Insulin Dependent Diabetes Trust

October 2007 Newsletter

Registered Charity No 1058284 - Issue No 54

Insulin Analogues - How Much More Evidence do we Need?

Let's take a look at the evidence now in the public domain:

- **Human insulins** are not superior to animal insulin - Cochrane Review, 2002

- **Rapid-acting insulin analogues** have only minor benefit for the majority of patients - Cochrane Review, 2004
- **Rapid-acting insulin analogues** are not superior to human insulin for the treatment of Type 2 - the Institute for Quality and Cost Effectiveness in the Health Care Sector [IQWiG], July 2006
- **Rapid-acting insulin analogues** are not superior to human insulin for the treatment of adults with Type 1 diabetes. The benefits for children and adolescents are unclear for lack of data - IQWiG, June 2007

- **Long-acting analogue insulins** can be used as an option for people with Type 1 diabetes but not for those with type 2 diabetes, except under special circumstances - NICE guidance, 2002.
- **Long-acting insulin analogues** are not listed for treatment of Type 1 and Type 2 diabetes because they are not superior to NPH human insulin - Canadian Expert Drug Advisory Committee [CEDAC], June and Sept 2005.
- **Long-acting insulin analogues** have only minor benefit, if at all, for the treatment of Type 2 diabetes - Cochrane Review, April 2007.

It is reasonable to say that there is little evidence that insulin analogues are superior to their predecessors but is this lack of

superiority important?
It may not seem so to some but this is not the case. Already 40% of people with diabetes have had their insulin changed unnecessarily, according to the evidence above and the newly diagnosed are automatically being treated with analogues, all at a significantly higher cost. So on what basis are analogues being prescribed? Assumptions? Sales hype from the insulin manufacturers to hook people on to the only insulins still in patent which can therefore be sold at a higher price and greater profit?

So insulin analogues have no benefits over previous insulins but what about their risks? Their long-term safety has not been established, they have always had the potential for carcinogenic effects and there is growing evidence of their mitogenic effects [cell multiplication which could lead to tumours]. So now there are real grounds to question whether these risks, high or low, are worth taking for analogue insulins that are not superior to their predecessors and more expensive. Compared to health risks, cost is less important but Professor Edwin Gale 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 specialist nurse educator at the same cost. [Diabetologia (20070 50:1783-1790]

While IDDT has been asking these questions since the introduction of human insulin, they must be answered and sooner rather than later. In discontinuing animal insulin and announcing the intention to discontinue human insulins, manufacturers are foisting insulin analogues upon us. Sadly in diabetes the choice of treatment has never truly rested with patients but soon it will not be our doctors that are making our treatment decisions but drug companies. This is unacceptable, harmful and sets a dangerous precedent for healthcare.

IDDT Goes to Westminster

Progress Report

Supplies of Wockhardt Hypurin Pork insulins
IDDT has followed up reports of difficulties obtaining Hypurin Porcine insulins and on each occasion and the majority of the times, Wockhardt has the insulin in stock and the problems are with misinformation from the pharmacy wholesaler.

Misinformation about future availability of pork insulin
Many people are being told by doctors, nurses and pharmacists that ALL animal insulins are no longer available – not so, it is only Novo Nordisk that have chosen to do this. Wockhardt has sent information to GPs, hospital diabetes clinics and PCTs but the misinformation continues! On further enquiry, part of the problem is that several GP and pharmacy databases are incorrect. We have pursued this with the Dept of Health and Wockhardt.

Meeting at the Dept of Health, September 5th 2007
This was chaired by Dr Sue Roberts, National Clinical Director for Diabetes and attended by the Chief Executives of Novo Nordisk and Wockhardt and a representative of Diabetes UK.

- Wockhardt confirmed their intention to continue to provide animal insulins. They have bought in several years-worth of the raw materials for which IDDT expressed gratitude!
- The misinformation problems were aired and the Dept of Health is now following up the issues of misinformation on professional databases with vigour.

NICE assessing all insulins

- Early Day Motion 535 tabled by Sandra Gidley MP – this called for NICE to assess all the insulins to provide the necessary information for patients and doctors to make informed choices. 107 MPs signed the EDM and many others supported it by raising the issues at Ministerial level.

- The All Party Parliamentary Group agreed to take forward a briefing paper prepared by IDDT and the then Minister of Health, Andy Burnham agreed to ask NICE to carry out an assessment of all insulins. When nothing happened another Health Minister, Caroline Flint denied that the Department had made this commitment. Lord Hunt then stated that the responsibility for this had been passed to Dr Sue Roberts who has formed a NICE Liaison Group which will also discuss our issues. He suggested that IDDT held a meeting with Dr Roberts.

IDDT Meeting [Jenny Hirst] with Dr Sue Roberts, September 5th 2007

Jenny explained IDDT's philosophy that people with diabetes should have an informed choice of treatment, be involved in decision-making about their own care. The lack of choice of animal insulin, people not being listened to and even being denied this choice, goes against these principles. Also that our request for NICE to assess all insulins is part of this philosophy to ensure that informed choice is available, including the risks of new analogue insulins and that treatment is cost effective eg if 150 people were prescribed an equally effective but cheaper human or animal insulin, another nurse could be employed to help with education and provide better care.

Dr Roberts was very open with what she hopes to achieve – a better outcomes equation, organised proactive services in partnership with engaged empowered patients to achieve better outcomes for people with diabetes. If achieved, very similar to IDDT's philosophy and one that will result in people having the choice of animal insulins! She is discussing diabetes-related topics with NICE and would like to meet regularly with IDDT to discuss progress and any concerns we have. A meeting is to be arranged in November/December this year.

Let's mark our success!

- We have an open ended commitment from Wockhardt that they will continue to produce animal insulins.
- We are now in direct and regular communication with Dr Sue Roberts who understands and listens to the needs of people with diabetes and even IDDT!

None of this would have been possible without our members, so many thanks for your enthusiastic support, determination and for writing numerous letters to MPs. I would also like to thank the many MPs who have supported us and especially members of the All Party Parliamentary Group for Diabetes, its Chairman Adrian Sanders MP and Earl Howe, Conservative Spokesman for Health in the House of Lords.

Apologies For the Misunderstsnding!

In IDDT's July Newsletter there was a short piece 'While on the subject of holidays' in which one of our members was concerned that the security measures at airports may prevent his wife from obtaining the Lucozade she always takes to treat her hypos. My response was that she could obtain a 'full-blown' Coke, any other sugary drink or a chocolate bar. I got a couple of comments about this advice, especially the chocolate because of its fat content! I know this is not standard advice for treating a hypo but I was trying to point out [1] that in emergency, anything sweet will do and [2] hypos don't always have to be treated with the same thing. Most people develop their own ways of dealing with hypos but in emergency, it may be a case of whatever is available! Sorry for the misunderstanding.

More About Insulin Analogues

Long-acting insulin analogues have mitogenic and antiapoptotic activities

Before reading further we ordinary mortals need some explanation of

the terms.

- Apoptosis is the normal self-termination of a cell's life to become replaced by another one, so antiapoptosis is the opposite.
- Mitogenicity is the promotion of division and proliferation of any cell, including malignant and non-malignant tumour cells.
- IGF-1 [insulin-like growth factor] is a hormone with a range of effects - promotion of cell survival, cell proliferation, inhibition of apoptosis, stimulation of metabolism.

The title of this research [ref1] sounds complicated, so I'll do my best to explain!

It has been known since their introduction, that insulin analogues have similarities to insulin-like growth factor [IGF-1] so might function differently from normal insulin and could cause cell multiplication [mitogenicity] – hence their potential to cause tumours.

This research tested whether the two long-acting analogues, Lantus [glargine] and Levemir [determir], show IGF-1 like activities including enhanced mitogenic and antiaopoptotic effects. Colon, prostate and breast cancer-derived cell lines were used in tests with IGF-1, regular insulin, Lantus and Levemir for different time intervals.

The results: both Lantus and Levemir show potent mitogenic and antiapoptotic activities which are significantly greater than those of human insulin and seem to resemble IGF-1 action.

