Insulin Dependent Diabetes Trust

January 2011 Newsletter

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At a time when 90,000 people have just lost the insulin they rely on, it seems inappropriate to wish you a 'Happy and Healthy New Year'. Nevertheless, the Trustees and Staff of IDDT send you our good wishes for 2011 and thank you for your help and support throughout 2010.

Human Mixtard 30 gone!

By the time you read this Newsletter, human Mixtard 30 insulin will have gone. Unsurprisingly, the manufacturers, Novo Nordisk, have ignored the needs and wishes of patients, doctors, health professionals and the NHS.

"If there was only one type of person with diabetes, we would only make one type of insulin."*[Practical Diabetes, Oct 2010, GP magazine, November 5th 2010,]*

Guess whose advert this was? Yes, you're right - Novo Nordisk!

Marketing is all about the use of words and they have succeeded in using them well. The advert was in fact advertising one type of insulin – analogue insulin. Let us not be fooled, there are three types of insulin, human, animal and analogue insulins, all necessary to suit

the different needs of people with diabetes. Novo Nordisk has made no secret of their intention to make only one type of insulin, analogue insulin, and in doing so they will fail to meet the needs of people with diabetes.

"Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society. Novo Nordisk's business is driven by the Triple Bottom Line: a commitment to economic success, environmental soundness, and social responsibility to employees and customers."
[About Novo Nordisk Canada, CDA 11.11.10]
Yes, customers, the people with diabetes, are last on the list.

"A commitment to economic success"
Novo Nordisk has announced record profits and their share prices continue to rise. The annual sales of their new drug, Victoza, are expected to reach $1 billion by 2012. So they have achieved "economic success" but not without harming the very people who provide their economic success! One GP signed the DTB petition with "I hope that Novo Nordisk will reconsider its decision to discontinue [Mixtard 30]. I won't forget if it will not!" Affecting their economic success by using insulin from other manufacturers may make them realise that their actions are unacceptable and will have repercussions.

Social Responsibility
- **Is it socially responsibl**e to remove Mixtard 30 that is used successfully by 90,000 people, all of whom will have to go through the process of getting used to a different injection device, a different insulin, how it works for them?
- Is it socially responsible to remove the Innolet injection device so the most vulnerable people with diabetes are in a position where they can no longer self-inject and they lose their independence?
- Is it socially responsible to remove Mixtard 30 that is used by children, especially when the only pre-mix alternative from Novo Nordisk is the analogue, NovoMix 30 which is NOT approved for use in children under the age of 10 years?
- Is it socially responsible to remove Mixtard 30 and expect people to use analogue insulins which, for the vast majority of people, do not offer any advantage over human insulins in terms of efficacy, long-term outcomes or safety and cost the NHS and taxpayer significantly more?

IS IT ARROGANCE, INFLUENCE OR WHAT?
The ability of Novo Nordisk to ride rough shod over patients' needs is deplorable. How do they get away with convincing doctors and health professionals to use insulin analogues when the evidence is clear, and there's now plenty of it? For the majority of people analogues are not superior to 'conventional' human insulin and importantly, their long-term safety has not been established. All the analogues are significantly more expensive than human or animal insulins, NICE does not recommend analogues as first choice treatment, we have a cash-strapped NHS and a lack of diabetes services in many areas of the country. Yet figures suggest that the analogues have cornered the largest share of the market in the UK – why?
So the questions have to be asked:
- How does Novo Nordisk manage to persuade doctors and health professionals to ignore NICE guidance and all the high quality evidence? Why do they prefer drug company information to carefully assessed evidence-based information from NICE?
- How does Novo Nordisk manage to persuade these same people to ignore the unnecessary extra cost of analogue insulins in our cash-strapped NHS?
- How do we end up in a position where it is OK to use unnecessarily expensive insulins and waste money that could be used to provide more essential services, not to mention blood glucose test strips?
- How have Primary Care Trusts [PCTs] been persuaded to ignore the increased cost of analogue insulins? PCTs are very quick to save money by restricting insulin pumps and test strips, so why do they ignore the high cost of analogues?

One way is marketing. Some of the marketing tricks are obvious - we have seen them all before, the obvious one being the use of the injection device to 'sell' the type of insulin. When insulin pens were

introduced in the 80s Novo Nordisk only made them for human insulin, so if people wished to continue to use pork insulin, often because of adverse reactions to human insulin, then they were denied the pen and had to use a vial and syringe. Only a few years ago when they wanted people to move from human Actrapid to NovoRapid, they made Actrapid available vials only so if people wanted to inject with a pen, they had to change insulin.

Then another way of marketing is to use 'big names' in the diabetes world to carry out research into their new insulins – if the 'big names' say the new insulin is OK, it must be!

Where does the Department of Health fit in?

- They openly admit to being in consultation over the discontinuation of Mixtard 30, so why were they not able to 'persuade' Novo Nordisk that 6 months withdrawal of insulin used by 90,000 people was not long enough?
- Exactly who was involved in the 'consultation', were patients represented, if so which patients? IDDT was certainly not invited, yet we are invited to consultations with NICE and to have links with NHS Choices, so why were we ignored on this one?

Reporting An Adverse Reaction To A Drug Or Insulin

With the change to a different insulin, some people may experience adverse reactions. An adverse reaction can occur immediately, within hours, days, months and even years. If you think you have an adverse effect or reaction it is important that you report it through what is known as the Yellow Card Scheme. You only have to suspect, not prove, that the symptoms are due to the drug or insulin you are taking.

- You can make a Yellow Card report online at http://yellowcard.mhra.gov.uk/ or download the form, print and post to the address at the bottom of the form.
- You can obtain a Yellow Card form from pharmacies, GP surgeries or by phoning freephone 0808 100 3352 (available weekdays 10:00 and 14:00)
- You can make a report by phone on the Yellow Card hotline as above.

Reporting adverse reactions is an important part of ensuring the safety of medicines.

Good news in Canada!

If you live in Canada obtaining animal insulins is difficult and expensive. Hypurin pork insulin is licensed in Canada but is very expensive but beef insulin is not available and up to now people have had to import it from the by 'Special Access' arrangements – again this is a difficult and expensive process.

IDDT's Trustee in Canada, Carol Baker, has now managed to import beef insulin through this process from Argentina but at a much lower cost. If live in Canada and would like further information on how to do this, please contact Carol at:
iddt_cda@yahoo.com Tel 1 (250) 477 8564 or write to her at 2647 Mt Stephen Avenue, Victoria, British Columbia, V8T3L5

News From Nice

NICE changes afoot – losing the power to decide on new drugs

The National Institute for Health and Clinical Excellence [NICE], often referred to as the 'medicines watchdog' is to lose its power to turn down new medicines for use on the NHS. NICE has looked at the evidence for the cost effectiveness of drugs and has also said 'no' to pharmaceutical companies which has helped to drive down the cost of drugs to the NHS. In future it will offer advice on which drugs are effective and on quality standards but will not decide on whether drugs should be funded by the NHS, so is it going to become just a library of information? Paul Flynn MP said perhaps what many are thinking,

"The decision represented a "surrender" of objective, science-based judgments to a reliance on "big pharma""

Instead groups of GPs [called consortia] in areas around the country will decide whether a drug should be funded or not. It can be is hard for us ordinary mortals to understand all the coalition government's proposed changes in the NHS but if groups of GPs are to make the decisions about whether drugs can be funded, won't this increase the postcode lottery? A group of GPs say in Leeds could decide to fund a drug whereas a group in Bournemouth could decide not to fund that same drug.

