

Another Year - 2008!

The Trustees of IDDT send their best wishes for 2008 to all our members and readers. It's a time to make New Year resolutions even though sometimes we know in our heart of hearts that we won't keep them! However flippant or serious our resolutions may be, they do mean that we have looked at our lives and decided that there are things that we would like to try to change. Perhaps it is the trying that is really important. Diabetes is a condition where we have to try all the time, whether as someone with it or as a parent or carer.

I am sure there are others that will join me in a New Year wish that in 2008 all our trying will be appreciated when we go to the diabetic clinic. Our results may not be what the doctor or nurse want to see, but that doesn't mean we haven't been trying. It doesn't mean that

we deserve a slap on the wrists or to be told 'you must have been eating the wrong things'! Some useful and practical advice on how to achieve their targets without increasing the numbers and severity of hypos would help but so too, would some praise!

Perhaps only those who live with diabetes can appreciate that we can try our utmost but sometimes, it just goes adrift and we don't know why. Perhaps you have to live with diabetes to understand that this and the constant trying can just get us down - the Americans call it 'diabetes burn out'. A bit of praise, encouragement and understanding wouldn't go amiss and can play a big part in preventing 'diabetes burn out'.

What's IDDT's resolutions for 2008? That we will keep trying too! At the end of 2007 Novo Nordisk pork insulin disappeared but the need for pork insulin has not. IDDT will continue to do all it can to

ensure the Department of Health keeps its promise that pork insulin will continue to be available.

We will also continue to try to ensure that people with diabetes have the informed choice of treatment they deserve. If this means that we raise issues that are unpopular in some quarters, so be it. If this means that we identify gaps in research to show that the treatments of adults and children with diabetes are not evidence-based, we see this as step forward as it highlights the need for further research.

We will continue to hold the view that it is unacceptable for people with diabetes to be automatically treated or changed to the latest insulin or drug, simply because it is 'modern'. There has to be evidence of benefit and superiority and as patients, parents and carers, we have to know that new insulins and drugs have been fully investigated using outcomes that are important to us, such as comparisons of mortality and complications rates, quality of life and above all, that long-term safety is known. As individuals we can all play our part in ensuring that our treatment is not changed simply because a new 'modern' insulin or drug has come on the market – we just have to ask for the evidence about risks and benefits of the proposed changes in treatment.

IDDT is a relatively small organisation but just as individual people with diabetes try, so does IDDT. We have no hidden agenda, no outside influences upon us and we are completely independent of the pharmaceutical industry. We are motivated by the need for people who live with diabetes to have an informed choice of treatment, to have treatment that is individualised to their needs and that is known to be safe.

To help us achieve these goals, we could all make the same resolution for 2008 – that we will be more assertive, we will not be afraid to ask questions about our treatment, we will not unquestioningly accept changes and we will be involved in making decisions about our own diabetes and ultimately, our health.

Your Opinion Counts

Creative Market Research Ltd [CMR] is a specialist research company operating exclusively in the field of healthcare. They are effectively the channel through which people with diabetes can feed back their ongoing experience direct to the meter, pen and insulin manufacturers, a process that helps to drive the development of better and more effective products.

CMR operates to the highest ethical standards and is meticulous when it comes to patient confidentiality. Research at CMR is internet-based and involves no phone calls

If you have access to the web and are prepared to share your experiences for the benefit of yourself and others, log on at: www. medisurveys.com

If you would like to help improve the products you use every day, join the panel.

If you have any problems or questions do call Sue Reynard on 01473 832211 or email her at sue@creativemarketing.co.uk

Diabetes and Your Skin

After a time I think that most of us start to realise that diabetes can affect almost every part of the body and the skin is no exception.

Facts about skin

- It is the largest organ of the body.
- The skin of an average sized adult covers about 18 square feet and weighs about 7 pounds.

Structure of the skin

The skin is made up of three layers: the epidermis, the dermis and the subcutaneous layer.

The epidermis - is the outer layer of the skin and contains cells that determine skin colour and protect against damage. Epidermal cells are constantly being warn away and replaced with new ones. Damage to this layer of the skin is not normally a problem because it repairs itself very quickly but in people with diabetes this healing process is often slower than in people without diabetes.

The dermis – is the layer under the epidermis and contains:

- blood vessels and sweat glands to help regulate body temperature
- nerve endings
- hair follicles
- sebaceous glands [glands that produce oil] to help prevent loss of too much sweat by coating the skin with a layer of oil.

Injury to this layer of the skin is a greater problem than injury to the epidermis especially for people with diabetes. As diabetes can affect the nerves and blood vessels, the dermis can cause the skin to become dry. Once it is dry, it can crack and become open which means it is more difficult to heal.

The subcutaneous layer – is below the dermis where fat is stored. The sweat glands originate here and it supports the blood vessel and nerves that feed the outer layers of the skin. Any damage or injury to the dermis or subcutaneous layers will cause pain as they both carry the nerves, this assumes that the nerves are not damaged by diabetic neuropathy or any other cause. The pain caused by a response from the nerves to the brain acts as a protection eg if you touch a hot oven, it is the nerves in the dermis and subcutaneous layers of the skin that pass pain messages to the brain. In diabetic neuropathy [nerve damage] the nerves do not work properly so pain is not felt and there is a risk of further injury due to lack of feeling of pain.

Diabetes can affect your skin

If blood glucose levels are too high and you pee a lot, then this can lead to dehydration. Then the blood vessels and glands that normally keep your skin moist can be affected causing dry skin. Dry skin can cause premature aging but more importantly, the dry skin can crack and infections can develop and this is made worse by the slower healing due to diabetes.

Prevention is the best

As with many aspects of diabetes, preventing the problem from arising is the best course of action and as with all things connected with the care of diabetes, firstly this means aiming for blood glucose levels and blood pressure to be as near normal as possible, eating a healthy diet with plenty of fluids and taking regular exercise. [I know we've heard it all before!] It is also important to look at your skin to detect any changes and to keep all your skin clean and moisturised with moisturisers, lotions or creams and this is not just important for the ladies!

Lower Carb Diets may be Recognised, at Last!

Up to now the American Diabetes Association [ADA], and most other diabetes organisations, have been unwilling to recommend significant carbohydrate reductions / restrictions. Their reasons have been that the diet is too difficult to follow and increasing fat and protein may cause health problems. However, there is increasing evidence that low carbohydrate diets can help people with Type 2 diabetes including weight loss, reduction in blood sugars and often a marked decrease in triglycerides and long-term studies are showing that the feared illeffects are not present. As many people are aware, low / restricted carb diets also help people with Type 1 diabetes so we will have to wait for the publication of the new ADA recommendations Diabetes Care, January 2008] to find out if they are going to include Type 1 diabetes too.

Latest News...

On Avadia

30TH October 2007 – as reported in previous Newsletters, the Type 2 drug Avandia has been shown to increase the risk of heart attacks and there has been debate about whether or not it should be pulled from the market. Europe has decided that there should be stricter warnings about its risks. In the US in July an outside panel voted 22 to 1 to keep it on the market with stricter warnings. In October 2007, the FDA did decide to allow Avandia to remain on the market but with a 'black box warning' – the strongest warning that can be given by the FDA. However, the interesting thing is that the vote in favour of not pulling Avandia from the market was by the narrowest of margins, 8 to 7. So if one person had voted the other way, Avandia would have been pulled from the market, which can't be expected to fill patients with confidence about its safety! There has been criticisms that the proceedings have not been made public so we don't know why almost half of the experts voted against Avandia remaining on the market.

And would you believe? Research presented at the European Association for the Study of Diabetes in September 2007 showed that drinking green tea was as effective as Avandia at lowering blood glucose levels in people with Type 2 diabetes who were just able to tolerate sugar. And without the risk if heart attack! Green tea contains the antioxidant epigallocatechin gallate and at the end of the 10 week trial, the green tea extract was also found to preserve insulin-producing tissue and offered other protective effects in the pancreas.