The researchers comment: this supplements the work by Eckhardt et al which found that all insulin analogues tested were more mitogenic than insulin and this mitogenic effect was greater in cells from patients with a high IGF-1 receptor system expression so putting such patients at greater risk than those with a low IGF-1 receptor system expression.

Note: this research is continuing and is being funded by IDDT as part of the policy to address uncertainties in insulin treatment.

Ref 1 Doron Weinstein, Zvi Laron, Haim Werner. Long-acting insulin analogues have mitogenic and antiapoptotic activities. US Endocrine Society Meeting, Toronto, June 2007

Ref 2 Kristian Eckardt, Claudia May, Marlis Koenen, Juergen Eckel. Enhanced Mitogenic Potency of Insulin Analogs in Human Fibroplasts and Smooth Muscle Cells is mediated by IGF-I Receptor Signaling Diabetes, ADA Diabetes Care, June 2006 Vol 55 Suppl 1 463-P

New Review - Rapid-acting analogues are not superior to 'human' insulin for Type 1 diabetes

Yet again we are reliant on Germany for another review that helps to inform our decisions about insulin treatment [ref 1]. Unlike the UK where the Dept of Health has refused our lobbying request for a National Institute of Clinical Excellence [NICE] assessment of all insulins, the German Federal Joint Committee actually commissioned IQWiG to compare the benefit of rapid-acting insulin analogues versus human insulin for Type 1 diabetes. So one has to wonder why this doesn't happen in the UK?

The insulins investigated were, Humalog [lispro], NovoRapid [aspart] and Apidra [glulisine].

What did the review find?

- **Adults** - there is currently no evidence available to demonstrate a superiority of rapid-acting insulin analogues in the treatment of adults with Type 1 diabetes. The value of the evidence and design of studies so far are inadequate and do not allow conclusions regarding most important patient goals, such as the reduction in long-term complications or overall mortality.
- **Children and adolescents** – due to lack of data, the benefit of rapid-acting insulin analogues in children and adolescents is unclear [an uncertainty!]. Novo Nordisk has carried out long-term comparative studies in this group of patients but they are

withholding some of the results.

- **Pump therapy** – no long-term studies were available therefore it remains unclear whether adults would benefit and what advantage patients would have by using analogues with insulin pumps [an uncertainty!]. The same applies to children and adolescents as only fully published short-term studies are available. Novo Nordisk sponsored 2 long-term studies in children and adolescents but to date, both studies have only been partially published and unlike Sanofi-Aventis and Lilly, Novo Nordisk were not prepared to provide the information needed for the review.
- **Quality of life, not a fair comparison** – in some studies patients treated with insulin analogues assessed their quality of life as higher and they were more satisfied with treatment than those using human insulin. IQWiG did not evaluate this finding as evidence of an additional benefit, because it was not based on a fair comparison – patients in the human insulin group were asked to adhere to a fixed injection-meal regimes but the analogue group were not. [As we know, it is quite possible to use a flexible regime with all types of insulin.] So it is unclear whether the patient satisfaction was due to the insulin or to the more flexible regime prescribed by the physicians.

What conclusions can be drawn from this?
Basically it is simple, there is no evidence that rapid-acting insulins are any better than human insulins for adults with type 1 diabetes. It is unclear whether they are of any benefit to children and adolescents. It is also unclear whether they are of benefit any groups of pump users. They are, of course, significantly more expensive to the NHS! So once more, this review raises big questions:

- Why is the Dept of Health so unwilling to follow Germany's lead and have all insulins assessed by NICE for risks/benefits and cost effectiveness?
- Why are Primary Care Trusts that are so obviously short of funds, spending unnecessary amounts on insulin analogues that have no proven benefits over less expensive human and animal insulins?
- Why are adults and children with diabetes being changed to insulin analogues when they have no proven benefit?
- Could all this be anything to do with heavy marketing of insulin analogues because they are the only insulins in patent, therefore more expensive and more profitable?

And by the way, a touch of curiosity: why was Novo Nordisk unwilling to provide the necessary information to IQWiG?

Ref 1 Rapid-acting insulin analogues versus human insulin in type 1 diabetes, the Institute for Quality and Cost Effectiveness in the Health Care Sector [IQWiG], Germany, June 2007

Taking More and More Medications

IDDT is frequently contacted by people expressing concerns that they are being advised to take more and more medications. Some are concerned that all drugs can cause side effects, while others simply do not want to take more drugs than absolutely necessary, especially if the evidence of benefit has not been shown. Here is an example…

ACE inhibitors to protect the kidneys
ACE Inhibitors are normally used to treat raised blood pressure [hypertension] but increasingly they are being prescribed to people with diabetes to protect their kidneys, even if they have normal blood pressure. It has been shown that both ACE inhibitors and angiotensin receptor-blockers (ARBs) are effective treatments for people with hypertension, early diabetic nephropathy, or both [ref 1]. But does this mean that all people with diabetes should be put on one of these drugs?

According to Dr B Hirsh [ref 1], most people put on ACE inhibitors for renal protection do OK. However, the evidence for using ACE inhibitors for this reason was from a study of mostly people with Type 2 diabetes over the age of 55 [MICRO-HOPE trial published in

2000]. This showed that use of the ACE inhibitor, ramipril, significantly reduced the combined outcome of myocardial infarction, stroke, or cardiovascular death by 25%. But do the results of this study apply to younger people with Type 1 diabetes where the drug is being used to protect the kidneys?

There are no randomised controlled trials investigating ACE inhibitors for the prevention of diabetic renal disease in people with normal blood pressure and relatively good blood sugar control. Dr Hirsh also says that he is unaware of any recommendations by any diabetes or kidney society for this use. So although ACE inhibitors are prescribed frequently for kidney protection to people without raised blood pressure, this is based on assumptions of benefit not evidence of benefit – yet another uncertainty in the treatment of people with diabetes.

Dr Hirsh makes 3 key points:

1. People should be treated as individuals and while a drug may work for many people, it doesn't follow that it will for everyone.
2. Both treatment and preventative treatment should be based on evidence that they actually do what they are intended to do.
3. All drugs can have side effects and these need to be assessed against any known benefits.

Note: these statements also apply to the widespread recommendations that people with diabetes over the age of 40 should take statins and aspirin – not everyone can tolerate them.

Example: one of our members with blood pressure the low side of normal but a small amount of protein in her urine [microalbuminuria] was prescribed ACE inhibitors to protect her kidneys but they lowered her blood pressure so that she fainted and frequently felt lighted-headed. She was unsafe to drive, not because of hypoglycaemia, but from the use of ACE inhibitors to protect her kidneys!

Recommendations: 'Ask about Medicines' supported by the Dept of Health recommends people to always ask questions about any new medications, why they are necessary, what are the side effects and what evidence there is that they are safe and effective.

Ref 1 ADA, DOC News July 1, 2007 Vol 4, Number 7

Sourcing Information

Patient information leaflets - available to people with visual impairment
Patient Information Leaflets [PILs] are the leaflets found inside packs of medicines. For those with internet access, PILs are available for all UK medicines from the electronic medicines compendium at www.emc.medicines.org.uk

A new service is available for people who are blind or visually impaired - called X-PIL. The X-PIL website www.medicines.org.uk/XPIL.aspx provides a number of electronic formats:

- the original package insert
- in large font [18-22 point]
- in a version that can be used by a screen reader

Over the coming months over 2,500 PILs will be available on the X-PIL web site and by the end of 2007 PILs will also be available in audio MP3 format. You can also listen to a PIL by telephoning the Royal National Institute of the Blind [RNIB] Medicines Information Line (tel 0800 198 5000). You can also request PILs in a number of different formats - large/clear print, Braille or on audio CD.

Using the internet as a source of information
Many of us use the internet as a source of information, sometimes as our main source. Searching for health information is no exception to this but we do have to be aware that there are some not very reliable

websites. A UK study carried out at three Birmingham hospitals [ref 1] suggests that most patients prefer internet sites recommended by doctors and also that carers are more proactive in finding information this way.

In questionnaires and interviews, the study investigated 800 recently diagnosed cancer patients' and 200 carers' use of, and attitudes to, the internet as a source of information compared with other sources. The average age of patients was 63 and of carers 43.