The pharmaceutical industry must be rubbing its hands together at the prospect of NICE losing its powers to judge cost-effectiveness!

On a positive note, NICE will still be reviewing the evidence for effectiveness of drugs and issuing advice. This is available to doctors and to us as patients, so we can use this information when discussing our treatment options.

Diabetes one of NICE's quality standards
In August 2010 NICE announced nine new quality standards that it will develop during 2010/11 and the management of Type 1 and Type 2 diabetes are in the nine topics.

What are NICE quality standards?
They are markers of excellent care produced by joint consultations between the NHS, social care professionals, along with their partners and service users [patients]. They are derived from the best available evidence, such as NICE guidance. Quality standards set out the 'structures and processes of care' and will focus on the best outcomes for patients as well as cost effectiveness. They are a set of specific, concise statements that provide clear definitions of high quality health and social care, cost effective patient care covering treatment and prevention of different diseases and conditions so organisations can improve quality.

Quality standards are supposed to enable:
- **Health and social care professionals** to make decisions about care based on the latest evidence and best practice.
- **Patients** to understand what service they can expect from their health and social care providers.
- **NHS Trusts** to quickly and easily examine the clinical performance of their organisation and assess the standards of care they provide
- **NHS Trusts Commissioners** to be confident that the services they are providing are high quality and cost effective.

So what will they do for us as patients?
Patients and the public can use NICE quality standards to know what quality of care they can expect to receive from the NHS. NICE quality standards are not mandatory, in other words, they don't have to be put into place although the care system is obliged to have regard to them in planning and delivering services. However, they will provide us, the patients, with something concrete to use to ensure that we are provided with the treatment and care that we can expect. Let us hope that the NICE quality standards for diabetes will be widely disseminated, not just via the internet, so that patients are aware of them if the care they are receiving is lacking. Once these standards are available, IDDT will publish them.

Latest Guidance from NICE
NICE issues guidance on the use of Victoza [liraglutide] for Type 2 diabetes
Victoza [also called liraglutide] is a drug for Type 2 diabetes which triggers the release of insulin and also blocks a hormone called glucagon which stops insulin from working properly. It also reduces the appetite by the stomach remaining full for longer. It works in a similar way to Byetta which has been on the market for some time.
Victoza is not the only possible treatment for your Type 2 diabetes and your healthcare team should discuss your options and whether Victoza is suitable for you.

What does NICE Guidance say?
In October 2010, NICE issued guidance on the use of Victoza

[liraglutide] as a possible treatment option for some people with Type 2 diabetes. It recommends:

- Victoza at a dose of 1.2mg once a day.
- It does not recommend that Victoza at the higher dose of 1.8mg a day because there is no evidence that this higher dose works any better.

The guidance for who can have Victoza is quite strict and a little complicated.

You should be able to have Victoza if:
When you have been given two other drugs for Type 2 diabetes, metformin and either a sulphonylurea or a thiazolidone [eg Actos], if you blood glucose level is not under control **AND**:

- You have a high body mass index [BMI over 35 or higher and problems associated with high body weight OR
- Your BMI is under 35 and losing weight would help other health problems, or taking insulin would greatly affect your ability to work. [For example a taxi driver who would lose his job if he went on to insulin which does happen with some local authorities.]
- You should also be able to have Victoza if you only take one other drug for your diabetes if you cannot use metformin or a sulphonylurea for medical reasons or if you have a bad reaction. This also applies to thiazolidinediones and DPP-4 inhibitors.

If you are already taking Victoza at a dose of 1.2mg and you don't fit into the above, or you are taking Victoza at a higher dose of 1.8mg, you should be able to continue to do so until you and your healthcare professional decide it is the right time to stop.

How long should you go on taking Victoza?
NICE recommends that treatment with Victoza 1.2mg per day should only be continued if it is proved to be beneficial after 6 months and this is defined as a drop of 1% in HbA1c 6 months after starting treatment.
Note: NICE guidance on all aspects of diabetes are available on IDDT's website, just click on http://www.iddt.org/nice-guidelines/

Research News

Artificial Pancreas
Professor Joan Taylor from De Montfort University has invented and patented an artificial pancreas which she believes could 'revolutionise' the treatment of diabetes. This new artificial pancreas is made of a metal casing containing a supply of insulin kept in place by a gel barrier. When blood glucose levels rise the gel barrier starts to liquify and lets insulin out. The insulin goes into the veins around the gut, then into the vein to the liver so mimicking the normal process of a person without diabetes. As the insulin lowers the glucose level in the body, the gel reacts by hardening again and stopping the supply of insulin. So the right amount of insulin is released automatically when the body needs it. The artificial pancreas would be implanted between the lowest rib and the hip and topped up with insulin every few weeks. It is undergoing pre-clinical trials and Professor Taylor hopes to move onto clinical trials and if these are successful, the device could be available in the next 5 to 10 years, probably only for people with Type 1 diabetes.

Artificial pancreas, more news
The findings of the largest and longest study using an insulin pumps and continuous glucose sensor has shown that people who used this combination achieved better control of their blood sugars than those using insulin injections. *[New England Journal of Medicine, 22 July, 2010]*

Companies are working on producing a combined device known as the artificial pancreas or closed loop system which will monitor blood sugars and automatically deliver the appropriate amount of insulin. However, in this study, people using the pump had to manually adjust their dose in the same way that people taking insulin injections do. The results showed that even without the automatic closed loop system, combining the insulin pump and sensor can help people achieve optimal blood glucose control.

The lead researcher said, *"We were able to get blood sugar down into the range where we can prevent long-term complications and we did it without causing it to drop too low."* However, he went on to explain that hypoglycaemia, low blood sugar, is the bigger concern for people who tightly manage their blood sugars and current treatments are increasingly helping people to avoid high sugars but this results in low blood sugars.

An editorial accompanying the publication of the study questioned whether the devices would work as well in the real world of diabetes clinics as the expert training and guidance received by the people in the clinical trials cannot be duplicated in a busy clinic. It also points out that this technology takes diabetes self-management to the next level and patients really do need "to be pretty skilled in using the information provided by the sensor effectively."

We are still several years away from the final closed loop system to be used safely and effectively and the reduction of severe hypoglycaemia has still to be addressed.

