are any adverse effects when the drug is used on the wider population and for a longer time. The Medicines Control Agency, now the Medicines and Healthcare Products Regulation Agency, [MHRA] is responsible for the safety and effectiveness of the drugs we use. [The CSM is part of this body].

So where were they during the years when women's lives were put at risk by HRT? Where were they when the masses of adverse reactions were reported with GM 'human' insulin? GM insulin was the first GM drug ever to be used in man, so why did they not insist that post marketing surveillance was carried out?

For the answer, perhaps we need look no further the Commons Public Accounts Committee [June 2003]. It accused the MCA's efforts to improve patient safety as *'lacklustre'* and that *'the leaflets and labels on medicines designed to provide patients and doctors with important information about risks, are poor.'* These accusations could certainly be levelled at them over GM insulin.

Condemnation of the system indeed! But what action did the CSM/ MHRA take as a result of the Million Women's Study?

It ruled that the NHS must tell women of the dangers of HRT - a failure to recognise that it is not some impersonal monolithic NHS that will have to tell women of the dangers but our already overworked GPs!

But the CSM stopped short of advising that women should come off HRT saying, "For short-term use of HRT, the benefits outweigh the risks for many women. For longer-term use, women should be aware of the increased risk of breast cancer and other adverse effects."

For want of a better expression, this seems like a 'cop out' as it leaves GPs and women to decide what to do. Many women will not be able to make a truly informed decision - to do this we need help, guidance and the translation of research findings into layman's terms. Surely in its role as protector of public health, the CSM should issue a one-page statement for doctors and patients stating the facts as they are presently known. The government happily puts large clear health warnings on cigarette packets, so why is there such reluctance to issue such statements about medicines?

Why is it avoiding taking any positive action on the HRT findings? What is it afraid of? Does it show a 'lacklustre' approach to its monitoring of HRT over the last 20 or 30 years? Should it have been more forthcoming and issued earlier warnings to women? Is it afraid that its experts may be criticised because they may be the same experts that have been responsible for promoting HRT as the wonder treatment to keep women looking young, energetic with a healthy interest in sex? It is not the first time we ordinary mortals in IDDT have questioned the role of the CSM - we have raised all these questions in relation to the adverse effects of GM insulin.

But where are the patients/consumer organisations?

The existing CSM system for monitoring the safety of medicines is not working well enough to protect the health of the public but patients/consumers and their representatives seem amazingly quiet! The pharmaceutical industry is not going to call for a tightening of the system, its not in their best interests and many in the medical profession seem to rely on the views of a few 'experts' who may or may not have connections with industry. If we, as consumers, simply

sit back and assume that the safety of our medicines is happily under control, then we will continue to have a future where our health and lives are unnecessarily put at risk by medicines. So perhaps it is up to patients and their organisations to demand change.

- Formal independent post-marketing must be carried out in large populations that are truly representative of those likely to take the new drug and it must be long-term to assess mortality and adverse reactions that occur after short, medium or long-term use. The results must be made public.
- Patients must be provided with evidence of the risks and benefits and if there is no such evidence, then they should be told this too.
- Patients, like doctors, should be warned that a medicine is new so they know it has only been subjected to limited research and its long-term safety has yet to be demonstrated.
- Advertising of prescription medicines is illegal, but pharmaceutical companies use press releases in ways that often amount to free advertising. There should be guidelines for journalists which are policed to ensure that they are not subtly advertising new drugs for pharmaceutical companies.

Lessons must be learnt!

The HRT research now provides evidence for women to have an informed choice. If only this were true for GM insulin! We do not have the evidence to provide the assurances we need about the safety of GM insulin, despite the fact that too often patients' reports of adverse reactions have been ignored. This does not bode well for people with diabetes as their treatment and future health is being based on assumptions of unproven benefits and not on evidence of benefit.

Thanks to the Cochrane Review [ref 2] we know that GM is not superior to animal insulin and that there have never been investigations into the development of complications, mortality rates or quality of life. The Cochrane Review has empowered us to exercise our right to informed choice but this choice is limited because important aspects of research have never been carried out and absence of evidence is not the same as evidence of absence.

Lessons must be learnt from the Million Women Study and the experience with GM insulin by all those responsible for the safety of medicines but we also need to learn lessons. We must not to unknowingly be guinea pigs and not be afraid to ask our doctors about our choices, their risks and benefits and we must not be afraid to say 'No'. If necessary, we must be assertive to ensure that our treatment choices are as informed as they can possibly be.