- 4.8% of patients but 48% of carers accessed the internet directly for cancer information.
- Helplines had a low use [2.9% of patients and 19.3% of carers] which the authors describe as not cost effective.
- Carers were more likely to seek information for themselves, possibly as a way of coping, but patients were more likely to use information chosen by someone else and wanted the hospital doctor to provide internet sites. There was a high usage of sites recommended by doctors.
- Use of internet information was low in ethnic minorities.
- High levels of satisfaction were reported for internet information rating it higher than booklets or leaflets.

The authors concluded that the internet is an effective source of information for those who use it.

Ref 1: 'A Study of information seeking by cancer patients and their carers,' Clinical Oncology, vol. 19, June 2007

Hypertension

Up to 65% of people with diabetes, both Type 1 and Type 2, have hypertension – raised blood pressure. It is caused by atherosclerosis, a thickening of the blood vessel walls narrowing the blood vessels so that blood flow is restricted. Long-term high blood pressure increases the risks of other diabetic complications such as stroke, coronary artery disease, retinopathy and nephropathy [kidney damage].

Blood pressure measurements

The numbers that are given as your blood pressure results eg 130 over 80 are systolic and diastolic pressure readings. The systolic reading, the top figure, is your blood pressure as your heart beats and the diastolic is the pressure between beats. With hypertension, both systolic and diastolic readings may be high, or the systolic alone may be high but both types can lead to serious complications if not treated.

Presently normal blood pressure is defined as 120/80 mmHg for people without diabetes and 130/80 mmHg for those with diabetes and/or chronic kidney disease but these definitions can vary in different countries.

Symptoms

Usually there are no symptoms with mild or moderately high blood pressure so it is important to have your blood pressure checked regularly. Many people now use home blood pressure testing kits but it is advisable to talk to your doctor about this. If blood pressure is extremely high the following symptoms can occur:

- headaches
- visual problems
- abdominal or chest pain
- shortness of breath
- dizziness
- nausea

Treatment

Medications that may be prescribed to reduce blood pressure include diuretics [often called water tablets], angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers, beta-blockers, and calcium channel blockers. It is also often recommended that adults with diabetes take aspirin daily.

Note: recent research [ref1] has recommended that doctors stop routinely using beta-blockers to control high blood pressure as other hypertension pills work better and cause fewer side effects eg fatigue and sexual dysfunction. For many years beta-blockers and diuretics were the standard treatment for high blood pressure but evidence is now suggesting that diuretics and newer blood-pressure medications are superior. Beta blockers work by blocking the effect of adrenaline on the heart which slows down the heart so that it does not have to work as hard, so the researchers emphasise that there is strong evidence to support the use of beta-blockers in people who have had a heart attack or those with progressive heart failure.

Prevention

- Stay a healthy weight - excess weight increases the risk of high blood pressure.
- Exercise can help to lower blood pressure.
- Eat a balanced diet, low in saturated fats, cholesterol, salt and high in fruit, vegetables and non-fat dairy products.
- Don't smoke and keep alcohol at a moderate level.
- Stress can raise blood pressure – try relaxation methods

Ref 1 Journal of the American College of Cardiology Aug. 27th, 2007

Winter's Coming and so are Colds

Flu' and pneumonia jabs.
Don't forget that people with diabetes are seen as priorities for both the flu' jab and vaccination against pneumonia – both are free.

The common cold
Rhinoviruses are responsible for about half of all common colds in children and adults. School children usually catch between 7 and 10 colds a year, and adults two to five. Common colds and flu can be transmitted by hands and contact with commonly-touched surfaces.

Echinacea 'can prevent a cold'
Taking the herbal remedy echinacea can more than halve the risk of catching a common cold, according to US research published in The Lancet Infectious Diseases. These results are in conflict with other studies that have shown no beneficial effect. However, this research found that echinacea decreased the odds of developing a cold by 58%, the duration of colds by a day-and-a-half and may reduce the severity of coughs, headache and nasal congestion. In one of the 14 studies reviewed, echinacea was taken with Vitamin C and this combination reduced cold incidence by 86% whereas used alone, it reduced cold incidence by 65%.

Echinacea is a collection of nine related plant species indigenous to North America and it is thought that it may work by boosting the body's immune system. There are over 200 viruses capable of causing colds, so it could be that echinacea has a modest effect against rhinovirus, the most common virus, but marked effects against other viruses.

The researchers found that more than 800 products containing echinacea were available, and that differing parts of the plant, flower, stem and root, were used in different products. They said more work was needed to check the safety of these different formulations.

Professor Ron Cutler, of the University of East London told the BBC: "People with impaired immune function might benefit from taking echinacea during the winter months to prevent colds and flu, but that healthy people did not require long-term preventative use."

People with Type 1 diabetes have an impaired immune system, so it may be worth thinking about taking echinacea but as with all herbal remedies, you should discuss this with your doctor.

Could You Help With Research?

- **Do you have Type 1 diabetes? Are you aged 21 - 36 and were diagnosed between the ages of 12 and 16?**
- **Would you be prepared to talk about your experiences?**

Emily Deacon, Trainee Counselling Psychologist at City University is looking to recruit a small number of people who fit into the above categories for a study to find out what it is like to be diagnosed during adolescence. The study has been given ethics approval by City University.

To find out more, contact Emily on: tel 07815964199 or emilydeacon@yahoo.co.uk

Education, Education, Education!

Nurses identify barriers to good self-management and strategies to overcome them

If you don't understand the title it means what stops us, people with diabetes, from achieving 'good' management of our diabetes. This was addressed at an American symposium [ref1] of 50 nurses and other health professionals. I don't know about readers, but I find this irritating before I even start to read what they actually think - it may be well intentioned but it seems patronising and judgmental to not involve the views of people with diabetes.

Having said this, most of the barriers they identified were not the fault of patients but the fault of health systems. While these are views of health professionals in America, many of the barriers they identified apply in the UK and I guess, many other countries. Here they are:

- difficulty navigating the healthcare system
- the lack of self-care education following diagnosis
- imited time with healthcare providers
- under-valuation of the importance of patient education
- the complexity of diabetes education
- inadequate patient health literacy.

None of these 6 points are the fault of patients, not even the last one - they are the fault of the health systems that are supposed to provide treatment, care and education.

The symposium's solutions to these problems all centred around the importance of education - need for more time with health professionals, developing better approaches to teaching self-management and research to show the value of patient education [do we really need yet more research on what is obvious?]. Finally they concluded that health professionals "need to assume that patients have a low level of health literacy and to use media other than print, such as DVDs, in the educational process." Thanks a bunch! No problems with using DVDs etc - they are very useful as they can be watched over and over again but please don't assume that all patients have a low level of health literacy - this really is patronising!

Has the term 'education' made the situation worse?

In terms of 'education' we have to look at Type 1 and Type 2 diabetes separately - they are different conditions that require different information and different approaches.

If we look back at Type 1 diabetes 30 years ago, we didn't have diabetes specialist nurses, we didn't have many doctors who were specialists in diabetes and paediatricians who specialised in diabetes were a rarity. But we did have 'patient education' although it was rarely referred to as such - in fact it was automatically all part of diagnosis and treatment.

You only have to attend an IDDT Conference to see that people who have had Type 1 diabetes a long time know how to count carbohydrates, know about the value of exercise. If blood sugars are high, they don't simply inject more insulin but mow the lawn or go

for a long walk. They understand the relationship between insulin, carbs and exercise. All this was achieved as a natural part of being diagnosed with diabetes, it wasn't called 'education' and there was no need for research to prove its cost effectiveness!

So when did all this change and why?
There is probably a whole range of reasons but some are obvious:

- people with Type 1 diabetes used to see their hospital clinic doctor at least 6monthly, and more often if necessary, with time to talk through any problems and what adjustments to make – ongoing 'education' although it wasn't seen as such. Now there is an annual MOT - less time with a specialist doctor and less time for education. Moving people with Type 1 diabetes from hospital clinics to GP surgeries has had questionable benefits, as many people report that they know more than the GP!
- Replacing carb counting with 'healthy eating' in the late 1980s meant that people received less 'education' about diet. Learning to count carbs automatically meant learning to understand adjusting insulin and the relationship with exercise. That carb counting is now being seen as the way forward, DAFNE courses etc, brings a wry smile to some us, but sadly there is a whole generation of people with diabetes and health professionals who have an information gap that needs filling.
- The reliance on HbA1cs as a measure of blood glucose control has also had an impact. Health professionals tend to think that a good result means that you must be doing OK, so perhaps less time is spent on education? But it could be that a good HbA1c is achieved by huge effort or because you are having lots of hypos, so education is still vital.
- More complex insulin regimes have meant a greater need for education. Juggling 4 or more injections a day, interpreting blood glucose results necessitates health professionals spending longer with each patient, or it should. A little time spent listening to the needs of each individual person, could reduce the need for time consuming, complex education eg some people prefer two injections a day.