Will it be possible to test the skin instead of finger pricks?
Researchers have found a way to measure blood glucose by shining near infrared light on the skin with the aim of minimising pain and inconvenience. [Journal of Analytical Chemistry, July 15, 2010] The technique can reveal blood glucose levels by simply scanning the arm or finger without the need to draw blood. The researchers have been developing this technique for about 15 years but one of the major problems has been that the near infrared light only penetrates about half a millimeter below the skin so it measures the fluid around the cells [interstitial fluid] not the amount in the blood. To overcome this, the researchers developed an algorithm that relates the glucose in the blood and the glucose in the fluid so allowing them to predict blood glucose levels from the interstitial fluid.

This calibration is more difficult immediately after eating because the blood glucose rises rapidly but it takes 5 to 10 minutes for the glucose in the interstitial fluid to rise accordingly. So interstitial fluid measurements do not give an accurate picture of what is happening. To address this 'lag time' the researchers developed a new calibration method called the Dynamic Concentration Correction [DCC] which includes the rate at which glucose diffuses from the blood into the interstitial fluid. A clinical study is planned to test the DCC in the autumn of 2010. So lets hope there may be a day when finger prick blood tests are a thing of the past.

HbA1c targets below 7% achievable in half or people with Type 2 diabetes on insulin
An HbA1c target of less than 7% is recommended for most patients with Type 2 diabetes to reduce the risks of complications, although this target does vary between countries.

Results from a systematic review of 48 trials with a total of 30,588 patients suggest that an HbA1c target of less than 7% is achievable in 40-54% of people with Type 2 diabetes depending on their insulin regime.

The different insulin regimes were basal [long-acting insulin only, biphasic [pre-mixed insulin], prandial [short-acting insulin at meal times] or basal bolus [long-acting insulin and pre-meal insulin]. The numbers achieving HbA1cs of less than 7% on the different regimes were as follows:

- Basal – 41.4%
- Biphasic – 46.5%
- Prandial – 39.6%
- Basal bolus – 53.9%

Hypoglycaemia ranged from 0 to 4.71 events per patient per 30 days and weight gain from 1.75 to 3.00 kg depending on the type of insulin treatment.

Basal insulin alone is used as the first option when starting insulin treatment in people with Type 2 diabetes because of reduced numbers of injections and blood glucose testing but about 60% of people on this regime did not reach target HbA1cs. If targets are not achieved,

then usually meal time injections of short- or rapid-acting insulin is added or pre-mix insulin is given, but even so only about half reach the target blood glucose levels. *[Diab Res Clin Pract, Sept 2010]*

Question: are the targets set at an unachievable level for half of people with Type 2 diabetes? To be given targets that are not reached can make people feel inadequate, as if they have failed so they feel discouraged and perhaps depressed. Setting targets for the individual people at levels that are achievable seems a better way and may encourage people to gradually do better as they get used to using insulin. Giving some praise a long the way also helps.

Treatment Uncertainties In Type 1 Diabetes

A Priority Setting Partnership – progress report

It seems a long time ago but in 2009 the development of a 'Priority Setting Partnership' for treatment uncertainties in Type 1 diabetes began under the leadership and guidance of the James Lind Alliance. The aim of the partnership is to gather treatment uncertainties from patients, their families and clinicians and then prioritise10 treatment uncertainties. This means that the top 10 uncertainties are common to both patients and clinicians – those who actually are at the 'sharp end' of Type 1 diabetes. Once this exercise is complete, partners will share, encourage and lobby research funders and groups to take up these priorities for future Type 1 diabetes research to encourage future research that is important to patients and their doctors. As the principle of patients having a voice is so close to our hearts, IDDT Trustees agreed to fund this process.

The Partnership

This includes NHS Evidence – diabetes, Juvenile Diabetes Research Foundation, Insulin Dependent Diabetes Trust, Diabetes Research Network, Diabetes UK, Scottish Diabetes Research Network, UK Database of Uncertainties in the Effects of Treatments [DUETs] and the James Lind Alliance and help from those in primary and secondary care.

What are treatment uncertainties?

These are research questions about the treatment of Type 1 diabetes that we don't have the answer to yet. You can see what has already been gathered from existing research reports and from a workshop held in 2009 by visiting
http://www.library.nhs.uk/duets/SearchResults.aspx?tabID=294&catID=14514

What has the Partnership achieved so far?

- 583 people completed the online and paper survey asking for their treatment uncertainties. They included people with Type 1 diabetes, family members and health professionals who care for and treat people with diabetes.
- 1,141 treatment uncertainties were submitted.
- 251 did not relate to the treatment of Type 1 diabetes and were excluded from the current process, but are interesting and will receive attention later in the project.
- The steering group agreed some categories for the submitted treatment uncertainties before the survey, so all submissions have been allocated to these. They include condition management [for example, medication, monitoring and lifestyle], pregnancy, delivery of care and many more.
- There are many repeated treatment uncertainties so these are being combined and where appropriate a 'catch all' research question developed to reflect the original submissions. We call this indicative uncertainties.
- Finally treatment uncertainties are being checked for genuine uncertainty, in other words, are we sure that the question hasn't already been answered by existing summaries of research?

Here are some examples of treatment uncertainties submitted:

- Do the current rapid acting insulins for the treatment of Type 1 diabetes mirror well enough the pattern of raised blood sugars after a meal?
- Do hormones, in females with Type 1 diabetes, impact on blood

glucose levels?
- What is the most effective teaching methods for informing patients with Type 1 diabetes about the importance of eye and foot screening?
- Does continuous blood glucose monitoring reduce the frequency of long term complications of diabetes?
- What is the best treatment for people with Type 1 diabetes presenting with insulin resistance?

What next?
We will embark on a priority setting process in the New Year that will be transparent, and include the perspectives of people either living with Type 1 diabetes, or treating and caring for people with diabetes, [and sometimes both]. This may include a voting exercise, by organisations and individuals that have participated so far, and there will be a final workshop whereby participants talk about and vote for research priorities. The methods that we use will depend on the size of the final long list of treatment uncertainties that need to be prioritised, and the numbers of people who want to be involved. The excellent response to the survey has resulted in the largest dataset yet for the James Lind Alliance, and this presents us with new challenges in priority setting!

If you want to take part, please register your interests with the JLA to: Patricia Atkinson, James Lind Alliance, Summertown Pavilion, Middle Way, Oxford, OX2 7LG e- mail patkinson@lindalliance.org Tel 01865 517635

For more information, visit the James Lind Alliance website: www.lindalliance.org

Just To Remind You – New HbA1c units

From April 1st 2011, HbA1c results will be reported only in the new units, mmol/mol. The HbA1c will be reported in units of 'mmols per mol' or 'mmols/mol' and not as a percentage figure. This measurement is going to be international so that all laboratories will be using the same measurements.