Ref 1 The Lancet Vol 362; 9 August 2003:419-427

Ref 2 Cochrane Review of 'Human' and animal insulin; July 2002: www.update-software.com

Ref 3 The Lancet Vol 362; 9 August 2003:414

Ref 4 Science News, vol. 119, June 27, 1981:407

HRT - the rising evidence

July 2001 - New England Journal of Medicine - not enough proof that HRT prevents heart disease, HRT should not be prescribed for healthy women solely for the prevention of heart disease.

Early 2002 - a report from 28 international experts said that other than for the relief of menopause symptoms, there is doubt that oestrogen replacement provides health benefits for other conditions including Alzheimer's disease, depression and osteoporosis. It did not suggest abandoning HRT altogether, simply that it should be used for its original purpose - to alleviate symptoms of the menopause.

July 2002 - a long-term study in the US investigating healthy postmenopausal women was halted early so that the participants were not put at unnecessary risk as the evidence of harm from breast cancer, increased risk of heart disease, stroke and blood clots, outweighed any evidence of benefits.

March 2003 - another US study was published early on-line by the New England Journal of Medicine because of health implications.

16,000 healthy women were randomly selected to receive a placebo or a combination of oestrogen and progesterone. The results showed that HRT did not improve women's quality of life, general health, energy, mental health, memory or sexual functioning after a year compared with those who took the dummy pill.

Rae Price' Diary

In IDDT's July Newsletter Rae had discovered that her hope of an islet transplant was dashed because she had a trace of protein in her urine, indicating that her kidneys were not working well enough. Rae's next step is to look into pump therapy, so read on…

Went to see the Prof today and waited an hour and a half to see him as the clinic was running late. During the first hour I thought I might be a bit low and asked an auxiliary if she had a blood testing kit. "What's one of those?", she asked. After explaining it to her she managed to find one. My blood sugar level was 2.4 so she offered me some digestive biscuits. I laughed my socks off and said if you think that will make any difference you have a lot to learn. I then took the bottle of lucozade out of my bag and downed half of it thinking I would save the rest to have on my way out so I would be safe driving home.

The Prof went on and on about red tape surrounding the funding for this pump which, it seems, doesn't measure your sugar levels at all and doesn't warn you of impending hypo. So what's the point was my next question.

It seems they think my problems with hypos etc are caused by gastroparesis and that a square bolus over a period of 3hrs will work better than one large dose. Eventually after the Prof had finished going on about the red tape I said to him "Well are you not going to ask how I've been then??" He then went on and on again about the pump until I had to say to him "HYPO". He managed to call a nurse in with a blood test kit and then promptly disappeared!!!

My sugar had fallen to 1.3 and the nurse got me into the next room whilst another asked me if I wanted tea or coffee!!!! I just said coffee with 2 sugars please and a piece of that cake you're cutting up. I managed the cake before everything stopped working and only remember calling the doctor an idiot when he put the venflon in my arm. THIS WAS A DIABETIC CLINIC FOR CRYING OUT LOUD!!!

They then tried to admit me to the hospital so I told the doctor he was just being silly and asked what were my sugar levels now? 15.8 he said. Yup kickback time and they still wouldn't let me leave until I had had something to eat. I got home about 7pm, totally depressed and wishing that I just hadn't bothered going.

Updates From Last Newsletter

Yet more on patients being able to report adverse drug reactions! Regular readers will remember that I greeted with great acclaim the government's announcement that from February 2003 patients themselves would be able to report adverse drug reactions [ADRs], albeit through NHS Direct. But when our members rang NHS Direct, they knew nothing about it - further enquiries showed that it had all been delayed because Lord Hunt had resigned over Iraq!

Then the new Minister of Health, David Lammy, announced that on April 25th the first phase was starting at NHS Direct in Beckenham. This did actually happen and one of our members in the area reported his ADRs to GM insulin to NHS Direct only to discover that the nurse handling the call would then decide whether or not to report this to the Medicines Control Agency! So I was naive to think that the changes would actually give patients a greater access to directly report their adverse reactions - the government's announcement merely amounts

to patients being able to report to certain nurses as well as doctors! Sorry for believing the spin!