Then there is Type 2 diabetes...
There are huge numbers of people with Type 2 diabetes who also need education about their condition and to add to this problem there are campaigns to diagnose more people without the necessary education and care programmes being in place. Again there is insufficient education about the value of diet and exercise and as more people with Type 2 are being treated with insulin, this again requires even more time spent on education.

Education costs money…
Patient education was one of the targets in the National Service Framework for Diabetes, so it should be available to all, but it costs money. Sadly Primary Care Trusts [PCTS] do not seem to recognise education of people with diabetes as a priority or that money spent on education now cannot be measured in immediate costs but in savings on future costs. If more people end up as hospital in-patients as a result of lack of education, at several hundred pounds a day, then providing education now makes economic sense. But this seems to pass over the heads of decision makers!

Where do we go from here?
We can't put right the wrongs of the past but we do have rights. If your locality is not providing good care and good education to help you live with diabetes, then write a letter of complaint to your local PCT. Don't do nothing - if enough people complain there is a better chance that services will improve. In complaining you are supported by a Health Commission Report on diabetes services which says that the NHS is largely failing on diabetes self-care. Remember, improving community services and the potential for self-management of long-term conditions such as diabetes is also one of the government's key policies.

Health Commission report in diabetes services, July 2007
The Report said PCTs in England were offering basic diabetes care such as yearly check-ups but PCTs had to do better in supporting people to manage their condition - just offering basic needs is not enough to prevent complications of diabetes or for people's general

wellbeing. It warned that almost 130 out of more than 150 PCTs failed on home support - 73% were rated as 'fair', 5% were rated as 'excellent', 11% were 'good' and 12% were 'weak'. Being rated as 'fair' means people with diabetes are being given yearly check-ups and tests such as for blood glucose and blood pressure levels and PCTs rated as 'fair' or 'weak' were not commissioning services that offered enough support to people with diabetes to manage their condition.

The Report recommended key improvements all providers of diabetes services need to make:

- Improve care planning between people with diabetes and their health professional.
- Increase the number of people attending education courses.
- Increase the number of people having blood glucose levels of 7.4 or less.
- All providers and commissioners of diabetes services need to work more closely together to reduce emergency admission rates

Your views: We'd love to hear your views and experiences, write to Jenny Hirst, IDDT PO Box 294, Northampton NN1 4XS or e-mail jenny@iddtinternational.org

Ref 1 "State of the Science on Nursing Best Practices for Diabetes Self-Management," sponsored by the American Journal of Nursing. July 2007

Cochrane Reviews

As we have said before, Cochrane reviews help to make treatment decisions and here a couple that may be useful:

Psychosocial interventions for erectile dysfunction

A meta-analysis was carried out looking at all the research for erectile dysfunction to compare the effectiveness of psychological treatment [therapy] and treatment with oral drugs, vacuum devices or other psychological interventions. The reviewers searched for randomised controlled trials carried out between 1966 and 2007 and found 11 trials involving 398 men. Their conclusions were:

- group psychotherapy therapy improves erectile dysfunction in selected patients
- focused sex group therapy was more effective than no treatment
- men who received group therapy and Viagra [sildenafil] showed significant improvement of erectile dysfunction and were less likely than those receiving only Viagra to drop out
- no difference was found when comparing the effectiveness of psychological interventions with local injection and vacuum devices.

Ref: Melnik T, Soares BGO, Nasselo AG. Psychosocial interventions for erectile dysfunction. Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD004825. DOI: 10.1002/14651858. CD004825.pub2.

Low Glycemic Index Diets Better for Weight Loss

A new Cochrane systematic review from Australia found that the low glycaemic index diet [GI] is satisfying and has proven benefits. The glycemic index ranks foods rich in carbohydrate based on their effect on blood sugar levels.

Low GI foods, such as lentils, sweet potatoes and apples produce more consistent blood glucose levels compared to high GI foods such as white rice and French fries. Previous studies suggest that keeping blood sugar levels steady throughout the day may stimulate more weight loss so the reviewers evaluated randomized controlled trials that compared weight loss in people eating foods low GI foods to weight loss in people on higher GI diets or other types of weight loss plans. The conclusions were:

- Those eating low GI foods dropped significantly more weight - about 2.2 pounds more than those on other diets.
- Low GI dieters also experienced greater decreases in body fat measurements
- None of the studies reported adverse effects associated with consuming a low glycemic index diet.
- The low GI diet is more satisfying than other diets so people are less inclined to feel hungry and therefore are more likely to maintain this diet than other strict diets on which they feel hungry.
- Low GI diets appear to be effective even in obese people – obese low GI dieters lost about 9.2 pounds, compared with about 2.2 pounds by other dieters.
- People eating low GI foods experienced greater improvements in total blood cholesterol and LDL [bad] cholesterol.

The message really is that the success of low glycaemic diets lies with the person's willingness to comply with its nutritional principles.

Ref 1. Low glycaemic index or low glycaemic load diets for overweight and obesity. (Review) Thomas, DE, Elliott EJ, Baur L. Cochrane Database of Systematic Reviews 2007, Issue 3.

Drug Company Funding of Trials Greatly Influences the Outcome

Researchers at the University of California examined 192 published results of trials comparing one statin [cholesterol-lowering drug] to another or to a non-statin drug between 1999 and 2005. Their findings showed two key points:

- if the reported results favoured the test drug, the trial was about 20 times more likely to be funded by the maker of the statin rather than the comparison drug company.
- if the conclusions favoured the test drug, the trial was about 35 times more likely to be funded by the maker of that drug rather than the comparison drug.

The significance of this study is that if drug trial outcomes are largely determined by who pays for the trial, we don't really know which the best drug is. We do need to know if a new drug really is better when compared to older less expensive drugs.

PLos Medicine, June 7, 2007

More Information on Avandia

To use or not to use? Older Drugs are the Best!

In the last Newsletter [July 2007] we reported details of a study published in the New England Journal of Medicine suggesting that the risk of heart attack increased in people using the Type 2 diabetes drug, Avandia. The advice in most countries was 'people using Avandia should not stop taking it', but both doctors and patients were left in a quandary.

UK researcher calls for a re-think, July 27th 2007

Further research was published in Diabetes Care, August 2007 involving over 78,000 people with Type 2 diabetes using rosiglitazone [Avandia] and pioglitazone [Actos] which resulted in researcher at the University of East Anglia calling for regulatory authorities to have a re-think on both drugs. The findings suggest that both drugs cause a doubling of the risk of heart failure and that this may be caused by fluid retention. This additional research showed that:

- one in every 50 people taking the drugs over a 26-month period will require hospital admission because of heart failure which, according to lead researcher Dr Yoon Loke, means that Avandia and Actos could have caused 'thousands of additional cases of heart failure'.

- Heart failure developed even in patients taking a high and a low dose of the drugs and in some patients taking a lower dose than normally prescribed.
- The average time for heart failure to develop was 24 weeks after starting the drugs.
- Although heart failure is thought to be a problem affecting older people, 25% of the cases occurred in people under 60 - in both men and women

So the researchers concluded that there is no particular category of patients who are safe from these risks. The patient information leaflets for both Avandia and Actos say that they should not be used in people known to have heart failure but this study now suggests that the drugs can cause these problems in people without a history of heart disease.

What is heart failure?
It occurs when the heart muscle is too weak to pump as efficiently as it should.

Typical symptoms include breathlessness, swollen ankles and feet, and extreme tiredness. People with heart failure are more prone to potentially dangerous conditions such as: abnormal heart rhythms, stroke and heart attack.