On Anti-Obesity Drugs

British Medical Journal, 16.11.07 – a meta-analysis review of 30 trials of anti-obesity drugs suggests that in many cases ant-obesity pills achieve little in terms of weight loss. 20,000 obese people weighing on average 100kg [15.7 stone] reduced their weight by 2.9kg with orlistat [Zenical and Alli in the US], 4.2kg with subtramine [Meridia] and 4.7kg with rimonabant [Acomplia] but it was unclear whether this was sufficient to have big health benefits. Orlistat reduced the incidence of Type 2 diabetes in one study and all three drugs lowered

certain types of cholesterol. A separate study in The Lancet the same week, found that patients given rimonabant were at increased risk of severe psychiatric events, including suicide.

Distributors of orlistat have applied for it to be an over-the-counter drug [OTC] in Europe as it is in the US but in an editorial in the BMJ Prof Gareth Williams, said, "Selling antiobesity drugs over the counter will perpetuate the myth that obesity can be fixed simply by popping a pill and could further undermine the efforts to promote healthy living, which is the only long-term escape from obesity." He is concerned that casual users will abandon it due to the unpleasant side effects, such as oily stools and faecal incontinence. Its modest benefits which are equivalent to leaving a few French fries off the plate, eating an apple instead of an ice cream or having 10-20 minutes sex.

In March 2007 the United Nations' International Narcotics Control Board [INCB] issued a warning about the rise in the use of weight loss drugs in a number of countries stating that they are being used indiscriminately in some countries to feed society's obsession with being slim. Some countries have introduced measures to reduce their use but in others such as Argentina, Australia, Brazil and the US, their use has risen significantly. According to the INCB these drugs can be addictive, they stimulate the central nervous system which could produce serious adverse effects if used indiscriminately and overdose is potentially dangerous.

On Byetta

New warnings about Byetta issued by US FDA - Byetta [exenatide] is a recently approved injectable drug to treat Type 2 diabetes that is proving very popular, being used by 700,000 people worldwide. It works by mimicking the effect of incretin hormones produced in the gastrointestinal tract to boost the release of insulin triggered by glucose.

In October 2007, the drug regulatory body in the US, the FDA, issued an alert that there is a suspected association between Byetta and pancreatitis in some cases. Pancreatitis is inflammation of the

pancreas that can kill the insulin producing beta cells if left untreated. The manufacturers have agreed to add information about acute pancreatitis to the precautions section of Byetta's label, already included in the EU approval labelling. The FDA said that doctors should tell patients taking Byetta to seek prompt medical care if they develop unexplained, persistent severe abdominal pain which may or may not be accompanied by vomiting. Byetta should be discontinued if pancreatitis is suspected and if confirmed, Byetta should not be restarted.

Can Byetta be substituted for insulin in people with Type 2 diabetes already using insulin? A study carried out by manufacturers of Byetta, Lilly, has shown that this was possible in less than two thirds of patients without alteration of glycaemic control. However, in an editorial, the design of the study is highly criticised because no attempt was made to optimise insulin treatment and therefore the results could well be biased in favour of Byetta – good for marketing it! [Diabetes Care Vol 30, No 11]

November 2007, the once a week version of Byetta is superior to the currently used twice-daily version. A 30-week study involving 295 patients with type 2 diabetes compared HbA1c levels. Once-weekly Byetta showed a statistically significant improvement of about 1.9% compared to an improvement of about 1.5% for twice-daily Byetta. Similar weight loss of about 8 pounds (3.6kg) on average was seen with both patient groups. The once-weekly version may not receive approval until 2009 and may be beaten to the market by Novo Nordisk's type 2 drug liraglutide.

Just a thought.......Since the 1980s, the recommended diet has been high carbohydrate/ low fat diet for the general population as well as people with diabetes. 25 years later we have a population that is more overweight and obese than ever before. Common sense would suggest that the recommended diet isn't working. Isn't it time for a rethink by the powers that be?

And anoter......The pharmaceutical industry spends £850 million a year marketing its products to UK GPs. Does this influence GPs

when it comes to writing prescriptions? It is claimed that it doesn't but if this is the case, it seems a waste of their £850million!

For the Ladies

Pregnant mums with diabetes - important message

An issue that has been raised with IDDT is that mums who have given birth to healthy babies have had their babies removed from them and placed in the special baby care unit – even in hospitals with a 'good reputation'. Some pregnant diabetic women are being told that their newborn baby will be placed in the special care unit as if this is a necessary and normal procedure.

Obviously this could be necessary on health grounds but many diabetic mothers are being separated from their babies for no other reason than hospital convenience or 'hospital policy'.

Recently the Confidential Enquiry into Maternal and Child Health [CEMACH] stated that in over half of mothers with Type 1 and Type 2 diabetes their babies are automatically moved to a special care baby unit. CEMACH goes on to say that if the babies are healthy at birth there is no reason for this and it has negative impacts – breastfeeding becomes difficult because infant formula is used in the special care unit and newborns' body temperature becomes harder to regulate. It does not require a report from CEMACH to know that mums and their newborn babies are better not separated unless there are health grounds for doing so.

The Chief Executive of CEMACH has stated that more babies could stay with their mothers than is presently the case and mothers with diabetes should be encouraged and supported to breastfeed their babies. He goes on to say that if these aims were achieved, it should be better for both mother and baby and also save the NHS money.

IDDT advice to pregnant women with diabetes: make sure that you know the hospital system before you are due to have your baby and make it clear that you don't want to be separated from your newborn baby unless there are medical grounds for doing so.

Analogues and pregnancy

Naturally pregnant women or those considering pregnancy are always concerned about any medications they take at this time. Clearly women with diabetes have to take insulin but still need to know about any safety issues for both themselves and the unborn baby. Here is some information that may be helpful.

Lantus - some experimental studies have shown that insulin analogues have growth-promoting effects and concerns have therefore been raised that use of Lantus insulin during pregnancy could cause excessive foetal growth and other problems. Reuters reported that a review actually recommended Lantus was not used during pregnancy, but called for further studies to investigate its safety.

A small study carried out in Oxford [ref 1] involving 20 pregnant women with Type 1 diabetes and 44 with gestational diabetes [diabetes during pregnancy] investigated the safety of Lantus [glargine]. Half the women used Lantus and the other half 'standard' insulin.

There were no significant differences in birth weight between infants born to Lantus users and those born to standard insulin users. [The rate of excessively large babies was actually slightly lower in the Lantus group: 38 versus 41%.] The groups were also comparable in terms of infant complications, admission to special care infant units, and congenital abnormalities.

The authors recommend that large trials should be carried out to confirm the efficacy and safety of Lantus for the treatment of pregnant women with Type I diabetes and those with gestational diabetes.

Ref 1 British Journal of Obstetric and Gynecology, April 2007

NovoRapid – information from the manufacturers of NovoRapid [NovoLog in the US] states: "There are no adequate well-controlled"

clinical studies of the use of NovoRapid in pregnant women. NovoRapid should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus."

A recently published study [ref 1] concluded that NovoRapid is as safe and effective as GM 'human' insulin in pregnant women with Type 1 diabetes as the mother and pregnancy outcomes were the same. In this study the long-acting insulin used was NPH insulin, a 'human' intermediate insulin and NOT an analogue insulin.

Ref 1 Diabetes Care, April 2007

For the use of other analogues in pregnancy, the Specific Product Characteristics documents say:

Humalog: Data on a large number of exposed pregnancies do not indicate any adverse effect on pregnancy or on the health of the foetus/newborn.

Levermir: There is no clinical experience with Levemir [insulin detemir] during pregnancy.Caution should be exercised when prescribing to pregnant women.

Apidra: There are no adequate data on the use of Apidra [insulin glulisine] in pregnant women. Caution should be exercised when prescribing to pregnant women.

Fertility in women with diabetes has improved

A population-based study in Sweden followed 5978 women hospitalised for Type 1 diabetes at age 16 or under during 1965-2004. They compared them to standard fertility rates of expected births and compared the number of newborns with congenital malformations to the general population.

The good news is that reduced fertility was confined to those diagnosed before 1985 although the presence of complications reduced fertility in all years. The number of new born babies with congenital malformations was 11.7% in the years 1973-1984 but

dropped significantly to 6.9% during 1995-2004. The researchers suggest that stricter metabolic control during the last 20years may well have helped to improve fertility and reduce the number of new born babies with congenital malformations. Yet another good reason for keeping 'good' control. [Diabetes Care, June 11 2007]

Girls and women skipping injections to lose weight.