The relationship between the old HbA1c and the new measurements will be:

Old HbA1c [%]	New HbA1c [mmol/mol]
6.0	42
6.5	48
7.0	53
7.5	59
8.0	64
9.0	75

- So if you are aiming for HbA1c targets of 6.5% and 7.5%, the new units will be 48mmol/mol and 59mmol/mol.
- Normal blood glucose [in someone without diabetes] is 4 - 6% but in the new units it will be 20 - 42mmol/mol.

Different Infant Formula May Prevent Type 1 Diabetes

According to Finnish researchers, offering babies at high risk of developing Type 1 diabetes a special formula when weaning them off breast milk may offer some protection against the development of the antibodies associated with Type 1 diabetes. 'High risk' is those who have a family history of Type 1 diabetes.

The special formula was extensively hydrolyzed which means that the proteins in the formula are already partially broken down and

more readily available for digestion. Comparing two groups of babies, one receiving standard formula and one the hypdrolyzed formula, the researchers found that the hydrolyzed formula cut the rate of developing diabetes linked antibodies by about half.

Previous research has suggested that breastfeeding may offer some protection against the development of these antibodies possibly because breastfeeding delays the introduction of regular formula which contains complex proteins. However, it has not been proved that cow's milk formula leads to an increased risk of Type 1 diabetes and there are experts who don't agree with the Finnish researchers recommendation of weaning a baby to extensively hydrolyzed formula if a member of the family has Type 1 diabetes. *[New England Journal of Medicines, Nov 11, 2010]*

Reports from the European Association for the Study of Diabetes Annual Meeting

Communication about Hypoglycaemia needs to improve

The results of a survey of patients and health professionals suggest that communication about hypoglycaemia between health professionals and patients with Type 2 diabetes needs to be improved. The findings for the UK were:

- 74% of the 50 staff interviewed said they always asked patients if they had experienced hypoglycaemia since their last appointment but 92% suspect that patients are not always forthcoming with information.
- Of the 82 patients with Type 2 diabetes, 50% said they do not regularly discuss hypoglycaemia with their GP or other health professionals but 88% had some degree of worry that they may experience it in the future.
- Around a third of patients say they believe hypoglycaemia to be inevitable because of their medication so they rarely discuss it and another said they do not discuss it with health professionals because they don't understand it.

Clearly education and information needs to be improved, especially about hypoglycaemia for people with Type 2 diabetes. It is well known that for people who use insulin, the fear of hypoglycaemia is the most common day to day worry or fear whether they have Type 1 or Type 2 diabetes. For people with Type 2 diabetes taking metformin as their only diabetes medication, hypoglycaemia does not occur. However, hypoglycaemia can occur if a second medication is added from the group of drugs known as sulphonylureas. They work by stimulating the islet tissue in the pancreas to produce insulin. This has a blood glucose-lowering effect which can lead to blood sugars being too low, which is hypoglycaemia.

So if you are unsure whether the medication you are taking can cause hypoglycaemia, it is important to talk to your doctor or health professional. If hypoglycaemia could occur as a result of the medication or insulin that you are taking, it is important that you know how to treat it.

Fear of hypoglycaemia blocks HbA1c control

Research suggests that fear of hypoglycaemia is an important barrier to people with Type 2 diabetes obtaining optimal blood glucose control [HbA1c results]. Information gathered from over 5,000 people with Type 2 diabetes showed that those who reported any hypoglycaemic event had reduced quality of life and treatment satisfaction. The researchers said the fear of hypoglycaemia may be directly affecting willingness to intensify treatment [eg take more drugs or insulin to lower blood sugars] and that it might also be a reason why people don't always take all the prescribed treatments. It was slos said that 'the huge problem of compliance' [meaning lack of compliance!] remains a barrier to improved glycaemic control.

I don't think any of this is rocket science!!!!

Sculpture To Celebrate The Birth Of Sir Frederick Banting

On October 29th 2010 a sculpture was unveiled at the Banting House National Historic Site of Canada in Ontario. It was Frederick Banting's idea that led to the discovery of insulin. The idea came to him in the middle of the night on October 31st 1920 at a time when diabetes which generally affected people under 30, meant a slow death caused ultimately by very high blood glucose levels.

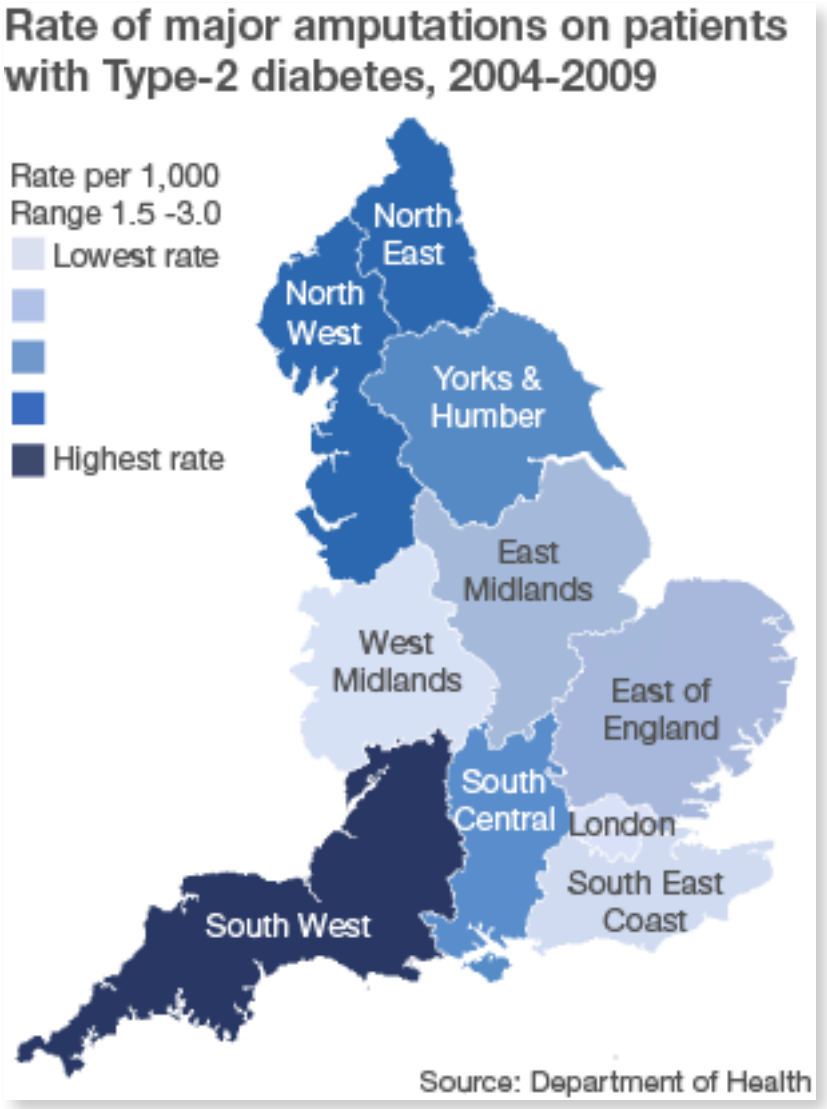
Banting had been reading about the pancreas and also that diabetes could be artificially caused in dogs by removing the pancreas. Lying in bed thinking about these things, he realised that this suggested a connection between the hormone produced by the pancreas and the body's ability to process sugar. He wrote this in his notebook in just 25 words, words that changed medical history forever and saved the lives of millions of people with diabetes – the discovery of insulin.