Restrictions on the number of blood glucose strips

You may remember that we have received reports from members that some GPs are refusing to supply blood glucose test strips to their patients with Type 2 diabetes [although this has also applied to some people with Type 1]. The grounds for refusing tests strips were:

- "Research has shown that day to day variations in blood sugars play no part in decision making regarding your medication"
- "The HbA1c test is the crucial test and this should be done annually and if you have a medication change, it will be re-tested after 4 months."

IDDT wrote to David Lammy on May 2nd but apparently this letter was 'lost' and discovered 2 months later, after he had moved jobs! During this time Jenny wrote to her own MP to request a reply and also to Rosie Winterton, the new Minister of State for Health.

Response from Rosie Winterton:

- The National Institute for Clinical Excellence [NICE] guidance on the management of blood glucose in Type 2 diabetes [September 2002] found evidence that self-monitoring does not necessarily improve overall blood glucose control.
- Health professionals are expected to take guidance from the NICE fully into account when exercising their clinical judgement for individual patients. But NICE guidance does not override the individual responsibility of health professionals to make appropriate decisions for the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

The patient's version of the NICE Guidance for Type 2 diabetes makes the following points:

- To help prevent health problems associated with diabetes, it is important to monitor and manage your blood glucose levels.
- Expect a lab assessment, HbA1c every 2 to 6 months.
- Your doctor or nurse may also discuss self-monitoring with you. This doesn't replace the lab assessment [HbA1c] but it may help some people.

So NICE does NOT specifically recommend that people with Type 2 diabetes should be denied their glucose test strips - just that evidence has found that it does not improve overall blood glucose levels. It is worth noting that NICE recommend HbA1c tests should be done every 2-6 months, not annually as our member's GP said!

We have written back to Rosie Winterton to point out that self-monitoring is more than just overall glucose levels but about day to day living with diabetes. Knowing where your blood sugars are enables people to take action - those with non-insulin Type 2 diabetes can eat less or exercise more if their sugars are high and eat more if they are low. Those with insulin treated Type 2 can adjust their dose but above all, self-monitoring also enables people to have greater confidence in their day to day lives, knowing that they have a better chance of detecting unexpected low blood sugars and taking action to avoid the unpleasant feelings of highs. We also argue that if people do not know how to do this, then this is a problem with diabetes education and not a reason to refuse test strips.

If you are denied blood glucose test strips, please let us know. In the meantime, we recommend that you use all these points in discussion with your doctor but really this is one battle that should not have to be fought!

From Our Own Correspondents

Dear Jenny,

Thank you for the terrific article on joint and muscle problems in the July newsletter. It highlights an area of diabetes that is very unreported.

Two years ago, I discussed with my GP, that the arches under my feet were terribly sore. This condition was deemed fairly common and viewed as problems associated with the tendons contracting in my leg and feet. I had orthotics made and since then my feet have been fine.

However, just recently, my right hand has developed Dupuytrens Contracture. I have mentioned this to my specialist, and apart from the diagnosis, a 'wait and see' prognosis is the usual remedy until the hand becomes restricted in movement. Also, my right wedding ring finger, a short while later developed a trigger movement associated with "trigger finger."

I believe that all three recent episodes with my feet and hands are interrelated and are caused by the tendons effected by the long-term condition of diabetes.

In contrast to Rae Price's article, I have been on animal insulin for most of my life, so this may contradict Rae's belief that her pains in the feet and hands were due to human insulin. In addition, my diabetic control over the last 20 years has been excellent, averaging 5mmols/l, so I believe this is not caused by poor control, but a long-term chronic condition.

It would appear that the cause of joint and muscle problems are not very well understood by the medical fraternity. Informative articles written in the last IDDT newsletter are important in highlighting this little understood condition to all the community. Well Done!

e-mail Mr GM
Australia

My little boy is worth it!
Dear Jenny,

I wrote to you from the US several months ago and you sent me literature about animal insulins and explained that you are advocates primarily for diabetics who wish to use animal insulins.

You folks have changed our lives forever. Our son Joshua was diagnosed just before he turned 3 in 1995. We first wrote to you shortly after he was diagnosed. He has always been on humulin insulins (which we now refer to as synthetics) but we read the literature and could not believe that all the side effects he has always had were from the synthetics, so we immediately switched him to pork insulin. IT IS NOTHING SHORT OF A MIRACLE!!!!! No more phantom leg pains, no more lows we didn't see coming, AND most of all my little boy has turned into the sweetest, easiest to get along with little boy we have ever seen. (This is in comparison to how he has been since being on synthetics). He's all boy don't get me wrong, he is not perfect but this change in him is like the difference between Dr Jeckyll and Mr Hyde. Another thing Joshua is going on 11 yrs now and this change has also drastically changed his appetite also. He isn't eating anywhere near as much as before.