Diabetes UK estimate that 1 in 3 women with diabetes under the age of 30 in the UK are missing insulin injections at any one time, to help them lose weight with a high proportion of these are teenage girls. These figures are based on a small study carried out in Oxford in 1999. Nowadays it is referred to as 'diabulimia' and it is an eating disorder that can have serious health consequences. The reason for the weight loss is that missing insulin injections results in very high blood glucose levels and ketoacidosis, similar to the state before diagnosis so there is quite a large weight loss quite quickly. Although 'diabulimia' is not recognized as a medical and psychiatric condition, in the US doctors have issued warnings about this misuse of insulin.

With today's pressures to be thin, teenage girls and young women easily discover that not carrying out some or all their injections results in swift weight loss but those that have done it, admit that they feel ill a lot of the time, also tired and thirsty. One of the problems is that people who are doing this are unlikely to own up to it at the time but there will be many who admit that they have done it at some time in their lives. For parents who are wondering why their daughter's blood glucose levels are erratic, this could be one possible explanation.

Genetic variation may account for severe PMT

Researchers have found a genetic variation that makes women more likely to suffer from the most extreme form of premenstrual tension or syndrome. They carried out genetic tests on women suffering from premenstrual dysphoric disorder (PMDD) - sometimes referred to as severe or extreme PMT and discovered that the women had mutations in hormone receptor genes and also in a gene that regulates the part of the brain responsible for mood.

The symptoms, such as severe depression, irritability and anger can have a severe impact on quality of life, both for the women and their loved ones. This research is only at a very early stage and more work will have to be done but eventually it could help scientists to develop a diagnostic test and discover drugs to treat it. [Biological Psychiatry, Oct 15, 2007]

Poor sleep may lower women's libido

A study has found that low libido during menopause may be linked to disturbed sleep and this is the first time that sleep disturbances have been independently associated with diminished sexual desire. Of the 341 women in the study, 64% reported a low libido and 43% said they had trouble sleeping. The study author suggested that it seems reasonable that night sweats can disturb sleep and poor sleep can reduce energy levels for everything, including sex. [American Journal of Obstetrics and Gynecology, June 2007]

News in Brief

Inhaled insulin has failed

Exubera, the first inhaled insulin has failed to appeal to doctors and patients and in October 2007 the manufacturers, Pfizer, announced that they were pulling it from the market and would be offering advice over the next 3 months on alternative products. The lack of sales is blamed on the size of the inhaler, injections of long-acting insulin still being necessary and concerns about long-term safety.

IDDT has not been alone in saying that industry should have consulted people with diabetes about what is important to them and for the majority, injections are not the worst part of having diabetes – it is the daily grind of living with testing, with thinking about food, with planning ahead, the fear of complications – do I need to go on?

The financial press referred to Exubera as a 'market flop' and that Pfizer is writing off the huge amount of \$2.8billion (€1.96bn). Global sales only achieved \$4million.

Lilly and Novo Nordisk are developing their own versions of inhaled insulin expected to reach the market in 2009 and 2010/11 respectively. Both companies have stated that they will continue to develop these products. We shall see...

Nasal insulin delivery

Nasal drug delivery systems have been around for some time but there have been problems. Now NanoDerm, an Israeli company, has developed a system that seems to combat the difficulties and make insulin delivery through the nose not only a viable option but perhaps a better option that inhaled insulin. The system is based on nanodroplets [very, very tiny] of 10-50nm that form a gel in the nostril so far less insulin has to be given nasally to lower blood glucose levels than with inhaled insulin. These lower volumes are less likely to cause irritation to users. It's already been tested in rabbits...

Changes in warnings for Zyprexa

Many psychiatrists have expressed concerns that the antipsychotic drug Zyprexa [olanzapine] raises blood glucose levels that can lead to Type 2 diabetes. On October 8th 2007, the manufacturers, Lilly, officially agreed that Zyprexa carries a greater risk of causing raised blood sugars than almost all other drugs in the same class. Following discussions with the FDA [the US drug regulatory body] new warnings have been added to the label for Zyprexa and Symbyax [a combination of Zyprexa and Prozac]. In addition to warnings of raised blood sugars, the new labels also warn of raised cholesterol and tryglycerides and of weight gain. [Lilly has paid out \$1.2million to settle lawsuits from people claiming that they were not warned of these risks.]

Report Coming Soon - 'Insulin and Cancer'

The first International Workshop 'Insulin and Cancer' took place in Germany in October 2007. It was a 2-day meeting of leading scientists and clinicians from countries around the world who gathered to debate the issues surrounding insulin analogues, their links to retinopathy, their similarities to insulin-like growth factor, their mitogenicity [cell multiplication] and their possible carcinogenic potential. The meeting was totally independent of the pharmaceutical industry and IDDT was one of the sponsors. A full report will be published in the April edition of IDDT's Newsletter.

Particularly for Children...

We reported in the October 2007 Newsletter that Eli Lilly launched a second re-useable insulin pen product – the Humapen Luxura HD pen for use with Lilly insulin 3ml cartridges. This is now available in the UK. It can deliver insulin in smaller doses with 1-30 units of insulin and allows dosage to be adjusted forward or backward in half-unit increments so setting errors can be corrected without wastage. It will be useful to those needing a small dose, especially children.

To support children and their carers, Lilly are providing a pack of educational materials with the Humapen Luxura HD featuring cartoon character Hu-Mee the Frog and including a booklet, lunchbox, insulin pen case, monitoring diary and Hu-Mee stickers. For more information visit www.lilly.com

Report of the 2007 Annual Meeting of IDDT

As ever, the meeting was well attended - over 130 members and non-members. Many described the meeting as enjoyable and thought provoking – just what it should be. It was an opportunity to look at different ways of living with diabetes and the various treatment options. It once again made us realise that many people with diabetes have never been given choices whether these are choices about diet, types

of insulin or different insulin regimes.

'30 Years of Synthetic Insulin, are people with diabetes getting the best deal?'

Co-Chairman, Jenny Hirst, opened the meeting with the launch of this new IDDT Report. The report highlights a recent article [ref 1] by Professor Edwin Gale et al entitled 'Nice Insulins, pity about the evidence' in which he acknowledges that there is no evidence of benefit from the use of insulin analogues and questions whether people with diabetes are getting the best deal. "When the choice is between treating 150-200 patients with long-acting analogues instead of 'human' insulin or employing a full-time nurse specialist educator at the same cost – which would be best for patient care?"

When children with diabetes are receiving suboptimal care, and Primary Care Trusts (PCTs) are unable to fund educational programmes, diabetes specialist nurses or provide essential self testing strips for diabetic patients, it is shocking that PCT budgets are being consumed by ever-increasing insulin costs that provide little benefit to patients.

The Report calls for:

- Studies of 'human', analogue and animal insulins to be carried out to compare the outcomes which are important to patients mortality rates, complication rates and quality of life.
- The long-term safety and efficacy of insulin analogues to be established.
- Investigation into the cost effectiveness of insulin analogues to ensure that valuable NHS resources are not being wasted on these significantly more expensive insulins that have no substantial advantages over 'human' and animal insulins.
- The development of comprehensive guidelines on the use of all insulins by National Institute for Health and Clinical Excellence [NICE] to provide informed choice and to protect the safety of people with diabetes.

IDDT has raised these important issues by sending the Report to MPs

who have supported IDDT's call for insulin choice, to primary care trusts all of whom need to look at their expenditure on diabetes and to diabetes associations across the world, especially important for countries where safe but affordable insulins are vital for the survival of people with diabetes.

If you would like a copy of this Report, please contact IDDT on 01604 622837, write to IDDT, PO Box 294, Northampton NN1 4XS or visit the Homepage of our website www.iddtinternational.org

Ref 1 Nice Insulins, pity about the evidence. Diabetologia (2007) 50;1783-1790. Holleman F, Gale EMA.

'How you can achieve normal blood sugars with diet and insulin' Dr Katharine Morrison, a GP whose teenage son has Type 1 diabetes gave a talk on how she has chosen to look after her son's diabetes. The points she made were:

People with diabetes deserve the choice over:

- Dietary education
- Insulin regime
- Blood sugar monitoring regime
- Complications monitoring regimes and treatment of complications.

What levels of blood sugar control is right for you?

What are your personal circumstances? What degree of blood sugar control do you want to have? For instance, safe target blood sugars differ if you live alone, are a driver, are pregnant or are a teenager, a toddler or are elderly.