Some lesser known facts about Sir Frederick Banting:

- He was the youngest person in history to receive the Nobel Prize in Physiology or Medicine in 1923.
- He was decorated in the First World War.
- He had Canada's first man-rated centrifuge built in Ontatrio.
- He had the first decompression chamber built in Toronto and this technology is still used today to allow for the pressurization of cockpits in planes.

Amputation Rates Vary Across England

At the end of November the Department of Health produced what is being called the 'atlas of care' which covers the variation in levels of healthcare across the country of 34 conditions. The work was carried out during the last government but the coalition supports the need and agrees that the aim is to try to improve healthcare. Diabetes is one of the areas covered and the figures show that 70 people with Type 2 diabetes have amputations every week in England.



One of the complications of diabetes that can happen is neuropathy which can lead to loss of sensation in the feet and this together with poor circulation can leave them vulnerable to injury. These injuries

can become infected and ulcerated and if the infection becomes too severe, amputation of a foot or the leg below the knee becomes the treatment of last resort.

The Department of Health figures reveal that the variation in major amputation rates across the country is tremendous and for example, the rate in the South West is 3 in 1000 diabetic patients which is almost double the rate in the South East. The shocking part of these statistics is that with good care and treatment at the right time, it is estimated that 80% of these amputations could be prevented. The atlas also shows a big variation in the percentage of people with diabetes who are receiving all the essential checks to monitor their condition which includes the simple foot checks which can prevent amputations.

Sir Muir Gray who led the research within the Department of Health said: “Most people in the health service are so focused on what they are doing, working so hard, they’ve got no ideas if they are doing better or worse than someone else. The atlas is now going, for the first time, to give them a clear idea of where they are”.

But not only does the atlas show those working in the NHS how well, or otherwise they are doing, it also shows us, the patients. So if you are not receiving the checks for your feet, or there are delays in receiving treatment, then use the atlas to argue your case for better care either with your practice or your Primary Care Trust [PCT]. It is people with diabetes who have to live with the consequences of poor or mediocre footcare.

NHS Diabetes – response

In a press release Anna Morton, the Director of NHS Diabetes said: “……we have already rolled out our hospital footcare guidance developed with our partners at Diabetes UK, called Putting Feet First. We are also working on a series of case studies, due to be published shortly, which will provide examples where quality has been dramatically improved while costs maintained or reduced. These case studies will lead the way for NHS Trusts treating people with diabetes and enable them to implement evidence-based good practice which has already been pioneered by others.”

Here’s how it can be done - Paddington Hospital has better footcare and less amputations

Just before the atlas was published, there was an article in the press about St Mary’s Hospital, Paddington which showed that people with diabetes are less likely to have amputations than most other hospitals in the world.

In this hospital’s area 4.2% of people with diabetes have a major limb amputation compared to 10.2 % in the whole of England. So how is this achieved? By a multi-disciplinary team with close links to community centres and GP practices so that as quickly as one working day after going to your GP with a foot ulcer, a person with diabetes will have access to the care they need to prevent the problem from getting worse.

Clearly one of the questions we all have to ask is, if this can happen at St Mary’s Hospital, why can’t happen at other hospitals around the country?

There are clear messages from this for people with diabetes

- **if your feet are not checked at your regular diabetes check ask for this to happen**
- **don’t delay seeking help if you have foot problems, go to your GP straight away,**
- **stress how important it is that there are no delays in being referred for further help and treatment.**

Note: while talking about footcare, here’s a tip about Flip flops

One of the warnings to people with diabetes is never to walk barefoot, especially not on holiday because this increases the risk of injury. According to podiatrists, flip flops are the worst offenders for causing foot injuries in the general population – more than 200,000 visits to GPs and hospitals are caused by wearing flip flops costing the NHS £400 million every year.

If you would like a free copy of IDDT’s Leaflet on

Neuropathy, give us a call on 01604 622837 or e-mail enquiries@iddtinternational.org

Blood Pressure

High blood pressure is a key concern for the general population but especially for people with diabetes. High blood pressure [hypertension] often causes no symptoms and no immediate problems. If you have high blood pressure your heart has to work harder to pump blood around your body and over time this can weaken it. It can also damage the walls of the arteries or cause a blockage and both of these situations can cause a stroke. So high blood pressure is a major risk factor for serious cardiovascular diseases such as:

- **Coronary heart disease** where the main arteries supplying blood to the heart become clogged with fatty deposits [plaques].
- **Heart attacks** where the blood supply to the heart is blocked.
- **Strokes** where the blood supply to the brain is interrupted.
- **Thrombosis** caused by blood clots in the blood vessels.
- **Aneurysm** where there is a weakness in the blood vessel wall which forms a bulge in the blood vessel.

According to NHS Choices www.nhs.uk in 90 – 95% of cases in the general population there is no single identifiable reason for a rise in blood pressure but all the evidence suggests that lifestyle plays a significant role. The main factors influencing high blood pressure are:

- age – half of people over 75 have high blood pressure
- lack of exercise
- overweight
- poor diet
- excessive alcohol consumption.

In the general population about one in three adults in England have high blood pressure with around 18% of men and 13% of women are not receiving treatment for it. People of Afro-Caribbean origin are more likely to develop high blood pressure than other ethic groups.

How is blood pressure measured?

Blood pressure is measured in millimeters of mercury [mmHG]. Two measurements are used:

- **Systolic pressure** – the blood pressure exerted when the heart beats to force blood around the body.
- **Diastolic pressure** – the blood pressure when the heart is resting between beats.

The measurement of the systolic pressure is given first for instance 120 over 80 or 120/80mmHg and this means the systolic pressure is 120mmHg and the diastolic pressure is 80mmHg.

High blood pressure and diabetes

About 25% of people with Type 1 diabetes and about 80% of people with Type 2 diabetes have high blood pressure. Unfortunately as we are aware, having diabetes raises the risk of heart disease, stroke, kidney disease and other complications, so having high blood pressure raises these risks even more.

High blood pressure is usually defined as having sustained blood pressure of 140/90mmHg or above but if you have diabetes your doctor will probably want your blood pressure to be below 130/80mmHg because of the greater risks associated with diabetes and high blood pressure.