He has always been our first priority May god bless you for your work here and please use our testimony if it will help other people.

Karen A Conrad
E-mail

Note: Karen was able to buy pork insulin because insulin is still an over the counter medicine in the US

Wow!
Dear Jenny,

Wow. Thank you for a great website. Yours is the best compilation of information on the 'human'/animal insulin issues I have found. My

husband, Vic, has been a Type I diabetic for almost 30 years and was placed on 'human' insulin about 7 years ago. His doctor had been unable to come up with anything to help him with his hypogylcemic unawareness (mostly he just chastised him for not 'being good'). So Vic started looking for answers on the web, and found out about the 'human'/animal insulin debate from several websites. He has been on regular pork insulin for 3 weeks now but still human NPH (long-acting), and is sensing his hypoglycemia better. His color is better, his sugars are better, his outlook is better, my outlook is better...you get the idea.

It's still not 100%, but I think as we get the peaks and valleys in his blood sugars to even out more, things will continue to improve. Already the rises and falls in sugars are slowing down and are not as extreme. His before and after blood sugar charts are really fascinating. We also want to switch the NPH over to pork. He sees a new doctor July 2, and I think we'll use some information from your site to reinforce our position.

e-mail from Janet from Pennsylvania, USA

Much better control and more……
Dear Jenny

Sorry its taken me so long to up date you. Since my change to porcine insulin on 8.4.03 [which my diabetes nurse said wouldn't change any thing], I have had much better control of my glucose levels, better control of my temper, less aching of my joints [although my legs still ache for no reason] and no yeast infections, which is a major result on its own. My last fasting blood test came back with every thing OK and my condition seems a lot more controllable, another bonus is that the pen is a better design than my old one.

e-mail Gentleman from the Midlands

Target Tales

Audit Commission Report
The Audit Commission assessed every hospital trust in England to see if they are meeting the targets set out in the NHS plan, July 2000. It found that while progress was being made in some areas, mainly waiting times, trusts were failing to meet other key targets. Over half of the trusts have been diverting money away from future projects, such as buying medical equipment, in order to meet targets. The Commission called for fewer targets and for ministers to allow managers and medical staff to be left to decide how to achieve them, with the Chairman, James Strachan pointing out that there is a real risk that the value of billions of pounds of new public money will not be maximised.

NHS Targets in A&E
An official audit, carried out in late March, showed 85% of the 207 A&E departments in England met this target during the week in which statistics were collected. But a study by the BMA found that in the following week the figure dropped to 63%. Hospitals had bussed in temporary staff, made staff work double shifts and cancelled routine surgery to meet the target.

Targets blamed for blindness
The clinical director of Bristol Eye Hospital told a Commons committee that waiting targets for new appointments had been achieved at the expense of cancellation and delay in follow-up appointments. His hospital cancelled more that 1,000 appointments a month and some patients had waited 20 months longer than the planned date for their appointment. Over the past 2 years, 25 patients, mostly those with glaucoma or diabetes had lost vision as a result of delayed follow up.

GPs scrapping advanced appointments to meet waiting time targets
The NHS Plan requires GPs to reduce the waiting time for appointments to no more than 48 hours by 2004. But many GPs say that the only way they can meet these targets is to scrap advanced appointments and tell patients to phone on the day they want to attend. Dr Peter

Holden, a senior member of the BMA GP Committee, is among the doctors whose surgeries have adopted this policy, estimated to be 20% of GP practices. His surgery had been forced to scrap advanced appointments or lose £9000 a year funding from the local primary care trust for failing to meet targets. He described the 48hour target as 'election fodder'!

Government claims hospitals are cleaner

Every hospital in England has been given a 'traffic light' rating by the Dept of Health for cleanliness and catering. The latest assessment gave 78% of hospitals a green rating for their cleanliness compared with 60% last year, for catering 43% received the green light compared with only 17% for last year. But a recent survey of 95,000 patients showed that 11% said the bathrooms and toilets were dirty and 7% said the wards were dirty.