Dr Morrison's choice for her son is to try to completely avoid diabetic complications from high and swinging blood sugars and to try to achieve normal blood sugars his regime is:

 Low carb / low glycaemic index diet with good carb counting skills

- Avoid snacks a protein rich breakfast helps to avoid hunger pangs for snacks.
- 7 units maximum for each insulin injection
- · Careful matching of insulin type to food type
- Consistent exercise regime.

To absolutely minimize the risk of complications Dr Morrison suggested:

- Testing frequently with very strict levels of eating to the meter test results
- Fasting and pre-meals targets of 4.7 to 5.2 mmols/l and one hour after meals below 7.2mmols/l and 6.0mmols/l 2 hours after eating.
- Resistance training exercises.

Dr Morrison pointed out that this type of regime requires time to learn all the information, to plan and prepare food and to learn the skills involved. Audience discussions emphasised the need for choice of different approaches and many people felt that this strict and time consuming regime was not a practical option for living as normal a life as possible with diabetes.

'Fitness, Motivation and Adherence' was the theme of John Roberts' talk.

Between 20 and 70% of people starting an exercise programme will drop out within 6 months but John pointed out that people do not plan to fail, they just fail to plan. He highlighted some the reasons for stopping exercising [familiar to many of us!] and gave us some tips to overcome these:

"I get frustrated when I do not get results" – ask yourself if your goals are realistic and remember that progress can take weeks and getting support can help.

"I get bored easily" – so try new routines, join an exercise group, implement exercise into everyday activities.

"Exercise is not enjoyable or fun for me" – combine it with something you do enjoy, vary the type of exercise, watch TV or read during exercise.

"I don't know how I am going to find the time" – so break up your exercise to short sessions, limit TV watching, make commitments to specific times.

"I'm tired" – exercise at the same time, you will feel more energetic after you begin, keep regular bed times.

John's final points were:

- You can always find a reason not to exercise.
- New healthy habits are simple to acquire.
- Think of the benefits versus the risks.
- Shift the mindset to positivity.

Discussion groups

This year more time was given to discussion groups, the most popular ones being about insulin regimes and carbohydrates, showing once again the need for people with diabetes to be provided with better education.

This was followed by a panel discussion and the meeting ended with Dr Anne St Aubin Roberts giving a personal account of her experiences of diagnosis and learning to live with diabetes.

IDDT would like to thank all the speakers and group leaders and the people who attended for making our Annual meeting such an interesting and enjoyable day.

IDDT Annual Conference 2008

A date for your new diary – IDDT's Annual Meeting for 2008 will be held on Saturday October 18th. We hope that you will be able to join us!

Sick Day Rules

Professional advice - sometimes it needs a government health warning!

A member of IDDT who attended our Annual Meeting brought with him a leaflet from his diabetes clinic 'Diabetes and Sick Day Rules'. He has no wish to be difficult but he was extremely concerned at the advice being given. So I might add was everyone else.

In the section for people with insulin-treated diabetes, these Sick Day Rules quite correctly say that:

- NEVER STOP insulin injections
- illness such as 'flu or a chest infection may cause the blood sugar to rise [actually any illness or even slight infection, can cause blood sugars to rise].
- blood sugars should be measured at least four times a day, before meals and before bed.
- If the appetite is poor replace normal meals with fluids milk, Lucozade, fruit juice.

But the problems arise when it gives advice on increasing the doses of insulin!

It advises that:

"if the blood sugar is between 10 and 15mmol/l give 6 units extra of clear insulin before each meal and at bedtime; if between 15 and 20mmols/l give 8 units extra of clear insulin before each meal and at bedtime; if over 20mmols/l give 10units extra of clear insulin before each meal and at bedtime."

Just at a glance there are some obvious mistakes here that could be dangerous!

- It says clear insulin for those on rapid-acting and long-acting analogues, both insulins are clear. It should not be assumed that people know that it actually means the short or rapid-acting insulin what about the relatively newly diagnosed?
- It doesn't say whether people have to increase their insulin dose as a result of one higher than normal blood test or several. Are people supposed to increase their daily dose by 24 units [4 x 6 extra units advised] as a result of one test that could just be an odd one?
- It advises on insulin dose increases without any regard for the dose of insulin being used on normal days. Some people only take 6 units or even less before each meal while others may take 20 or more units – so 6 extra units in some people is a doubling of the normal dose but in others it is a much smaller percentage increase.
- It does not consider the different types of insulin that people may be using which have different peaks and durations of actions. If people are using human or animal insulins before meals with twice daily intermediate-acting insulin, this advice could lead to hypoglycaemia as the short-acting insulin lasts longer and the intermediate insulins peak while there is still some short-acting working.
- What about people using pre-mix insulins? Whether using human, analogue or animal pre-mix insulins, then these 'sick-day rules, simply do not apply to them as most of them will not have any 'clear', short-acting insulin! Unless of course, it is OK to take pre-mix analogues which are clear. I don't know but isn't that just the point?

The possible thinking behind these Sick Day Rules...

Perhaps these 'Rules' were developed on the basis that everyone is

on the same type of insulin with the same regimes, which as we know is not the case. Perhaps the authors of the 'Rules' believe everyone with diabetes is the same, which we know is not the case. Perhaps they believe that everyone takes large doses of insulin regardless of the type of insulin used, which they don't as those on animal insulin tend to take less insulin, as do those on low or restricted carbohydrate diets.

To be fair these Sick Day Rules do advise people to seek medical advice if blood sugars are over 20 on more than two occasions, if vomiting develops, if moderate or large ketones are present or if you don't know what to do. But with Sick Day Rules like these, how can people be expected to know what to do? We can only advise that you check that you know the correct Sick Day Rules for you, for your insulin and for your regime.

Wrong Sized Shoes

A study at Dundee University of 100 people with diabetes found that 63 had badly fitting shoes – the wrong size and mainly the wrong width. [Int Journal of Clinical Practice, Nov 2007] People with diabetes who also have neuropathy [nerve damage] can lose the sensation in their feet and so damage from ill-fitting shoes can go unnoticed.

If shoes are too narrow, tight or loose, they can cause blisters or ulcers which can be slow to heal and lead to infections. Another concern is that people with neuropathy may choose shoes that are too tight because the increased pressure makes them feel the right size. In addition, feet get larger and broader in older people but they often continue to buy the same size. The study showed that a third of the patients said they took a different shoe size from the one they were actually wearing, probably due to the fact that shoes sizes vary from maker to maker. It also showed that only 29% of people checked their feet and legs regularly for any sign of damage that could lead to

problems and 22% never checked their feet.

There is a call for shoe manufacturers to standardize their shoe sizes and increase the range of width fittings. But there is a clear message here for people with diabetes — having well-fitting shoes may be expensive but not as costly as the damage that can be done by not doing this!

Changes we Need to see in 2008

Restriction of blood glucose test strips

There are increasing numbers of people having restrictions placed on the number of test strips being supplied by their GP including people with Type 1 diabetes and those with Type 2 using insulin. The Dept of Health has stated that there are no restrictions on the numbers of blood glucose strips that can be supplied, therefore restrictions are being made at local level, either by GP practices or by Primary Care Trusts [PCT].

There is research that shows that long-term blood glucose measurements [HbA1cs] are not improved by blood glucose testing. However, this research does not take into account that blood glucose testing is not just a matter of blood glucose control but also of giving people the security of knowing their blood sugars at any given time, especially important for people who have reduced or no hypo warnings. We know that some people take no action as a result of blood glucose tests but this is often because they don't know what action to take, so it is a failure in diabetes education, not their fault and not a reason to restrict strips.

Contradictions and mixed messages

- · We are told to test before every meal and before bed
- We are told to test every time we drive and if we are driving a long

way, to test every 2 hours. Where accidents have occurred, courts are increasingly looking at the numbers of tests people carry out in terms of whether or not they are taking a responsible approach to they diabetes.

- When ill, Sick Day Rules advise testing more frequently than normal.
- Extra testing if blood glucose levels go high or low for any reason.

Many people are only being supplied with one box of 25 strips for a month and this does not even cover one test a day!! Are we going back to the old days where people have to buy their strips, in which case those that can afford the high costs of strips will test and those that can't won't.