What is the current advice in the UK and Europe?
The advice from the Medicines and Health products Regulatory Authority [MHRA] and the European Medicines Evaluation Agency [EMEA] is that people should not stop taking these drugs but if they are concerned, they should talk to their doctor.

Experts at both the MHRA and the EMEA are re-evaluating the risks and benefits of both Avandia and Actos and the results are due to be published later this year. NICE, has said that if on the basis of the new research, the EMEA decides that the risks caused by these two drugs outweigh the benefits, they will issue updated prescribing advice which will take precedence over existing NICE guidance.

And in the US…
In July, the Food and Drug Administration [FDA] endocrine advisory panel voted almost unanimously that Avandia should remain on the US market but made a strong statement that it may increase the risk of cardiovascular disease.

On August 14th 2007, the FDA announced that the evidence was not strong enough to pull Avandia from the market but both Avandia [and any combination drugs that include the active ingredients in Avandia] and Actos will carry severe warnings about a risk of heart failure in some patients. The manufacturers of both drugs agreed to the 'black-box' warnings – the most severe that can be issued – stressing that the drugs may cause or worsen heart failure and patients should be closely monitored.

A separate FDA review of reports of side effects with Avandia and Actos, found cases of weight gain and build up of fluids both of which are warning signs of heart failure.

And a Cochrane Review recommends a very cautious approach
A Cochrane Review [ref 1] of Avandia led by Bernd Richter, M.D., of Heinrich-Heine University gave much more definite advice. It concluded that the benefit-risk ratio of Avandia in type 2 diabetes needs urgent clarification and new safety data should lead to a very cautious approach to its use and if possible, other antidiabetic medications should be used.

The reviewers pooled information from 18 randomized controlled trials including more than 8,000 participants. About half of the participants took Avandia and the others received either an alternative medication or a placebo.

Avandia gave about the same reductions in blood sugar levels as other oral antidiabetic drugs but when they looked at side effects, diabetic complications or death, patients taking Avandia gained up to 11 pounds in weight and the chance of developing oedema doubled [swelling]. This indicates that the drug causes fluid retention, which can

lead to shortness of breath and heart failure. The largest single trial showed evidence of raised cardiovascular risk, as well as increased numbers of broken bones in women. Richter makes several points:

- He questions “whether new studies with Avandia will be ethical given the fact that less-dangerous therapeutic alternatives exist.
- Patients who suffer from heart disease, especially congestive heart failure, should speak to their doctors about switching to another antidiabetic treatment. If you are a woman, especially if you are thin, you probably should avoid this medication due to the risk of bone fractures.

So what do people with Type 2 diabetes do now?

When the Avandia research first hit the news, the well known expert, Dr David Nathan questioned why a drug that increases the risk of heart failure should be used in people with type 2 diabetes who are already have an increased risk of it. This seems to be a fairly sensible approach when other drugs are available!

What are your choices?

Study shows that older diabetes drugs are safe to use

A study [ref 2] which began in 2005, before the fuss about Avandia and Actos, carried out an depth comparison of tablets for Type 2 diabetes, both old and new. It showed that older, cheaper drugs for Type 2 diabetes are as safe or safer than newer ones. Metformin stood out above the rest because it was less likely to cause weight gain and more likely than others to lower ‘bad’ cholesterol levels.

The results were as follows:

- all of the commonly used oral medications lowered blood sugar levels in much the same way. Despite heavy marketing of the newer, more expensive drugs, they showed no benefit unless a patient could not tolerate an older one. Taking two medications can improve blood sugar control, but also costs more and can raise the risk of side effects.
- Metformin [Glucophage] stood out because it offered the same level of effectiveness without causing low blood sugars, it lowered LDL [bad] cholesterol, there was no weight gain and it is cheap. The main drawbacks to metformin are digestive problems and diarrhoea. It can lead to a build up of lactic acid in the blood in people with moderate kidney or heart disease, so it should not be prescribed to anyone with either of these conditions.
- As with metformin, acarbose [Glucobay] does not increase weight whereas other drugs add 2 to 11 pounds.
- Sulfonylureas such as glimepiride, glipizide and glyburide can cause hypoglycaemia [the other drugs don’t] and they appear to have no effect on ‘bad’ cholesterol levels.
- Avandia and Actos findings were similar to those already discussed.

Conclusions of the researchers:

- Metformin looks to be the safest drug with the sulfonylureas also being highly rated.
- Further studies are needed to compare the long-term effectiveness of one treatment to another and to compare drug effects on quality of life and life expectancy. Additional research is needed to compare these findings with results for injectible medications, such as insulin and the new Byetta.
- It is important that people weigh up their treatment options with their doctor in order to make informed decisions about which medication suits their needs.

If you have Type 2 diabetes, we hope that this goes some way to help you make informed decisions about your treatment.

Ref 1. Richter B, et al. Rosiglitazone for type 2 diabetes mellitus (Review). Cochrane Database of Systematic Reviews 2007, Issue 3.

Ref 2. Annals of Internal Medicine, July 2007

Initial Impressions of Bangkok and Thailand

Part 2 - Adjusting to life in the tropics and the impact on blood sugar control

By Jack Haves

Hello again from a world outside the UK! If you've read my first chapter you'll understand who I am and why I'm here. If you missed my last report, then you'd better catch up! My name's Jack Haves and my aim is to communicate some helpful advice for fellow diabetics who will be travelling, be it alone or with family, to new destinations. These are related to my own experiences as a volunteer working for a charity teaching English in rural Thailand.

I arrived in Bangkok, the capital of Thailand, totally disorientated by the changed time zones. I felt like 3 days had been crammed into one, and it also felt like I'd eaten for 3 days in one! I'd had to do many more injections in the extended 'day' of travel than I would need to do in a normal day which was strange. It was OK for me though as I do short-acting injections (NovoRapid). I just had to do a lot of them! These experiences obviously relate to my particular type of insulin regime so they may not be relevant to someone on a different regime. I managed to maintain normal sugar levels without adjusting the insulin dosages by changing the times of injections.

My initial experience of Bangkok was not very pleasant partly due to the amount I ate in what felt like a drawn out singular day but also because of the change in culture. An example of this was amount of cockroaches crawling around the streets at night! That aside, the time change was my immediate problem. Thailand is 6/7 hours ahead of UK time. This meant having left the UK at mid-day I arrived in Bangkok at 6am in the morning whereas it was only midnight back home.

Adjusting to the local diet proved to be painless and my blood sugar control was fine. The Thai diet is highly reliant on rice and noodles and these foods have a medium glycaemic index. This means the energy is taken from the food more slowly compared to, for example, potatoes, so rice and noodles are better for maintaining steady blood sugar levels.

One thing I've largely avoided is traditional Thai deserts as they're highly sugary, but most of all particularly disgusting. I'll leave this to your own discretion of course! For the most part everything I've eaten in Thailand (and I am eating traditional Thai food) has been delicious and has changed my opinion on certain foods forever - I now enjoy roasted insects and if I'd been told that before I left the UK I would never have believed it.

Thailand's weather was different but in some ways similar to the UK's when I first arrived in late August. It rained, a lot. Being from England this made little difference to me but I'd never seen quite so much rain and having the ability to time your watch by it was quite something. Every night I'd go to bed hot, turning on a large electric fan to cool me. Then every morning at 4am I'd be woken in a shiver reaching out to the fan to turn it off. The problem was that I had a large taut mosquito net to deal with in my half awake, shivering state. All this was the consequence of the tropical rain during the night.

Well, as promised, I hope this has been a more entertaining chapter in the epic journeys of Jack Haves. Next time I will be coming to you with news of how I began teaching in my new home of Uthai Thani, new friends/pupils, my teaching day, diabetes awareness in my community, enduring rainy seasons and maybe a bit more.

Products That May be Useful...