Despite government claims that standards of cleanliness are improving, hospital acquired infections, such as the superbug MRSA, are increasing. A green rating for cleanliness has been given to 15 of the 20 hospitals with the highest rates of MRSA! A bit of government spin, could make us believe that the claimed improvement in cleanliness is also improving the control of hospital acquired infections, clearly not the case. It is the MRSA bug that matters to patients because at least 5000 people die each year as a result of infections in hospitals, one of the main culprits is believed to be the infrequency of staff washing their hands.

Star ratings!

According to government, this year's star ratings compiled by the independent 'watchdog', the Commission for Health Improvement, show that NHS services are improving across England. Opposition parties and doctors have dismissed this saying that ratings are 'ludicrous', 'pathetic' and 'unfair' and many patients would agree! The Chairman of the BMA said 'Nobody should judge how well a hospital is doing by looking at star ratings'. Does anyone actually do this, other than government politicians who want to make political gain? We patients judge on the service we receive with or without stars!

Islet Transplantation - A Patient's Experience

Interview by Lorraine Hill, British Columbia, Canada

"It's the greatest development since the 1920's" is how Heather-Ann Vaincourt describes the islet transplant procedure. She would have marked her 36th year as an insulin-dependent diabetic this year.

Instead, the 47year-old is the first person in British Columbia, Canada, to undergo the procedure that, as far as she's concerned, left her cured. It involves transplanting healthy insulin-producing cells into a patient with Type 1 diabetes. Since March, she no longer injects insulin and is maintaining normal sugar levels.

Heather-Ann learned of the surgery through her eye doctor. She was selected from a core group of 50 diabetics in Vancouver, picked for their age, history of diabetes, general health and complications that would not jeopardize the procedure. After being selected in June, 2002, she was told it could take months or years to find a matching donor.

"I was told I was picked at random" she says, but felt her low insulin requirements and ideal body weight contributed to being chosen. She had previously injected 6 - 8 units of Humalog before each meal, as well as 12 units of NPH before bedtime.

The cell transplant takes about an hour. Cells are collected from a deceased donor, a factor that hampers cell availability in Canada. Heather-Ann underwent the operation twice, which occurs often in this still-experimental stage. A small hole is pierced through a portal vein into the liver. The cells adhere and then produce insulin. She did experience discomfort and was administered a pain-killer during the second transplant which quickly sent her into "la-la land".

Her sugars do rise after eating now as they do in normal people, but she is injection-free. It is not without complications, however. Anti-rejection drugs must be taken on an empty stomach, and cause her slight side effects, such as occasional diarrhea. She can eat a

normal diet, but has been told not to over-indulge: “I can’t eat a whole chocolate cake,” she says, “But then again I wouldn’t want to.”

She speaks warmly of the surgeon who performed the transplant, Dr. Mark Meloche.

He performed Canada’s first successful islet cell transplant in Alberta in 1990, and “has a great sense of humour. Before the operation, he told me that he had slept well, and that if he could, I should have no problem”, Heather-Ann recalls.

She tests her glucose four times a day. And while the prognosis remains guarded, she is enthusiastic about the transplant. “A normal person wouldn’t consider this wonderful,” she admits, but is overjoyed at the energy she now experiences.

The injected cells equal about half a pancreas and do not multiply. So there is no guarantee that the cells will continue to function, or for how long. And anti-rejection drugs cannot be given until a donor is matched, so their effects are not known until actually ingested. She’s also experiencing a low white blood count, making her susceptible to colds and ‘flus. But she considers these complications minute in comparison to the highs and lows she once experienced.

In Edmonton, Alberta where the first Canadian diabetics underwent cell transplants, eight out of ten patients successfully became injection-free. About ten to 12 operations per year are expected to be performed in Vancouver. Diabetes affects about two million Canadians.

The Edmonton islet transplant progress

The good news
Two years ago Dr James Shapiro and his research team in Canada achieved remarkable success in transplanting insulin producing islet cells into people with Type 1 diabetes. A year after transplantation, 85% of the 33 people remain free of insulin injections. In the Summer 2002 edition of Countdown, JDRF, Dr Shapiro gave a very realistic approach pointing out that with only 30 to 40 people being given transplanted islets, it is very much still a research project and from this small number, only limited information can be obtained. When 300 or 3,000 people have received the treatment a great deal more will be known about the risks.