Diabetes clinics are giving all the above advice and even slapping wrists for not testing enough but when it comes to obtaining a prescription – it's a different story! The practice staff refuse to supply test strips or say to people using insulin 'you only need to test 2 or 3 times a week'. What value does this have to anyone?

What action can we take?

As there are no restrictions placed on the supply of test strips by the Dept of Health and their response to complaints is that Primary Care Trusts decide how to allocate their funding, then it has to be up to us as individuals to take action at local level. So if you do not receive the number of test strips you require:

- 1. Speak to the practice manager and explain how many tests strips you need and why.
- 2. If this fails to have any effect, make a formal complaint to the practice manager.
- 3. If this fails too, then warn that you will make a formal complaint to your local PCT.

In IDDT's experience, the complaint to the practice manager usually results in the required number of strips being supplied but if it doesn't, then make a complaint to your local Primary Care Trust.

Raising the profile of Type 1 diabetes

A frequent comment made to IDDT is that Type 1 diabetes is being sidelined in favour of Type 2 diabetes both in terms of research and public awareness.

Research - one only has to look at medical journals to see that the vast majority of research in diabetes is investigating Type 2 diabetes. While we can understand that Type 2 diabetes is reaching epidemic proportions and costing health providers huge amounts of money, this is not a reason to lose sight of the importance of research into Type 1 diabetes. The two types of diabetes are quite different and should be treated as such for funding and increased funding for either condition should not be at the expense of the other.

Many of those who have grown up with Type 1 diabetes can't remember life without it, whereas people with Type 2 diabetes have had at least 40 years free from diabetes. Type 1 diabetes cannot be prevented and it is a lifelong condition so the importance of research to investigate the unanswered questions should never be forgotten.

In answer to a Parliamentary Question on diabetes research expenditure [Oct 31, 2007] it was stated that the Department of Health supports NHS research and development through the National Institute for Health Research [NIHR] which presently includes a study involving identical twins with Type 1 diabetes. It also funds the Yorkshire register of diabetes in children and young people which is used in epidemiological studies [population studies]. In 2005-06 the Medical Research Council [MRC], one of the main agencies through which Government supports medical and clinical research, spent £13.9 million on research relating to diabetes although the division of MRC expenditure between the two types of diabetes is unclear [at least to we ordinary people!].

Public awareness – in many ways we have stepped back in time and the good work done in the past to raise the profile of Type 1 diabetes and the needs of those with it, has been undone. All too often, thanks to increased publicity about Type 2 diabetes and often

inaccurate press coverage, the public perception is that 'diabetes' is caused by being overweight or obese with no differentiation between Type 1 and Type 2 diabetes. Even this is incorrect because there can be a hereditary factor involved in Type 2 diabetes. But above all, this misconception that both forms of diabetes are caused overweight and lack of exercise carries with it the belief that diabetes per se is self-inflicted and one of the common statements to slim people with Type 1 is "Well you must have been overweight as a child"!!!!

While is extremely irritating, the underlying problem is much greater than just irritation. The lack of differentiation between Type 1 and Type 2 diabetes and the belief that diabetes is self-inflicted can and does affect the public attitude to those with Type 1 diabetes – less understanding of what their life with diabetes is really like and less understanding of their needs. This can have far reaching consequences from attitudes of employers, teachers, friends to reduced donations for research.

IDDT plans for 2008

We are discussing ways to raise the profile of Type 1 diabetes and the need for more research and we would like to hear your views and ideas, so please contact Bev or Jenny at IDDT on 01604 622837 or e-mail enquiries@iddtinternational.org

If you have internet access, you can start by signing a petition on the Downing Street website by going to http://petitions.pm.gov.uk/ DiabetesResearch/

"We the undersigned petition the Prime Minister to increase funding for research into a cure or alternative long-term treatments for diabetes Type 1."

Injecting and testing at school

In the last year one of the most frequently raised issue by parents of young children with Type 1 diabetes is the difficulties they are experiencing at school with injecting and blood glucose testing. According to a report published on World Diabetes Day: "Children's health is being put seriously at risk and thousands of families are

suffering emotionally and financially because of a lack of support for children with diabetes in schools."

This is partly being put down to school staff not being given enough training to help children with diabetes to manage their condition. Also blamed is that when surveyed, 70% of schools said that where children are unable to give insulin injections themselves, parents have to come in and do it for them. The charities involved in the survey and subsequent report have said that this is unacceptable as it can alienate and isolate children from school life and have serious repercussions for families. While this is absolutely true, it is worth remembering that long verbal and written battles between parents and schools also has repercussions – it risks the parents being labelled as 'nuisance parents' and draws even more attention to the child with diabetes which can also cause him/her to feel alienated and isolated.

This is a thorny problem but as with any other problem, there are two sides to the story. Undoubtedly the school system should provide for children with diabetes at school and Government Guidance [Managing Medicines in Schools and Early Years settings] requires schools to make arrangements for teachers to voluntarily administer medicines. However, teachers cannot be compelled to give injections, so it can be a matter of persuading a teacher to help.

A new website www.medicalconditionsatschool.org.uk was due to be launched in October but at the time of writing it is still not available. Hopefully this will provide clear guidance for both teachers and parents.

But we must look further and ask why has this problem arisen now?

Lunchtime injecting and testing at school has become much more of a problem as a result of multi-daily injection regimes [MDI] with insulin analogues. Rapid-acting insulin only has a short duration of action and doesn't last long enough to cover lunch. If young children are on a regime that requires a lunchtime injection and at least one blood glucose test during the school day, what are parents supposed to do?

At the risk of IDDT being outrageous yet again, there are other ways and we suggest asking several questions, the first being the most important of all.

- What is the evidence for children being on 4 daily injections a
 day and has this evidence taken into account quality of life? Does
 injecting at lunchtime make your child feel different from the rest of
 the class whoever carries out the injections? Is this causing your
 child extra stress [and this can raise blood sugars]?
- Have all the choices of insulins and insulin regimes been discussed with parents and children?
- Should insulin analogues be used in children?
- In prescribing MDI regimes, are clinics are fully aware of the difficulties that arise at schools and are they taken into account when transferring children to pre-meal injections?

Looking at the evidence for multi-daily injections in children

Firstly, studies which suggest that MDI is the best regime for children, nearly always quote the famous 1991 DCCT study which showed that tight control with 4 daily injections [MDI] results in better control [HbA1cs], less long-term complications but importantly, also a threefold increase in severe hypoglycaemia. But, and it is a big but, this study was carried out in highly selected ADULTS with Type 1 diabetes – NOT children, so it cannot and should not be assumed that the DCCT findings apply to children. However, there are two recently published long-term, large-scale studies investigating insulin regimes in children that have surprising results and raise serious questions about modern MDI treatments for children.

First study: Prevailing therapeutic regimes and predictive factors for prandial insulin substitution in 26, 687 children and adolescents with Type 1 diabetes in Germany and Austria. Diabetic Medicine, October 2007

The researchers classified the information about 26,687 children treated from 1995 to 2005 in 152 paediatric clinics, average age of 13.6 years and average duration of Type 1 diabetes of 5.4 years. 73%

were treated with 4 or more daily injections [intensive therapy], 14% with continuous subcutaneous insulin infusion [pumps] and 13% with 1-3 injections per day [conventional therapy].

The researchers concluded that:

- 87% of the children were treated with intensive or pump therapy but while this percentage increased over the period of the study, the average HbA1c [approx 8.0%] was almost constant – it did not improve.
- Those using insulin analogues received up to 11% higher insulin doses per day compared with those treated with human insulin – and higher insulin doses can lead to problems.

Second study: Continuing stability of centre differences in pediatric diabetes care: do advances in diabetes treatment improve outcome? Diabetes Care, September 2007

This international study in 21 paediatric diabetes centres investigated the influence of changes in insulin regimes and other factors on HbA1cs, hypoglycaemia and ketoacidosis. The 2,269 participants aged between 11-18 had had Type 1 diabetes at least a year. Fourteen of the centres had participated in previous studies so allowing a direct comparison of glycaemic control between 1998 and 2005.