Treatment

High blood pressure can be treated or prevented in some cases, by making lifestyle changes such as eating a healthy diet, exercising regularly and reducing alcohol intake. Often medication is necessary to lower blood pressure and people with diabetes may be given drugs known as ACE inhibitors [angiotensin receptor blockers] because they are thought to also have a protective effect on the kidneys. However, other blood pressure-lowering drugs may be used. ACE inhibitors may also be given to protect the kidneys even when blood pressure

is not high.

Blood pressure - recent research
Taking blood pressure pills at night
The findings of a 5-year study have shown that the timing of blood pressure medication with the person's body clock makes it more effective and offers greater protection against heart attacks, strokes and other cardiovascular diseases. *[Chronobiology International, Oct. 2010]* This could well change the way blood pressure medication is given and have a significant impact on the type of treatment people with high blood pressure receive. The results were quite amazing:

- The group of patients who took at least one of their medications at night had a third of the number of cardiovascular disease episodes experienced by those taking all their blood pressure medications in the morning.
- Taking at least one blood pressure medication at bedtime was best way to achieve normal sleep-time blood pressure but also the best way to control day-time blood pressure.

Historically, medical professionals have worked on the assumption that sleep-time blood pressure levels will drop by 10-20% from daytime levels. However, for many patients this doesn't happen and sleep-time therefore becomes a high risk period. If you are taking blood pressure tablets, then do discuss this with your doctor before making any changes.

Diastolic blood pressure too low has risks in Type 2 diabetes
Treating blood pressure so the diastolic pressure is below 70mmHF in people with Type 2 diabetes can increase the risk of cardiovascular problems according to recent research. [Healthcare Republic 16.11.10] The researchers, who studied 1,791 people with Type 2 diabetes and high blood pressure, said that although evidence supports the recommendations for the upper levels of blood pressure, there is little evidence on how far blood pressure should be lowered.

This research supported blood pressure levels of about 140mmHg and a diastolic [the lower number] of below 80mmHg. However, it also found that people with a diastolic pressure of below 70mmHG were nearly twice as likely to have a cardiovascular event as those with higher diastolic blood pressure. This risk increased at even lower levels of diastolic pressure – those below 60mmHG were 28 times more ;likely to have a cardiovascular event. If this is something that concerns you, then you should discuss it with your doctor.

Cholesterol Levels – What Are Fibrates?

One thing that came from the discussions at IDDT's conference in October 2010 was that quite a number of people had adverse effects when using statins, particularly simvastatin. It was interesting to note that often people are given a high dose when a low dose would be enough and would not produce the same degree of side effects. Recent research [The Lancet. 10.11.10] looked at statin use [although people with diabetes were excluded] in two groups of equal numbers of people and there were only 2 cases of myopathy [muscle pain and weakness] in the group on low [20mg] dose of simvastin compared to 53 cases for high [80mg] dose of simvastatin and the high dose only lowered cholesterol levels by 6%

I think most of us know by now that statins are prescribed as a prevention for many people, especially those with diabetes and others at risk of heart attack and stroke. Statins lower cholesterol and triglyceride levels in the blood. At the conference, Dr Charles Fox said that it is definitely beneficial to take statins but if the side effects are such that you can't, then don't take them because there are other drugs which, although not as efficient as statins, do work.

These drugs are known as fibrates and they have been in use for many years. Their use lessened with the introduction of statins. They are not first line choice for the prevention of cardiovascular disease and current guidelines suggest they should only be used for this purpose when a statin is not tolerated or is contraindicated.

The favourable effects of fibrates are:

- Increased HDL [good] cholesterol by about 9%.
- Decreased LDL [bad cholesterol.
- Decreased total cholesterol by about 8%.
- Decreased triglyceride [lipids/fats in the blood]
- How do fibrates compare to statins?
- Fibrates produce significantly greater reduction in triglyceride levels and increase HDL [good] cholesterol levels.
- Fibrates produce less reductions in LDL [bad] cholesterol and total cholesterol levels than statins.

Bezafibrate, ciprofibrate, fenofibrate and gemfibrozil are licensed in Europe and the UK. NICE does not recommend any particular fibrate for use in CVD prevention in those intolerant of a statin. The European Medicines Agency has recently confirmed that the benefits of fibrates continue to outweigh their risks but doctors should not prescribe them to newly diagnosed patients as first line treatment except for patients with severely high triglyceride levels or patients who cannot take statins. The Agency also noted new information and recommended that fenofibrate can also be used together with a statin in some circumstances when a statin alone has not been enough to completely control blood lipid levels.

Warnings

Similar warnings to statins are issued:

- Serious muscular side effects are rare but you should seek medical advice and stop taking fibrates if you develop unexplained muscle problems such as pain, tenderness or weakness.
- Pregnant women should not taken statins or fibrates.

Blast From The Past – Adding Glucagon To In Insulin!

The Mixtard 30 discontinuation has brought memories of when Novo Nordisk, and the other insulin manufacturers, removed animal insulins from the market. It clearly did for many other people too - it was noticeable on the Drug and Therapeutics Bulletin petition that many people recounted the difficulties and adverse effects they had when being 'forced' to change from animal insulin to human insulin.

For those of you who are unaware of what happened in the 1980s after the introduction of so-called human insulin, it is a long story but not an unfamiliar one in today's transfer of patients to analogue insulins. To cut this long story short, human insulin was introduced in 1982 amidst a blaze of claims that it was better than animal insulin although there was no research to prove this, and still isn't. Many people had adverse reactions to the new human insulin but they were not believed and many were dismissed as being 'neurotic' and imagining these effects by doctors, health professionals and diabetes organisations.

The most immediate and disturbing adverse effect was a loss of hypo warnings, indeed the expression 'hypo unawareness' was not used before the introduction of human insulin.

Much later, there was some acknowledgement of this and when a question was raised in the Lancet about why there should be a loss of warnings with the human insulin. It was very simply answered – when insulin is extracted from the pancreas of animals, a tiny amount of glucagon is also extracted and of course, glucagon is a hormone that triggers the hypo warnings. Of course, human insulin is made in a lab and has no natural glucagon in it.

'Novel Use of Glucagon in a Closed-loop System for the Prevention of Hypoglycaemia in Type 1 Diabetes', *[Diabetes Care, Vol 33, No. 6, June 2010]*

This recent study involved automated high-gain glucagon delivery with insulin in a small number of people with Type 1. It showed there was a significant reduction in the frequency of hypoglycaemia. When low-gain glucagon was delivered it did not significantly reduce the number of hypos but it did reduce the frequency of people taking

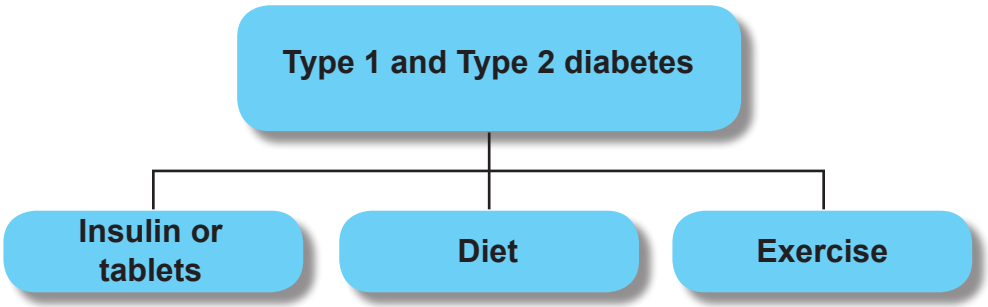
carbohydrate.