The not so good news - the Edmonton islet transplants are hard to duplicate at other centres

Dr Shapiro’s work has expanded to 8 centres in other countries with a goal of transplanting 36 people. This is being funded by a $23million grant from the Juvenile Diabetes Research Foundation [JDRF] and the National Institutes for Health in the US.

But bad news was announced at the American Transplant Congress [May/June 2003] when it was reported that the insulin-free rate at other centres is as low as 23% - only 3 out of 13 people remaining insulin free. There have been 15 cases of severe adverse events with one person needing a transfusion because of severe bleeding from the procedure. Most of the side effects were caused by the anti-rejection drugs. A further problem was that 40% of patients had to start treatment with statins because of new onset high cholesterol due to the anti-rejection drugs.

It is expected that in newer trials different combinations of drugs will be used to try to avoid these unwanted side effects.

Help IDDT - Clearance Sale Of Christmas Cards!

Instead of offering new design Christmas cards, this year IDDT is selling off our excess Christmas cards from last year at £2.00 per pack of 10. The designs are as follows: ‘Christmas Firs’ and ‘Red Santas’. If you can buy just one pack of IDDT cards, this would help to

raise much needed funds for IDDT. Please help IDDT and order your cards on the form enclosed with this Newsletter or contact IDDT, PO Box 294, Northampton NN1 4 XS or telephone 01604 622837.

Intersting New Website

This little website is well worth a look for those who have access to the internet. It describes the experiences of Vic, one of our US members who, when treated with synthetic 'human' insulin, lost his hypo warnings and eventually crashed his car. In their search for a better way of life, Vic and Janet discovered that there was the choice of using pork insulin. Life changed - Vic regained his warnings and felt in control of his diabetes again. They make the point that while synthetic insulin may suit many people, pork insulin works better for Vic. Visit their website at www.insulinquest.com

Australia

One 'mad' cow in Canada and IDDT- Australia has to jump into action!
In June 2003, a single case of BSE in a cow in Canada triggered a potential crisis for bovine insulin users in Australia. The Australian Quarantine Inspection Service [AQIS] put an immediate ban on the importation of Hypurin Bovine insulins, leaving people who can't use synthetic 'human' facing the prospect of knowingly taking insulin that adversely affects them.

But the ban was completely opposed to the March 2001 statement from the Australian Medical Officer for Health, Professor Smallwood who then said that *the potential risk from beef insulin is infinitesimally small but there is a very real risk to the health of people if their current treatment using bovine insulin is disrupted.*

Within hours of the ban, Ian Kershaw who runs the IDDT-AU website, e-mailed Senators and MPs to ask them to use their political influence to persuade AQIS to allow the importation of bovine insulin. Michael Ginges contacted the press and Larrane Ingram contacted Diabetes Australia and various other concerned people.

Investigations in Canada to provide evidence to dispute the ban
Carol Baker, IDDT's trustee in Canada immediately contacted the Canadian Food Inspection Agency who confirmed that their system for ensuring that any animal deemed condemned or unfit for human consumption, could not get into the food chain or the collection of bovine parts for medicinal purposes. They added that Australia, the US, Canada and the UK all basically follow the same principles of animal slaughter so Australia should realise that the pancreas of the affected cow did not get into the 'mix'.

Turnaround in 24hours!
Within 24hours the AQIS decision was overturned by the Therapeutic Goods Agency [TGA], the drugs regulatory authority. What a relief! But they stipulated that the information to prescribers should be in the form of a 'Dear Doctor' letter stating that *"the insulin was sourced in Canada and despite the risk of contracting BSE being extremely low, it is necessary to obtain informed consent from all patients using Hypurin beef insulin".* It should also contain a statement that "prescribers should transfer their patients if feasible to recombinant human insulin". [Only cows contract BSE, the human form is nvCJD!]

IDDT- International had to go into action!
This appeared to be quite different from the advice by Professor Smallwood in 2001, yet the actual position was no different.

We were concerned that the 'Dear Doctor' letter would cause unnecessary alarm and people may be 'forced' or 'persuaded' to change to synthetic insulin despite their previous experience of adverse affects.
IDDT faxed these concerns to the TGA and basically they told us to mind

our own business! '*I would like to point out to you that as a regulatory agency we deal with the sponsor regarding their product and not with other interest groups'. But it also said that 'No advice has been given to the sponsor by the TGA that contravenes the Chief Medical Officer of Health's advice on the 22nd of March 2001'.* So our points were taken on board and Hypurin beef insulin will continue to be available.