The average HbA1c result for the whole group was 8.2 and the HbA1c results for the different regimes were as follows:

Regime	HbA1c 8.2	Insulin dose [by body weight]
Miscellaneous	8.2	0.66
Twice daily premix	8.6	1.01
Twice daily free mix	7.9	1.00
Thrice daily	8.2	1.24
Basal bolus	8.2	1.03
Pumps	8.1	0.92

The researchers concluded that:

Despite many changes over the past 10 years including increased use of insulin analogues, basal bolus regimes [4 injections + a day] and pumps:

- participants in the 2005 study had a higher BMI [weight] and were on more intensive regimes than in the 1998 study.
- There has been no significant improvement in HbA1cs and no difference in the frequency of hypoglycaemia.
- Those using twice daily free mix of soluble/regular plus NPH [intermediate-acting] had lower HbA1cs than all other groups.
 "This suggests that the so-called conventional regimes may be superior to modern intensive regimes."
- HbA1cs on pump therapy were not significantly different from the total group even in centres where larger numbers of children were using pumps.

The researchers concluded that despite major and continuing changes in insulin and insulin regimes, glycaemic control has not improved over a decade in 21 international centres.

Then we have to look at the evidence and manufacturers' advice for the use of insulin analogues in children

There are ongoing concerns about the unknown long-term safety of insulin analogues in adults and children due to their similarity to IGF-1 [insulin-like growth factor]. In addition, trials investigating the safety and efficacy of insulin analogues in young children have not taken place, even in older children the trials have only been of short duration and in relatively small numbers of children. So the safety and efficacy of analogues in these age groups are unknown. The Special Product Characteristics documents produced by the manufacturers as part of the drug approval process make the following statements:

NovoRapid - no studies have been performed in children under the age of 2 years. It can be used in children in preference to soluble insulin human when a rapid onset of action might be beneficial.

Humalog - should only be used in children in preference to soluble insulin when a fast action of insulin might be beneficial.

Lantus - for the treatment of adults, adolescents and children of 6 years or above. Due to limited experience, the efficacy and safety of Lantus could not be assessed in children below 6 years of age.

Levemir – the efficacy and safety of Levemir were demonstrated in children and adolescents aged 6 to 17 years in studies up to 6 months but have not been studied in children below the age of 6 years.

So back to injecting at school...

Glycaemic control with safe insulins and a happy childhood are paramount for our children with diabetes. The above evidence gives choices that parents and clinics may not have considered. There is no way that IDDT would recommend that the best treatment for children should be sacrificed because the school system cannot handle it. But we have to be sure that children with diabetes are receiving the best treatment based on the available evidence. In all the coverage of this issue, the question of whether the best treatment for children is multidaily injections with insulin analogues is never addressed.

If injecting at school is a problem or your child does not want to have so many injections, the alternative of twice daily injecting is a very real option especially as recent research has shown that twice daily injections of short and intermediate-acting insulins appear to give the best HbA1cs, require a lower daily insulin dose that reduces the risk of diabetic ketoacidosis and there is less weight gain!

Note: this issue is covered in greater detail in the November 2007 Parents' Bulletin and this includes how a regime of free mix short and intermediate acting insulins works. If you would like a copy of this article, call IDDT on 01604 622837 or e-mail enquiries@iddtinternational.org

IDDT News

IDDT Membership cards to help you

Many of our members have asked us for both membership cards and cards that say 'I have diabetes' so in response to this we now have a credit card-style IDDT membership card. One side confirms membership of IDDT and the other states:

'I have diabetes. If I am disorientated or conscious, please call an ambulance on 999'.

The cards will be sent out with your next membership renewal letter but if you would like one immediately then call us on 01604 622837 or e-mail enquiries@iddtinternational.org

People who pay by standing order will receive their new cards during January 2008.

NB Clearly this card must NOT be used by members who do not have diabetes.

Just to remind you...

'Insulin: A Voice for Choice' By Arthur Teuscher

We told you about this book in our October 2007 Newsletter described by James Le Fanu, MD, FRCP, Columnist for the Daily Telegraph, as a "lucid analysis of the saga of human insulin should be compulsory reading for patients and professionals alike. This is a cautionary tale of how an over-mighty pharmaceutical industry has, under the guise of progress, adversely influenced the best interests of those with diabetes."

On October 22nd 2007, James Le Fanu wrote a piece in the Daily Telegraph describing the adverse effects that some people have with human insulin, how this may affect as many as one in four people and how this has largely fallen in deaf ears. The article included IDDT's details and once again, we received many, many phone calls from people who recognised the symptoms in themselves but knew

little about animal insulin and by people who had been informed that animal insulins were no longer available – not so of course. We are grateful for Dr Le Fanu for helping to keep people informed.

If you would like a copy of 'Insulin: a Voice for Choice' it can be purchased from IDDT for £12.50. To place an order, contact IDDT at PO Box 294, Northampton, NN1 4XS, Tel 01604 622873 or e-mail enquiries@iddtinternational.org

Standardisation of the HbA1c Test

The first stages of an international study have shown that the HbA1c truly represents average blood glucose levels measured at home by patients. If the final results of the study are the same as these earlier ones, then it is likely that doctors will recommend that HbA1c results will be reported in new average glucose units [AG] to enable patients to understand the results more easily. At present the HbA1c results are measured as percentage units and self monitoring as mmols/l which can lead to confusion. The aim is that the HbA1c results and self-monitoring can be reported in the same units.

The International A1C-AG study is comparing HbA1c results to thousands of blood glucose test results measured in 700 volunteers of various races and ethnicities with Type 1 and Type 2 diabetes and in people without diabetes over a 4 month period.

By comparing the measurement of HbA1c with the average glucose levels, an equation can be derived so that HbA1c results can be interpreted accurately as an average blood glucose level or AG. The study was scheduled for completion by September 2007 and already experts are recommending for standardisation across the world.

From our own Correspondents

Consultants really should listen to patients Dear Jenny,

I concur with the points being made in the July Newsletter [Listened to at Last] - consultants really should listen to patients.

I have had diabetes for over 20 years and in Sept 2006 I very reluctantly went back on to human insulin as my sugar levels were persistently high. For almost 18 months the consultant had been including on the notes that he sends to myself and my GP, that I wouldn't listen and there was nothing he could do without me transferring to the new synthetic human insulins.

Being a qualified engineer I could see the advantages of a faster acting short insulin, and reluctantly agreed, taking 3 dosages of short and initially 1 long but subsequently changed to 2. A diabetic nurse helped with the transfer and she insisted that one unit adjustment was all that was needed at a time, but I quickly proved that her incorrect, and 2 was required. When she went on holiday, a colleague took over and calculated that indeed, 2 was correct and that the 2nd long-acting insulin would be better with the evening meal, rather than prior bed. This did help, and we constructively increased the dosages quite a lot – quite a difference in approach which seemed to be more logical and worked better.

But my sugar levels were never really under full control, even varying from 20 in the mornings down to 2, but on a random basis. My HBA1c had reduced, but with such widespread variations only on odd days, something was still wrong. After 10 months I began to have blinding headaches, chronic nightmares at 7 am, and severe stiffness and pain in the lower legs, and could hardly walk. I was also hallucinating, going round in ever decreasing circles, and feeling pretty awful, with severe memory loss.

The nurse approached the consultant on my behalf, as my GP wouldn't give any answers, always referring me back to the Hospital, despite

the fact that he was the Practice Senior Manager, Diabetic contact, and they achieved top points for extra payments. As the Consultant was unable to bring a regular visit forward by even 4 weeks, my GP did agree to change me back to pork insulin.

After only 3 injections, most of the above symptoms disappeared, and the high and wide swings of sugar readings disappeared. I still have to have the latest HBA1c test, but believe this will again be down. True I still get some variations, but not as much as before. I am on similar dosages as the human, but about twice as much as the previous time on pork.

Over 20 years ago I started on pork mixtard, went on to monotard, then human insulin when the medical profession in its wisdom imposed the 'overnight' change of everyone to human. I only used human insulin for 3 days, as I was so ill, with many of the symptoms mentioned above. About 3 years later I had suspected colitis, and was transferred to human for about another 3 years, and was reasonably OK, except towards the end when I was really struggling again. Again many symptoms disappearing after my latest transfer back to animal. Overall I have quite a brittle condition, but consider many of the problems I have today are as a result of my time on human. When in America it was suggested that it could be an allergic reaction towards the preservatives in the insulin, but no-one would check that out over here. I am an intelligent diabetic and attend meetings and read widely about the condition.