For your feet - as we all know people with diabetes have to take care of their feet and regular inspection is especially important for people who have reduced feelings in their feet due to neuropathy [nerve damage]. The following products may be useful to you:

Loom Pedi Control Telescopic mirror - makes it easier to inspect your feet. It is a mirror 11cms in diameter on an 'arm' that extends to 54cms. One side of the mirror magnifies and the other is simply a reflection. Cost - £9.99

Pediwand Footfile - a footfile for removing dry skin from your feet, one side is course emery and the other, fine emery. Cost - £1.00

Dermasalve Foot & Heel Cream - contains no known irritants and contains natural oils like jojoba, aloe vera and wheatgerm to moisturise and sooth the feet. Cost - £5.99 for 100ml

For your eyes - many people find it quite difficult to put in eyedrops so that they don't run down the cheeks! Autodrop - is attached to the eye drop bottle to ensure that the bottle is held over the eye at the correct angle so that the dose is delivered in the right place. Cost - £2.99

These are all available from Owen Mumford's Medical Shop, to order contact:
Medical Shop 0800 731 6959 or order online at
www.medicalshop.co.uk

Insulin Developments

New technology that may bring an insulin tablet nearer
A new drug delivery technology called Oradel has been developed by an Australian biotech firm, Apollo Life Sciences. It is able to deliver large molecules which have previously had to be injected, in oral tablet form and the company's most advanced product is an insulin tablet.

The problem with insulin in tablets has been that it is digested in the stomach and therefore ineffective. Oradel allows the drug to survive the harsh enzymes in the stomach by stabilising it within a protective structure that consists of specific targeting agents which bind to naturally occurring transporters embedded in the intestinal wall. This binding promotes the uptake of the insulin [or other drugs] so that it crosses the intestinal wall and enters the bloodstream where the Oradel structure breaks down, releasing the insulin into the bloodstream.

In February 2007, Apollo announced successful results of toxicity studies in rats and rabbits for the oral insulin tablet showing that Oradel loaded with generic insulin was safe at both high and low doses. The slow-release formulation also avoided spikes in insulin levels, allowing sustained insulin release over at least eight hours. The insulin tablet will be entering clinical trials later this year.

UK company also developing oral insulin
A small UK company, Diabetology, has also developed a capsule to enclose insulin. It is resistant to the stomach acids and passes intact into the small intestine where it dissolves and releases the insulin and other materials that assist the insulin being absorbed through the intestine wall. The insulin is then transported to the liver where it creates a store that can be drawn on as necessary by the body.

The results of a small trial at Cardiff University involving 16 people with Type 2 diabetes who took the capsules before breakfast and before the evening meal showed the necessary changes in glucose metabolism - a rise in insulin levels in the body which lasted a long time. There were no safety concerns. One of the main advantages is that it did not lead to short-term peaks of high insulin in the circulation, unlike insulin injections, so has the potential to reduce the risk of hypoglycaemia and other adverse effects. It is at the early stages and a lot more work has to be done, but it certainly has the potential to make life a lot easier.

QDose may be a better inhaled insulin than Exubera
A new inhalable insulin being developed by UK and US firms, has just completed a glucose clamp study in the US and the results suggest

that the product could be better than Exubera, the first inhaled insulin recently to come on the market.
According to the study, QDose showed relative bioavailability of inhaled insulin at around 18 per cent compared to subcutaneous injection - 50-75 per cent greater than Exubera.
The QDose system also showed dose equivalence, i.e. two 0.75mg blisters delivering the same amount of insulin to the blood as a single 1.5mg blister. This has been a downfall of Pfizer's Exubera, which has been unable to demonstrate this dose equivalence, making dose decisions difficult for patients. This relative bioavailability means that the actual insulin requirement would be only a fraction of that required with Exubera so it would, or should, be cheaper. A further advantage is that it requires no additives unlike Exubera which contains mannitol, glycine and sodium citrate. The device is an electronic dry powder inhaler, which uses piezo electronics to deliver the chosen compound independently of the patient's inhalation flow rate.

Again note, we will have to wait several years for this and for safety studies to show no lung damage.

From our own Correspondents

The old story of good prescribing
Dear Jenny,

I am a late onset diabetic, FRCP physician aged 66 at diagnosis and regarded by some classifiers as Type 1.5 rather than Type 2. You correctly point out in your July 2007 Newsletter that Lantus [glargine] is not yet fully proven to be safe, but to me as a patient, I have been subject to far too many severe hypos needing ambulance resuscitation on a number of occasions when using Humulin L - all of them daytime and usually associated with exercise.

This is the old story of good prescribing, using the art of medicine to find out what suits the individual patient best. In addition to Lantus, I use a quick-acting insulin, I did get pork insulin on your suggestion for some months and it worked perfectly well as a daytime insulin but became unavailable in New Zealand in February 2007. I have gone back to Humalog and I am perfectly well on that and I have good physician medical care.

I have professionally looked after diabetics myself for many years and understanding diabetes as I do, gives me a great advantage over the average citizen. But you correctly promote that if pork insulin suits a patient best, then he or she should have it.

I am interested in your publication and value its arrival. Congratulations on your collective efforts.

Robin Scoular FRCP
Tauranga
New Zealand

Do you know about powdered sweeteners?
Dear Jenny,

I thought that readers of the IDDT Newsletter might be interested to know what Dr Richard Bernstein has to say about the common sweeteners - Sweet'n Low, NutraSweet and Splenda. "These are all non-carbohydrate sweeteners that can be used to satisfy a sweet tooth without, for the most part, affecting blood sugars. But when sold in powdered form, under such brand names as listed above, these products usually contain a sugar to increase bulk and will rapidly raise blood sugar. They all taste sweeter than sugar, so when you buy them in packets and powdered form, they usually contain about 96% glucose or maltodextrin and about 4% artificial sweetener. If you read the Nutrition Facts on Splenda, for example, it lists ingredients in order from most to least: dextrose (glucose), maltodextrin (a mixture of sugars) and finally sucralose. Most powdered sweeteners are sold as a low-calorie and/or sugar free sweeteners because they contain only 1 gram of sugar as compared to 3 grams of sucrose in a similar

paper packet labelled ‘sugar’.”

By e-mail

From one member to another…
Dear Jenny

Having had to fight for a long time to be put on to pork insulin can I pass this piece of advice on to other IDDT members: “If you think it may help you, demand the change to Pork or Beef Insulin and see how it goes”.

By e-mail

Flying
DearJenny,

I read your comments about drinks on flights in the July Newsletter. I have just returned from a trip via Melbourne, Zurich, Heathrow and Halifax, Nova Scotia, and as I am now allergic to amines and salyciates, as well as gluten and lactose, I was advised to provide my own food for the trips. As a result I was able to carry a litre of Rice Milk each time. I needed to have a doctor’s letter stating exactly what I needed to carry. At each airport the initial reaction was ‘no’ but on production of the letter, there was no trouble in carrying it on to the plane. I think that this emphasises the importance of a doctor’s letter for all medical needs when flying.

Mrs K.S.
Australia

IDDT News

IDDT new leaflet - ‘glossary of terms’

We have produced a new leaflet which will help to explain the words and terminology that we hear as part of the treatment of diabetes.

If you would like a copy of the new leaflet ‘Glossary of Terms’, just get in touch - give is a ring on 01604 622837, e-mail enquiries@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS. It is also available on our website www.iddtinternational.org

Don’t forget your IDDT Christmas cards!

To those who have already ordered them, many thanks for your help. If you haven’t got around to thinking about Christmas yet, please think of buying ‘Fun in the Snow’ IDDT cards. They are £3.25 per pack of 10 with 50p p&p a pack up to a maximum of £3.00.

The London 10K Run

Despite a wet weekend and being caught up in security problems, I am pleased to report that all our runners made it – some quicker than others! Chris O’Malley was the first of IDDT’s team to reach the finishing line. Many thanks to the runners but a huge thank you to you, our members for raising nearly £2000 in sponsorship to help our cause. All the sponsors names were entered into the prize draw and the winners of £50 Marks and Spencer’s vouchers were: D P O’Neill, S Chadwick and H Hatton.