Conclusions from this Australian experience
The most worrying aspect of this experience, is the ability of bureaucrats to be able to take an action without any consultation, any evidence or consideration for the effects on people's lives showing that we have to act to protect our own health needs. IDDT-International's ability to act quickly and in different countries resulted in a very quick turnaround in government department policy. The years of work developing IDDT-International have paid off.

News From Europe

EU Prepares to introduce new rules on complementary medicines
The European Union is preparing to introduce tough new rules on complementary medicines whereby manufacturers will have to show that herbal medicines are not a threat to public health. If approved by EU health ministers, some remedies will probably disappear from the market.

Research has shown that in the UK consumers spend £130million a year on herbal remedies, aromatherapy oils and other alternative treatments and it is predicted that this will rise to £200million by 2008. Consumer analyst, Mintel, surveyed 25,000 people in the UK and found that the EU changes could have a major impact on the manufacturers, bringing them into competition or even conflict with highly researched conventional medicines that have far greater financial backing.

The results of Mintel's survey show that:

- One in two people have visited an alternative health practitioner, such as an osteopath, aromatherpist or acupuncturist. This figure is even higher for men, with two out of three visiting an alternative practitioner.
- Overall one in five said they would prefer to take natural products to treat their ailments.
- One in five people are concerned about possible side-effects of complementary medicine and one in four said they would like pharmacists to provide more information about complementary medicines.
- One in four believe that alternative remedies can help to relieve common ailments such as back pain, stress, coughs and colds.

Important - the survey did show that people often take complementary medicines with pharmaceutical drugs and doctors have warned that this could put people at risk because some remedies interact with conventional drugs. This is also true for people with diabetes and you should always tell your doctor if you are taking any complementary remedies or supplements.

Another interesting comment IDDT has received from people who use alternative treatments such as reflexology and aromatherapy is that they feel more relaxed and often need to slightly lower their insulin dose.

Novo Nordisk - name change for human insulin

August 2003
Over the next 6 months, the Novo Nordisk range of synthetic human insulins are undergoing a name change - the word 'Human' will be omitted so that for example, what is now 'Human Actrapid' will become simply 'Actrapid'. The insulin products will remain the same and so there will be no need for a change of insulin type, dose or regime. The insulins below, as well as Novo Nordisk 3ml Penfill cartridges, will also have changes in the packaging and the patient information leaflets. These changes have been approved by the EU Commission and will apply throughout Europe.

The name changes are as follows:

Current name	New European standardised name
Actrapid Pen	Actrapid NovoLet
Human Insulatard Pen	Insulatard NovoLet
Human Mixtard 10 Pen	Mixtard 10 NovoLet
Human Mixtard 20 Pen	Mixtard 20 NovoLet
Human Mixtard 30 Pen	Mixtard 30 NovoLet
Human Mixtard 40 Pen	Mixtard 40 NovoLet
Human Mixtard 50 Pen	Mixtard 50 NovoLet
Human Actrapid [10ml vial]	Actrapid [10ml vial]
Human Insulatard ge [10ml vial]	Insulatard [10ml vial]
Human Mixtard 30 ge [10ml vial]	Mixtard 30 [10ml vial]
Human Mixtard 50 ge [10ml vial]	Mixtard 50 [10ml vial]
Human Velosulin [10ml vial]	Velosulin [10ml vial]
Human Monotard [10ml vial]	Monotard [10ml vial]
Human Ultratard [10ml vial]	Ultratard [10ml vial]

It is just a bit worrying that future generations will believe that Novo Nordisk synthetic insulins are actually insulin not the GM copy that they actually are!

Important for Novo Nordisk Pork Insulin Users

The names of ***Pork Actrapid*** and ***Pork Insulatard*** will NOT change but IDDT has concerns that confusion could arise when a prescription for Novo Nordisk pork insulin is dispensed. While we welcome the removal of the misleading name 'human', not stating some other alternative in the name or on the pack, such as synthetic or GM, in the name or on the pack, could lead to ***GM Actrapid*** or ***GM Insulatard*** being dispensed by the pharmacist in error.

We have discussed our concerns with Novo Nordisk and have been assured that

- the new human insulin packs look very different from the pork insulin packs and that there will be a warning on the side of the packs for the first 6 months
- the Patient Information Leaflets for the 'human' insulin range clearly state the origin in bold type in Section 1.