My other concern is that my consultant stood up at his annual Care Group review 2 years ago and said he was a big believer in animal insulins. 12 months later he was proud to announce he had been working closely with insulin manufacturers with their new synthetic human versions, and was very impressed with them. (ie Novo Nordisk Detemir and NovoRapid) I will not comment to my reactions. Was this the reason to push everyone on to human? Try listening to the patient once more!

Mr S.M. London

Feeling proud of myself!

Dear Jenny,

I know I shouldn't blow my own trumpet but I just had to let you know that after 40 years of Type 1 diabetes I have just received the result of my eye screening which showed no signs of diabetes affecting my eyes – thank goodness for animal insulin. While I was on human insulin I had terrible problems with my eyes and required stronger lenses each time they were tested but since I have been on animal insulin they have stayed the same.

I am also hitting HbA1cs around 7 so all in all, I am feeling quite proud of myself. I have to say that none of results came easy as it is an uphill struggle to keep things right. To put it into context, I take one tablet every morning for my blood pressure and the problem is solved but with diabetes it is a 24/7 job – testing and varying the insulin dose to suit. Even when you think you have got it sorted, it creeps on when you are not looking and goes up or down for no known reason! So as I said, you have to keep an eye on it all the time but it pays off.

Mrs T.T. Midlands

Metformin and weight loss

Dear Jenny,

I was pleased to read about metformin in your October 2007 Newsletter.I was diagnosed with Type 1 diabetes in 1997 and prescribed human insulin. After several years, having read all your information, I eventually had my insulin changed to animal insulin [much to the disgust of my then consultant!]. My weight steadied with animal insulin I stopped gaining. Then in August a new consultant prescribed metformin for me and I have lost about 10lbs since then and I feel fine. This has definitely given me the incentive to try to lose a bit more.

I enjoy the Newsletter. Keep up the good work

D.J. Scotland

Friendly and positive atmosphere

Dear Jenny,

I am sure you must have received a lot of compliments after the IDDT conference last Saturday [October 13th]. However I would just like to add our thanks for a mega informative day which was of so much benefit to us both.

The atmosphere was so positive and friendly that for the first time since being diagnosed I no longer feel alone. Although it will take many hours to recall and absorb a fraction of what we heard, it was great to meet you and your team so thank you for all your hard work and creating the IDDT.

Kindest regards

Mr and Mrs N.T. South

Now we Have 'Double Diabetes'!

In the past few years doctors have started to see patients with both Type 1 and Type 2 diabetes – meaning that they are not producing insulin [as in Type 1 diabetes] and the insulin they inject is not being used properly by the body [as in Type 2 diabetes]. So they are calling this 'double diabetes'. [New Scientist Oct 2007]

Diabetes Related to Hip Fractures

A review of 16 studies involving over 800,000 people who sustained a total of nearly 140,000 hip fractures has found that having diabetes, especially Type 1 diabetes, makes people more likely to have hip fractures. The review of 12 studies showed that people with Type 2 diabetes are 70% more likely to fracture their hip and in the review of 6 studies, those with Type 1 over 6 times more likely to do so. The researchers suggest that the cause could be diabetes complications, such as retinopathy, neuropathy, low blood sugars and stroke making people more likely to fall.

A study [J Cell Biochem, Nov 2007] refers to bone loss [which can lead to osteoporosis] as 'a less well-known complication of Type 1 diabetes' and that there are differences between bone loss in Type 1 diabetes and age-related bone loss. It suggests that possible contributors to the suppression of bone formation in Type 1 diabetes include: increased marrow adiposity, hyperlipidemia, reduced insulin signaling, hyperglycemia, inflammation, altered adipokine and endocrine factors, increased cell death, and altered metabolism.

Another study carried out in Germany [J. Bone Miner Res. Sept 2007 (9)] has shown the trends of longer life expectancy and a lifestyle of low physical activity and high-energy food intake contribute to an increasing incidence of diabetes and osteoporosis. However, people with newly diagnosed Type 1 diabetes may have impaired bone formation due to the absence of the anabolic effects of insulin and amylin, but in people with long-standing Type 1 diabetes, vascular complications may account for low bone mass and increased fracture risk. It is suggested that prevention of fractures caused by osteoporosis in people with Type 1 diabetes may include tight control of blood glucose levels and aggressive prevention and treatment of vascular complications.

People with Type 2 diabetes have an increased fracture risk thought to be caused by increased risk of falling. The research suggests that people with Type 2 diabetes may benefit from early visual assessment,

regular exercise to improve muscle strength and balance and specific measures for preventing falls.

A drug to treat osteoarthritis pain has been suspended

21st November 2007 - the Medicines and Healthcare products Regulatory Agency [MHRA] suspended the sales of Prexige because it can damage the liver. It is used to treat osteoarthritis pain and is in the same class of drugs as Vioxx, withdrawn 3 years ago for causing heart attack and stroke. The MHRA advice is that people who are in good health and benefiting from taking Prexige may continue on it but should see their doctor to discuss alternatives but people taking it who feel unwell should stop taking it immediately and see their doctor as soon as possible.

And by the way....... in the US the manufacturers of Vioxx, Merck, has agreed to pay \$4.85 billion to settle 27,000 lawsuits by people who claim they or their family members suffered injury or died after taking the drug. This is one of the largest settlements ever in civil litigation with Merck's legal defence fees running at \$600 million a year!

Research and the Internet

The need to be Careful

I was looking at one of the recommended websites www. childrenwithdiabetes.com when I came across the abstract for a study with the title 'Long-term efficacy of insulin' [published in Curr Med Res Opin 2007 Nov 5].

The objective of the study was: "To investigate the effect of initiating insulin glargine (LANTUS), a once-daily basal insulin analogue, plus an educational programme, on glycaemic control and body weight in patients with type 1 diabetes in clinical practice."

The conclusions were interesting: "Patients with type 1 diabetes treated

with insulin glargine over 30 months in combination with educational support and close clinical supervision decreased their HbA(1c) levels without weight gain versus previous treatment with NPH insulin or insulin lente."

So it would not be unreasonable to assume that everyone would be better switched from NPH [intermediate-acting insulin eg Insulatard] or lente [long-acting human insulin not available in the UK] to glargine [Lantus]. Indeed doctors are doing this. But you need to look more carefully...

This study looked at the records of patients who were treated with NPH or NPH+Lente who then received a diabetes education programme before being changed to glargine and being given close supervision for the 30months of the trial. In addition, to glargine, they were also given short-acting insulin with each meal. I'm sure you can spot the differences.

- 1. On NPH and/or lente insulins, they did not receive an education programme.
- 2. On NPH and/or lente insulins, they did not receive close supervision.
- 3. On NPH and/or lente insulins, they did not receive short-acting meal time insulins

So the research did not compare like with like and therefore it could not, or more correctly, should not have come to the conclusions it did. But then if they had compared like with like, glargine may well not have appeared any better than the old tried and tested insulins!

There are two messages for us here:

 Research - just because research is published does not means that it is good quality research. Before we let research influence our decisions, we need to look closely at the quality of the research itself, who funded it and whether or not the authors have any conflicts of interest ie drug company connections. • Websites - this study was on an often recommended website with no comments or criticisms and could so easily mislead people. So we need to be very careful when looking at websites, recommended or otherwise, and remember that a professional qualification on a website may appear to give it credibility but it does not automatically mean that the information is valid or correct.

The internet is a wonderful source of information but it is has to be treated with caution and remember that anyone can put anything up there but it doesn't mean it is correct.

Your Healthcare Team's Targets and what you can Expect

In this target-driven health system it is not always clear what is expected of us and what we should expect of the health system. Targets are set by healthcare teams and it is their job to try to ensure we achieve them. While we may not achieve them, we should know what they are.

Targets your healthcare team aim for you to achieve:

- Blood pressure: 130/80mmHG is the optimal target but 145/85 is the audit target for doctors
- Diabetes control as measured by the HbA1c test: less than or equal to 6.5 to 7.5 percent, where realistic.
- Cholesterol: total cholesterol equal to or less than 4.0mmols/l, LDL [bad cholesterol] 2.0, HDL [good cholesterol] equal to or greater than one 1.0 or an LDL reduction of 30%.

What you treatment you should expect to receive:

Feet - a trained person to carry out an annual assessment of your feet and referral where necessary.