Compulsory Reading

‘Insulin: A Voice for Choice’
By Arthur Teuscher

There can be no one who knows more about the human and animal insulin debate than Professor Arthur Teuscher. After fully synthetic insulin was made in 1975, he led the first clinical trial of synthetic

insulin in 6 people for 2 weeks and his subsequent article noted: *"Two patients experienced more sudden hypoglycaemic events than with animal insulin, but apart from that, synthetic insulin was well tolerated." In 1977 he received a personal congratulatory note from Charles Best, the discoverer of insulin.*

Of Professor Teuscher's new book, James Le Fanu, MD, FRCP, Columnist for the Daily Telegraph and The Sunday Telegraph, writes:

"Arthur Teuscher's 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. But it also tells the important story of how an alliance of physicians and patients has successfully campaigned to bring this issue to the public attention and thus guaranteed for those who need it continued access to the most appropriate treatment for their needs."

Members of IDDT are part of this story, so if you would like a copy of 'Insulin: a Voice for Choice' it can be purchased from IDDT for £11.50. To place an order, contact IDDT at PO Box 294, Northampton, NN1 4XS, Tel 01604 622873 or e-mail enquiries@iddtinternational.org

Warnings

Anti-obesity drug, Accomplia!
Accomplia [rimonabant] is the most recently licensed weight loss drug in the UK and Europe [June 2006]. It is the first in a new class of drugs which works by switching off the cannabinoid receptors in the brain that make people feel hungry. Accomplia is licensed for the treatment of obesity [BMI of 30 or above] and those who have a BMI of 27 with risk factors for Type 2 diabetes.

The Drugs and Therapeutics Bulletin [Vol 45, No 6 June 2007] reviewed Accomplia and described the adverse effects in the trials as follows:

- Most common - nausea [11-13% of patients], anxiety [5-8%] and dizziness [5-10%]. In the trial with people with diabetes, 5% reported hypoglycaemia.
- Around 15% of patients taking Accomplia withdrew from the trials because of unwanted effects, mainly psychiatric disorders such as depression, anxiety, irritability and insomnia.

But the US will not approve Accomplia!
In June 2007 the drug regulatory authority in the US, the FDA, refused to licence Accomplia [to be called Zimulti in the US] because of adverse effects in some people that prompted suicidal behaviour and caused other psychological side effects. In a study of 120 people using Accomplia, two committed suicide, one was considering it and another attempted to strangle his daughter. The manufacturers, Sanofi-Aventis, has withdrawn its application to sell Accomplia in the US.

Not so in Europe and the UK! In July 2007 the European Medicines Agency issued a warning that Accomplia heightens the risk of suicide among those also taking anti-depressants but has stopped short of suspending the drug, instead it is calling for a warning on the label to state that if a patient develops depression, Accomplia should be stopped. The National Institute of Clinical and Health Excellence [NICE] is currently assessing the drug for use on the NHS.

The other weight loss drugs available in the UK are:

- Xenical [orlistat] works by reducing fat absorption from the gut was given marketing authorisation in 1998.
- Reductil [sibutramine] which is an appetite suppressant, given marketing authorisation in 2004

Accomplia has not been compared to other less expensive drug

treatments for obesity. The Drugs and Therapeutics Bulletin has previously concluded that Orlistat is a reasonable option for obese people where diet, exercise and/or behavioural methods alone have failed. When looking at Accomplia it still maintains that this is the case because Orlistat has the most evidence for safety and efficacy.

What NICE [National Institute for Clinical Excellence] says about weight loss drugs: drug therapy for weight loss should be considered for patients who have not reached their target weight loss, or have reached a plateau with dietary, activity and behavioural changes alone.

New warnings on antidepressants [U.S. May 6 2007]
Many of you will remember the Panorama programmes about the prescribing of antidepressants to children and adolescents and their increased risks of suicidal thinking and behaviour. In 2005 the US Food and Drugs Administration [FDA] insisted on changes in the labelling to warn of this and also began a comprehensive review of 295 antidepressant trials. As a result they have now proposed that makers of all antidepressants update their warnings on their product labels to also include young adults aged 18 to 24 during initial treatment.

People on antidepressants should not stop taking them but if they have concerns, they should discuss them with their doctors.

The proposed changes also include statements that the scientific evidence did not show this increased risk in adults over 24 and in people over 65 antidepressants show a decreased risk of suicidal thinking and behaviour. To get this fully in perspective, the FDA is also reminding health professionals that antidepressants benefit many people.

Note: this is an example of post-marketing surveillance - drugs receive a marketing licence and after licensing when used on the wider population, adverse effects appear which require changes to the advice about a drug's use.

MRI - Reminder for insulin pump users!
Medtronic in Canada, suppliers of MiniMed Paradigm insulin infusion pumps, have issued a reminder to users that if the insulin pump is exposed to strong magnetic fields such as Magnetic Resonance Imaging [MRI], it may over-deliver insulin and cause severe hypoglycaemia. The company has become aware of three potential cases outside of Canada where direct exposure of the pump to MRI resulted in damage to the component that monitors and controls the movement of the motor used in Paradigm pumps.

As a result of new information, Medtronic now know that significant over-delivery of insulin can occur following exposure to strong magnetic fields and have issued the a warning: ***"YOUR PUMP MUST BE REMOVED AND KEPT OUTSIDE THE PROCEDURE ROOM IF YOU ARE UNDERGOING MRI."***

Pharmaceutical Industry News

The world's first digital insulin pen with memory
Lilly has produced a new insulin pen for use with Humalog. The HumaPen Memoir has a digital display that shows a record of the time, date and dose of the last 16 injections to help both patients and physicians to develop a diabetes treatment plan. It uses cartridges, has an internal battery lasting three years, and it comes with a two-year warranty.
According to Lilly, the pen has been designed to look like a writing pen rather than a medical instrument to make injecting in public more discreet. Interesting, as the first insulin pens in the1980s were like writing pens - the drug companies chose to make them large and instrument-like!

Memoir was first available in Finland and the Netherlands then launched in the US earlier this year. It is on prescription and costs $100, although Lilly is offering some patients coupons which reduce

the price to $45.

Eli Lilly also launched a second re-useable insulin pen product - the Luxura HD pen, also for use with Humalog. It can deliver insulin in smaller doses with 1-30 units of insulin deliverable in half-unit increments after the first unit and will be useful to those needing a small dose, especially children. Lilly describe Luxura HD as a cousin of a Lilly pen, Luxura, on the market in some European countries.

Impotence - once daily Cialis given EU approval
A once-daily version of Cialis, a drug to treat erectile dysfunction made by Lilly and similar to Viagra, has received marketing authorisation from the European Commission. It is the first drug of its kind to be used once daily. Marketing authorisation for Cialis at 2.5mg and 5mg has been granted.

The previous on-demand versions of Cialis at 20-mg and 10-mg doses have been available in the EU since 2002, but at a maximum recommended dose of one tablet per day taken shortly before sexual activity. In contrast with this and other products, this once-daily formulation of Cialis eliminates the requirement to have sex within a narrow time frame. According to the company, the once-daily version is intended for men intending to have sex at least twice a week.
Lilly expects the launch of the new doses in selected countries during the second half of 2007 and continuing throughout other EU countries during 2008. The recommended dose is 5mg a day, but can be reduced to the 2.5mg level based on individual tolerability.

Victory for the belief that people, not profits, must come first in public health.
Pharmaceutical giant Novartis challenged the law that allows India to refuse a patent for an existing medicine when it has been modified only slightly. But in August 2007 an Indian court ruled against Novartis as this was a direct attack against India's right to protect public health.

India supplies most of the world's affordable generic medicines to developing countries where patented medicines are unaffordable for most people. Novartis' legal challenge posed an enormous threat to millions of people, including those with diabetes. The decision will protect India's special role as the world's leading provider of affordable medicines to the poor and is a clear message to industry to respect developing countries' legal right to use the World Trade Organisation TRIPS (trade-related intellectual property) safeguards to strike the right balance between protecting public health and intellectual property.

Electronic Prescriptions

The Department of Health has announced the first Primary Care Trusts [PCTs] selected to use the Electronic Prescriptions Service.