They are going to issue warnings to pharmacists through pharmacy journals and supply fridge magnets to pharmacies. It remains to be seen if this will totally prevent mistakes happening, not just for the next 6 month but indefinitely.

IDDT issues the following warning:
ALWAYS check that you have the correct insulin BEFORE leaving the pharmacy. ALWAYS read the Patient Information Leaflet even if you have been using insulin for years, because this is where any changes will be reported.

Snippets

- Female redheads respond to pain killers better than women with other hair colours according to US researchers. Apparently this is because the genes that control pain pathways are linked to those controlling hair colour.
- A synthesised copy of an ingredient from the saliva of the Gila monster, a poisonous lizard, is being investigated jointly by drug companies Lilly and Amylin to see if it lowers blood sugars in people with type 2 diabetes. Amazingly 63 people with Type 2 have volunteered to take the drug called Exenatide. Injecting it twice a day helped half of them lower their blood sugars but it had one major drawback - nausea. 27% of the 'volunteers' reported upset stomachs and 14 people dropped out of the study, 6 due to nausea.
- Receptionists at GP surgeries in Swansea are to be sent on courses to learn to how to be nicer to patients after a surge of NHS complaints! The courses aim to make receptionists more

approachable and more cheerful and they will also be taught how to diffuse difficult situations.

- About 1 in 500 dogs and about 1 in 200 cats have diabetes. It is more common in older cats and dogs and is more common in some breeds of both cats and dogs.

Bits And Pieces

HbA1c test at home in the US – Metrika Inc. have been granted over the counter marketing approval for a pager sized monitor to enable people to measure their HbA1cs at home to obtain immediate results. The results are obtained in 8 minutes from a small drop of blood. It is available in the US by mail order or through pharmacies without a prescription at a cost of $22-25. Further information is available on Matrika's website www.A1cNOW.com or Matrika's toll-free number 877-A1C-4-YOU [877-212-4968]

Launch of third drug for erectile dysfunction in UK - clinical trials have shown that vardenafil [Levitra, Bayer/GlaxoSmithKline] is effective and reliable in a wide range of men with erectile dysfunction. Among men with diabetes 73% taking 20mg vardenfil showed a significant improvement in erections. Most adverse events were mild to moderate and transient - headache, flushing, rhinitis, dyspepsia, nausea and dizziness. Vardenafil is taken orally 25 to 60 minutes before sexual activity and is effective up to nearly 5 hours later.

New drops for glaucoma – people with diabetes appear to be more susceptible to glaucoma although this may be due to a higher detection rate because their eyes checked more regularly than the general population. Until a few years ago the main type of glaucoma, primary open-angle, was treated with twice daily drops of timolol. Several newer drops have become available and these have been reviewed in the Drugs and Therapeutics Bulletin [2003;41]. This shows that the drug, latanoprost, appears more effective at treating glaucoma, causes less side effects and is only required once daily although it has one unusual side effect - it causes darkening of the iris and the eyelashes and the long term consequences of this are not known. Latanoprost also costs almost 4 times as much as timolol.

Warning letter to Roche Diagnostics - the FDA uncovered 'serious problems' in the manufacture of Roche Disetronic insulin pumps during the inspection of their Swiss plant, Jan 27 to Feb 5. The FDA are expected to follow up investigations.

Samaritans, new e-mail support service - the Samaritans, the charity offering confidential support to people in despair or distress, has received funding to provide this service nationally. The new e-mail service is completely confidential and uses software that removes the identity of the sender and replies are received within 24hours or sooner. To use this service, e-mail jo@samaritans.org but this is just an extra service and their phone number is still 08457 90 90 90

CHCs in England given temporary reprieve - in the revision of the NHS complaints procedure Community Health Councils that have provided independent help and support to people wishing to complain, are to be scrapped. But they have been a temporary reprieve and will continue until December 2003 because of the delay in setting up the new systems! CHCs will continue in Wales and will deliver the new complaints advocacy service.

Attention Worcester Members!

Sue Morris, IDDT's Honorary Treasurer, is representing people with insulin dependent diabetes on the South Worcestershire Diabetes Network. Sue will be pleased to hear from anyone in the area on any aspects of their care.

Contact Sue on her home phone number, 01905 458309 or email sue.morris@talk21.com

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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