Forgive the cynicism and perhaps the anger
Forgive me, but some of us always did know that synthetic insulin caused a loss or a reduction of hypo warnings now suddenly a new piece of research has indirectly shown just that! If glucagon is added to insulin [as happens naturally with animal insulin] it reduces the frequency of hypos. The frustration comes because it wasn't just patients that knew this, there was research presented as early as 1980, before synthetic human insulins were licensed, showing that there was loss of hypo warnings with the new man-made human insulin.

Why angry? For a number of reasons – the knowledge and experiences of people with diabetes were ignored and there is a question that has to be asked. How many people around the world have suffered from more frequent hypos and unnecessary loss of warnings as a result of the use of synthetic human insulin?

Exercise Can Raise Blood Glucose Levels In Type 1 Diabetes

As the diagram below shows, exercise is part of the treatment fr people with Type 1 and even moderate exercise increases the risk of hypoglycaemia [low blood sugars] during and following the exercise.



In Type 1 diabetes, advice about how to look after blood glucose levels while taking exercise tends to focus on the prevention of hypos and this is understandable. However, the risk and fear of hypos may discourage some people with Type 1 diabetes from exercising. Apart from the obvious fears of having a severe hypo, there may be other less obvious fears.

- The embarrassment of temporary loss of co-ordination and performance that occurs during a hypo.
- In a team sport, letting the team down during a match.
- Some parents may discourage their children from taking part in physical activity or competitive sports because of their fears of a severe hypo. This is not good for the health of the child but it also denies them enjoyment with their friends.
- Fear about hypoglycaemia from exercise may be even greater if there is hypoglycaemia unawareness, which is an absence of the normal warning signs of impending low blood sugars.

Reducing the risk of hypoglycaemia when taking exercise
It is important to test the blood glucose levels before exercise or physical activity and if necessary, during it. Eating some fast-acting carbohydrate, such as sweets or a sugary drink, before starting to take moderate to strenuous exercise helps to prevent a hypo. It is also important to remember that strenuous exercise can cause a delayed hypo possibly during the night so regular testing afterwards can help to reduce the risk of this.

Surprisingly vigorous exercise can raise blood glucose levels
It is often not recognised that vigorous exercise can raise blood glucose levels and this effect has been shown in several studies. It appears that there is a level of vigorous activity which produces this response.

What type of exercise can raise blood glucose levels?
Here are some examples:

- Exercising at a constant speed for several minutes or longer eg swimming, running or cycling. A good way to judge is if the exercise is such that your breathing is deep and you cannot talk to

the person next to you.
- Playing a vigorous sport which includes short bursts of speed alternating with periods of moderate intensity eg football or tennis.

Why does vigorous activity raise blood glucose levels?
This level of exertion activates the sympathetic nervous system which in turn produces the 'fight or flight' response which helps the body meet emergency needs. Stress hormones adrenalin and others are released into the blood and they stimulate the liver to release glucose at a faster rate than normal. When this release is faster than the rate glucose is absorbed by the active muscle tissue, blood glucose levels rise. This process is similar to what can happen during a severe hypo – the body goes into a defense mechanism as a protection and the liver releases glucose to raise blood glucose levels.

With moderate intensity exercise, the stress hormones are not significantly produced and so blood glucose levels do not go up and will tend to drop, so a snack before the activity is advisable [or a lowering of the insulin dose].

Know how different types of exercise affect you
So the intensity of the activity or exercise strongly influences the blood glucose responses. Knowing how various types of exercise affect your blood glucose - is it likely to raise them or lower them - is important in trying to manage blood glucose levels. It also helps to avoid giving carbohydrate snacks when a particular type of exercise will raise glucose levels anyway and this could lead to hypoglycaemia.

The message here really is to know what happens to you and your blood glucose levels with different types of activity. Something as simple as light gardening or taking a walk can cause a hypo but a game of tennis may have just the opposite effect. This is what makes Type 1 diabetes such a difficult condition to manage!

Avandia Gone From The Market

The European Medicines Agency has recommended the suspension of the marketing authorisation for Avanda [rosiglitazone]and Avandamet – medicines used to treat Type 2 diabetes. This is as a result of accumulating evidence that Avandia increases the risk of heart disease and stroke to a point where its risks now outweigh its benefits.

These drugs were withdrawn from the market on October 21st 2010. The suspension will remain in place unless the marketing authorisation holder can provide convincing data to identify a group of patients in whom the benefits of the medicines outweigh their risks. The Committee's recommendation has now been forwarded to the European Commission for the adoption of a legally binding decision.

Restricted Access in America
The U.S. Food and Drug Administration [FDA] has not withdrawn Avandia from the market but will significantly restrict its use to patients with Type 2 diabetes who cannot control their diabetes on other medications.

The FDA will require that the manufacturers, GSK, to develop a restricted access program for Avandia under a risk evaluation and mitigation strategy. This will require Avandia to be available to new patients only if they are unable to achieve glucose control on other medications and are unable to take Actos (pioglitazone), the only other drug in this class. Current users of Avandia who are benefiting from the drug will be able to continue using the medication if they choose to do so.

Doctors will have to attest to and document their patients' eligibility; patients will have to review statements describing the cardiovascular safety concerns associated with this drug and acknowledge they understand the risks. The FDA anticipates that this strategy will significantly limit use of Avandia.

Listening to forums and blogs or just listening to patients
A new report suggests that internet forums and blogs could have effects on the reporting of drug adverse effects. May sound strange but forums and blogs were discussing the heart attack risks with Avandia as far back as 2003/4 but their concerns were ignored by doctors and the manufacturer, GSK. By 2005 there were more negative comments about Avandia risks but these were more about the frustration of weight gain and oedema. By 2006 the forum discussions involved other side effects with growing anger and frustration that doctors were 'disconnected' from their concerns and they had to discover potential problems on their own. In 2007 when the research came out that people on Avandia had more heart attacks, patients in forums and blogs expressed strong criticism of the drug, the manufacturers and doctors. In 2010, the FDA's decision not to stop the use of Avandia altogether has resulted in the anger now also being directed at the FDA.