- Eyes a trained person to carry out an annual screening and referral where necessary.
- Education about medication, diet, exercise and weight reduction where appropriate. This should also include discussions about your treatment options and topics such as driving, travelling etc.

Breath test to detect high blood sugars in children

Scientists may have found a way of monitoring for diabetes in children using breath analysis according to a study published in the Proceedings of the National Academy of Science Journal. Children with Type 1 diabetes were found to exhale significantly higher concentrations of methyl nitrates when they are hyperglycaemic [high blood sugars]. It is hoped that this could lead to the invention of a device that could warn people with diabetes of high blood sugars.

Continuous Blood Glucose Monitoting is Getting Nearer

One of the day to day worries for people with diabetes and parents of children with diabetes is hypoglycaemia, especially at night. A continuous blood glucose monitoring system with an alarm to warn when blood glucose levels drop too low or go too high will give greater peace of mind. We are not there yet but it is on the way.

US approves seven day blood glucose monitor

In June 2007 the U.S. FDA approved a blood glucose monitor for those over 18 which measures glucose levels continuously for up to seven days. The STS-7 Continuous Glucose Monitoring System measures glucose levels every five minutes throughout a seven-day period and it is aimed at tracking patterns in glucose levels that wouldn't be captured by finger prick tests that just give a snapshot picture at any one time. However, the FDA advise that finger prick tests must be used to decide on whether insulin doses should be increased.

The STS-7 System, manufactured by DexCom Inc. of San Diego uses a disposable sensor placed just below the skin in the abdomen to measure the level of glucose in the fluid found in the body's tissues [interstitial fluid]. The Sensor can be put in place by the patient and is said to cause minimal discomfort. An alarm can be programmed to sound if a patient's glucose level reaches pre-set lows or pre-set highs.

And for children

In the US, the Real-Time Continuous Glucose Monitor from Medtronic has been approved for use in children, and according to the company, paediatric-sized models of Medtronic systems will be available soon. The approval has been given for use in children aged 7 to 17 and was previously only given for use in adults.

The device uses directional arrows and display real-time blood glucose levels and trend graphs. Warning alarms alert parents and patients when blood glucose levels drop dangerously or rise above pre-set levels, even when children are sleeping. It will help to provide a sense of comfort that hypoglycemia will not go unrecognised and will be especially good for parents who get up all the time because they are worried about night hypos.

The device will show trends and patterns in blood glucose levels for instance the effects of exercise, lifestyle and diet but it is not expected that it will replace fingerprick tests - yet.

Research News

First patient successfully dosed with pig cell implant

In June Living Cell Technologies Ltd announced that it has successfully transplanted 6 people with Type 1 diabetes in a world-first Phase1/11 clinical trial under current regulatory standards. The patients will receive two low doses of the pig islet cells [DiabeCell] every 6 months

over a 12month period. This first low dose trial is to demonstrate safety. The company hopes to commercialise the product for general use by 2012. The trial s taking place at Sklifasovsky Institute in Moscow which has extensive experience in organ and xenotransplantation.

Age-related macular degeneration [AMD] and carbohydrates

AMD is the most common cause of vision loss in older adults in the general population. Researchers have carried out a study of 4,099 people between the ages of 55 and 80 and classified them into 5 groups according to the severity of their AMD and other factors.

The results showed that people who had regularly eaten a diet with a high glycaemic index [carbohydrates that quickly raise the blood sugar levels] had a suignificantly increased risk of AMD relative to those who had eaten a diet with a low glycaemic index [slowly absorbed carbs]. The researchers calculated that 20% of AMD cases could have been prevented if the study participants has consumed low glycaemic index diets. They state that AMD appears to share several carbohydrate-related mechanisms and risk factors with diabetes-related diseases, including eye and cardiovascular disease.

Cholesterol- reducing drug could also prevent retinopathy

A new study by the University of Sydney presented at a meeting of the American Heart Association in Florida [Nov 2007] revealed that a drug called fenofibrate could help to reduce the risk of retinopathy. Fenofibrate has been used in the UK for 30 years to control cholesterol levels however, the new research shows that it could also help to prevent retinopathy in people with Type 1 and Type 2 diabetes by up to 30%.

Statins and fibrates may prevent diabetic neuropathy

A large study conducted over 8 years in Australia in people with Type 2 diabetes has shown that two types of lipid-lowering drugs, statins and fibrates, significantly lower the risk of developing peripheral diabetic neuropathy [nerve damage]. The relationship between lipid-lowering therapy and the prevalence and incidence of peripheral neuropathy was assessed in 1,294 of people in the Fremantle Diabetes Study

between 1993 and 1996.

Statins and fibrates are already widely recommended for people with Type 2 diabetes to help prevent heart attacks and now it appears that they may have another use – to prevent nerve damage [neuropathy], a common complication of diabetes. The study showed that statins and fibrates reduced the risk of developing peripheral neuropathy by 35% or 48%, respectively.

Neuropathy is the most common form of nerve damage caused by diabetes and affects about 50% of people with diabetes. Finding medications that help neuropathy has proved difficult and still the usual advice is 'good blood glucose control'. The researchers state that people with diabetes should not shy away from taking statins or fibrates but statins are usually the first choice because of strong evidence of their protection against cardiovascular disease. [They do not mention the adverse reactions that many people have when taking statins!]

Snippets...

Vinegar in the mornings!

Researchers in Sweden say that vinegar in the mornings may be good for you. The researchers have been using it on people with Type 1 diabetes and say that it may speed up stomach emptying. This was just a tit-bit in a Newspaper so we have no idea how much they are recommending!

Onions cut heart disease risk

Meals rich in compounds known as flavanoids reduce the risk of early signs of heart disease according to research by the Institute for Food Research. The research focused on one flavanoid, quercetin, found in tea, onions, apples and red wine. It is metabolised very quickly by the intestine and liver and is not actually found in human blood so the

research looked at compounds produced after quercetin is broken down by the body. They found that in the case of the inflammatory process, one of the reasons arteries fur up, eating 100g to 200g of onions had an impact on the cells lining the arteries.

Spinach can reduce the risk of age-related macular degeneration Spinach, kale, cabbage and other dark green leafy vegetables are high in an antioxidant called lutein. New research studying the progress of 4518 people between 60 and 80 years old suggests that the lutein in these vegetables can reduce the risk of age-related macular degeneration. The greatest source of lutein is in raw kale followed by cooked kale, cooked spinach, cooked collard greens and cabbage. [Arch Ophthal, 2007: 125]

What next? Broccoli for the sun

New research on 6 people [only 6 people!] has shown that suncream made from 3 day old broccoli sprouts can reduce the effects of sunburn. Apparently, the broccoli cream does not absorb UV light to prevent it entering the skin but works by boosting the production of enzymes that protect the skin against UV damage. [Reported in the journal Proceedings of the National Academy of Sciences]

Almonds may help weight loss

Almonds are rich in mono-unsaturated fats and researchers in California compared two groups of people who ate low carbohydrate diets containing the same amounts of calories and protein. One group added 84 grams a day of almonds and the other group self-selected their complex carbohydrates. The results showed that glucose, insulin, diastolic blood pressure, total cholesterol, triglycerides and LDL [bad] cholesterol decreased significantly and by similar amounts in both groups. However, the group who ate the almonds had a greater and longer weight reduction during the 24 week study.

Warning - Smoothies adverts got it wrong

A Smoothie advert that claimed that the fruit drink can rid the body of toxins has been criticised by the Advertising Standards Authority [ASA]. The Smoothie is made by Innocent Ltd of acai berries, pomegranate

and blueberries. Acai berries are a nut-like fruit that grows in the Brazilian rainforests which contains high levels of anti-oxidants. The advert claimed that one of these Smoothies contained 'even more antioxidants than the average five a day' ie the five daily portions of fruit and vegetables we are all supposed to eat. The ASA ruled that neither the detoxifying nor the antioxidant claims could be backed by evidence and that smoothies and fruit juice could only count as one of the five a day portions.

A survey suggested that Innocent Ltd are one of the fastest growing companies in the food industry fuelled by the popularity of 'healthy' fruit juices and smoothies. Hardly surprising if everyone thought they were getting their five a day in one hit!

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

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From Your Editor – Jenny Hirst

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