The following PCTs have been selected to go live from 1st October 2007:

Berkshire East
Leicestershire County and Rutland
Liverpool
Southwark
Sunderland

No earlier than from 1st January 2008 the following PCTs will go live:

Berkshire West
Birmingham East and North
Blackburn with Darwin
City and Hackney
Haringey
Isle of Wight
Leeds
North East Lincolnshire

Nottingham City
Nottingham County
Suffolk
Trafford

Legal electronic NHS prescriptions can only be issued where the patient has:

- nominated one or more dispenser in his NHS Care Record,
- has confirmed that he intends to use that dispenser (or one of them) for the purposes of obtaining the drugs, medicines or appliances ordered on the electronic prescription,
- consented to the use of an electronic prescription on the particular occasion. Therefore, for the time being, the only time that pharmacists will be required to dispense against the electronic message is where the prescription has been sent using the nomination functionality.

Plain English people - what's the Nomination Functionality?

It is the patient's choice which dispenser they choose to nominate. The NHS Regulations 2004 are clear that a prescriber must not persuade a patient to nominate a dispenser recommended by the prescriber. If asked to recommend a dispenser, the prescriber is to provide a list of dispensers that operate the electronic prescription service [provided by the PCT]. The NHS (Pharmaceutical Services) Regulations 2005 prohibit pharmacies and appliance suppliers from offering inducements to encourage nomination of a pharmacy.

NHS News

NHS Choices - website www.nhs.uk
This is what we are told! NHS Choices is a service that aims to put you at the centre of your healthcare to help you make choices about your health, [little smile!] from lifestyle decisions to the practical aspects of finding and using NHS services. The aim is provide straightforward information that will help you ask your doctor the right questions about your health and any treatment you need [little smile!]. Then, with the doctor, you can decide on the course of action that's right for you – what treatment and, as far as possible, when and where to have it. [Important statement for those who don't receive a choice of insulins!]

NHS Choices gives [1] information on how to live a healthier life, [2] guides on the most common procedures, such as hip replacements, and conditions including diabetes and depression and [3] helps you and your GP pick the best provider for treatment or surgery and in 2008 you will be able to compare hospitals on their records for particular treatments or procedures, their cleanliness figures, rates of hospital-acquired infections, details of car parking and waiting times.

Even if you don't have a computer at home you can use of NHS Choices as all the material can be printed out, transferred to DVDs or made available through your GP, local library, or from any computer.

Complaints against GPs rise
The two leading GP insurance companies, which cover 9 in 10 GPs in England, dealt with nearly 300 serious complaints in 2006. One company had a tripling of the number of complaints since the new GP contract started in 2004 allowing GPs to opt out of providing night and weekend care. Many thousands of less serious complaints are dealt with at a local level by the individual doctor or PCT. The Medical Protection Society (MPS) state: *"The out-of-hours experience is increasingly a source of dissatisfaction for patients.*" Meanwhile a Dept of Health spokesman said patient experience was "generally positive".

Optometrists to get independent prescribing powers
Optometrists [ophthalmic opticians] are to get independent prescribing powers - specially trained optometrists will be able to write a prescription if they diagnose a problem with the eyes and the surrounding tissue that needs treatment. They will still refer patients

to an ophthalmologist for more specialized care.

Government to renegotiate NHS drug pricing, 2 August 2007
The Office of Fair Trading (OFT) recently issued a report on the pricing of drugs recommending replacing the current price and profit controls with a value based approach that will provide value for money for the NHS, better incentives to invest for companies and a more sustainable, stable system.

The Government's interim response was to agree that it was time the system was updated: "We agree with the OFT that it is time to develop a pricing system which is fit for purpose for the twenty first century."

Liberal Democrat Health Spokesperson, John Pugh MP said: "The relationship between the pharmaceutical industry and the British Government has been far too cosy for too long. This re-negotiation is a very welcome development. British taxpayers are paying some of the highest prices in the world for branded medicine. The current scheme is confusingly complex but has historically suited the pharmaceutical industry."

Association of British Pharmaceutical Industries [ABPI] was more measured, stating that they 'welcome the assurance from the Government that any new agreement will recognise the contribution of the pharmaceutical industry to the UK economy. The ABPI believes that a stable, voluntary agreement is crucial to retain the industry's major R&D investments – the UK's largest.'

We'll see what 2010 brings!

Poor and late hospital discharge information is putting patients at risk
GPs are supposed to receive information on medicine and treatment within 2 days of a patient being discharged from hospital to help in their follow-up care. The information is e-mailed, faxed or given to the patient to hand over. An NHS Alliance poll of 651 GPs found 70% often received papers late and many said the forms were incomplete and lacked important details that compromised patient safety including the patient's name, contact details, medication and treatment. In one instance, a discharge summary was received but failed to mention that the patient had just spent a week in intensive care following a stroke and heart attack.

58% of GPs reported the problems meant clinical care was compromised in the last year, with 39% claiming patients had been put at risk but nearly two-thirds of doctors said they had hospital teams in their areas who provided good, prompt information, proving it could be done. A Dept of Health spokeswoman said officials were looking to draw up a contract for hospitals in a bid to improve discharge information. [Why on earth is a contract necessary for something that should be done as a matter of course?]

NICE Is developing guidelines on diabetes and pregnancy
The National Institute for Health and Clinical Excellence [NICE] is currently developing guidelines on diabetes in pregnancy. These will cover the management of diabetes and its complications from pre-conception to the post-natal period and is expected to be published in November 2007.

Snippets...

HSC News global Quality of Life Survey
There are interesting findings in a global survey of people with a 'disability'. The most valuable factors that could improve their quality of life and identified as 'very important' by 75% of the respondents, were:

- getting the correct treatment/care/support.
- healthcare professionals sufficiently skilled/expert to do the job.
- doctors who listen to patients' opinions about treatment and care.
- not having to battle the system to receive the needed care.

Handshakes with your doctor

Research carried out in the US shows that 78% of patients wanted to be greeted by their doctor with a handshake and even more expect the hand to be washed between patients! The suggested reason for this is that in many cultures the handshake symbolises mutual respect. There were two studies looking at this and in one of them 415 people also listed other expected behaviours from doctors: smile, be friendly, attentive, polite, make the patient feel a priority and make eye contact. Perhaps just normal good manners!

Believe it or not, patients are now getting more time with GPs

GPs in England spend almost 40% longer on each patient consultation than they did in 1992/93, according to research published by the Information Centre for Health and Social Care.

- The average consultation time in 2006/07 was 11.7 minutes, up from 8.4 minutes.
- The number of consultations carried out by GP practices has risen - but the number of home visits has dropped from 9% of the total to 3%.
- GPs are working roughly the same surgery hours as they did when the last survey was carried out in 1992/93 but most are not working outside “normal” hours as they once did. In 1992/93 the average GP worked around seven hours a week outside surgery hours.
- The number of consultations at family practices across England has risen from 220.1 million in 1995 to 289.8 million in 2006 but a higher proportion are now undertaken by nurses - in 1995 it was one in 5 and now it is one in three.
- The number of consultations has remained constant but the number of telephone consultations trebled from 3% to 10%.

Katherine Murphy, of the Patients Association told the BBC that the GP service was getting worse despite the “inflated salary” of family doctors and that “trust and relationship is very quickly being eroded. They are not delivering patient-friendly service.”

Taking a break during exercise

Research in Japan has shown that taking a break when exercising burns off more fat than continuous workouts. They compared a 60 minute session on an exercise bike followed by a rest period with two 30 minute sessions with a 20 minute break in the middle. In the two session exercise with a break, there was a greater increase in free fatty acids and glycerol, which are released when stored fat is burned, than in the 60 minute session. In addition levels of adrenaline increased and insulin levels decreased much more in the exercise with a break than during the single session which may have added to the fat breakdown. This contradicts some of the present advice but may be worth a try. [Journal of Applied Physiology, June 2007]

Fat cats…

Research at Edinburgh University has shown that one in 250 pet cats in the UK have obesity related diabetes. Overweight cats are more than three times as likely to get diabetes, neutered males and Burmese cats being particularly at risk. Apparently cats’ lifestyles are changing just like their owners and they are tending to eat too much, gain weight and take less exercise!

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

IDDT welcomes the submission of letters and editorial articles for consideration of publication in future issues of the IDDT Newsletter. The editor and trustees do not necessarily endorse any opinions or content expressed by contributors and reserve the right to refuse, alter or edit any submission before publication. No part of this publication may be reproduced in any form without the prior written permission of the editor.

Insulin Dependent Diabetes Trust
PO Box 294
Northampton
NN1 4XS

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