The main message of the report is that forums and blogs are sources of patient experiences. They can now be monitored to pick up patients' reports of adverse effects with notice being taken of them, listening to patients instead of ignoring them with the consequent effects being that patients are angry and are very entrenched in their decisions and closed to any new arguments to sway them otherwise.

Now it's suspected problems with Actos!
Naturally people are expressing concerns if they are taking Actos [pioglitazone] which is from the same family of drugs as Avandia. This is a justified concern as all drugs in this family can cause fluid retention which in turn, may cause heart failure. Therefore along with other drugs in this family, Actos should not be given to people with a history of, or any stage of heart failure.

However, in addition to these basic facts, the US FDA, has notified health professionals and patients that it is carrying out an ongoing review of information about Actos [pioglitazone]. This is as a result of the findings of a 10 year study to investigate whether Actos is associated with an increased risk of bladder cancer.

Five years into the study there was no statistically significant association between Actos use and bladder cancer risk. However, further analyses were carried out and the results show an increased risk of bladder cancer among patients with the longest duration of use of Actos as well as those who had the highest total dose over the time. The FDA is advising people to talk to their doctors if they are worried and not to stop taking it unless told to do so by a health professional.

Being A Blood Donor With Diabetes

After many years of being a blood donor, on his last visit to donate one of our members was told he couldn't donate blood because he was using Victoza to treat his Type 2 diabetes and they didn't know if his blood would be acceptable. He went round in circles to try to establish whether or not he could give blood, including going to the manufacturers of Victoza, Novo Nordisk, who could not advise him.

We found this information and more on the UK Blood Transfusion and Tissue Services website and thought it may be useful for other readers who give blood or are considering becoming donors.

If you have Type 1 or Type 2 diabetes, you must not donate blood if:
1. You require insulin treatment.
2. Your diabetes medication has been altered in the last 4 weeks.
3. You are having problems feeling faint, fainting or giddiness.
4. You have or have had heart failure.
5. You have renal impairment requiring dialysis, the use of erythropoietin or similar drugs, or are either under active investigation or continuous follow up for renal impairment.
6. You have required surgery for a blocked or narrowed artery including any type of amputation.
7. You have or have hand gangrene, ulcers or wounds related to loss of sensation.

8. Have had a transplant of pancreatic tissue.

You can be accepted as a blood donor if:

1. If you have been diagnosed with pre-diabetes or gestational diabetes but don't require treatment.
2. If your diabetes is controlled by diet or oral medication or injectable medication other than insulin eg Exenatide [Byetta®] or Liraglutide [Victoza®], that has not been changed in the last 4 weeks. [Recently updated to include Byetta and Victoza]
3. If previous treatment with insulin [including bovine] was stopped more than 4 weeks ago.
4. If gangrene was not related to diabetes or peripheral vascular disease [e.g. it was due to hypothermia or meningococcal meningitis] and all wounds are fully healed even if amputation was required.

From Our Own Correspondents

Back to my old self!

Dear Jenny,

I have been using pork insulin since being almost killed, losing my hypo warnings and my character being altered by so-called human insulin. Following problems with night and early morning hypos I finally agreed to try keeping pork insulin as my pre-meal three-times-daily injections and a dose of the long-acting analogue, Levemir at night, which certainly eliminated the aforementioned hypos.

However, after 6 months both my wife and I were concerned that my character may have again been affected in the form of depression and sometimes feeling lethargic and lacking energy. My wife thought I may also have become more short-tempered, something that certainly happened with human insulin.
My doctor wanted to treat the depression, but I resisted to date as I am naturally resistant to unnecessary treatments. I did appreciate that I may have had depression or a combination of this and increasing age (I am 61 and normally very active and healthy). Or.....I wondered if it could be due to Levemir?

So about a month ago I decided to swap my night time Levemir back to pork Hypurin Isophane. Within 2 days I no longer suffered with depression or suicidal thoughts and very quickly I had regained my previous energy levels and my "old", happier personality, much to my family's relief. A tremendous transformation, and so fast!

Does this personality change happen with anyone put on Levemir or similar insulins for the first time or does it just occur to only some poor souls changed from animal insulins to analogues during the course of their treatment? Why are these problems kept "under wraps" by the medical profession?

I will now stick with Hypurin insulins, even though my HbA1c results are likely to rise a little compared with the post Levemir results.....a small price to pay for getting my life back. Thanks again for your help.

John Bruton
IDDT member

Here's just the reason we have developed the Hospital Passport!

Dear Jenny,

I was admitted to hospital with a number of fractures to my left ankle. In A & E a nice young doctor took my details and when I told him I had insulin dependent diabetes and he said "Type 2 then." Needless to say, he got a look from me and puffed himself up to his full height and said, "I did a 4 month course on diabetes" so I told him that I had had it 24/7 for 35 years! My partner was instructed to bring in all my medication and my repeat prescription card but during my 5 day stay, I was questioned about my medication on nine or ten occasions and once at 2.00 am! They went apoplectic when they saw that I take

animal insulin, saying how bad it was for me.

My medication was locked in a drawer and I had to ask permission for access. Dinner was at 18.00 and I rang my bell to get my insulin at 17.05, my meal was on time but my insulin arrived at 18.35. I was bed ridden for 5 days and during this time, I was overdosed by staff on two occasions and underdosed on two occasions. I had 5 visits from the Pharmacy about my insulin and they could not provide test strips for my meter, saying it was too new. By the third day [Sunday] before my breakfast I used my last test strip and was hypo at 2.8 so had two rolls and strawberry jam followed my meals during the day. On the Monday at 2.30 am a nurse woke me up to ask about the hypo I had had 17 hours earlier! There was little left for me to do except to ask him if he had kept the receipt for his diabetes training so he could get his money back.

The ignorance in this hospital was appalling and it is supposed to be one of the best in the country.

Mrs K.M.
Oxon

Holiday Insurance

Dear Jenny,

Look out and do some homework before you buy travel insurance - the differences between companies claiming to be the “best” is quite surprising. I needed to renew my annual world wide health insurance and looked up a few companies, one of which is linked to Diabetes UK and another I’ve used previously. The difference between the quotes (for exactly the same condition/cover/quotes) was over £150!

The insurance company I have used previously and bought this time is Insureandgo - I used this company for my gap year and they consistently come out as very competitive (and helpful). By the way, I don’t work or have any connections with either company, it’s just a bit of information that others might find useful.

By e-mail

Product News

Senso Card Plus Talking Meter

This is a blood glucose meter that speaks the readings for increased clarity and independence of people who are visually impaired. It has been available through BBI Healthcare but this company is no longer distributing it.

Both BBI and the RNIB are now supplying another talking meter, the Clever Chek. However BBI will continue to supply the strips for the Senso Card Plus meter.

The contact details for BBI Healthcare are: tel 01792 229 333 or fax 01792 897 311

Injection pens

- OPtiSet, Opticlik and OptiPen Pro 1 will be discontinued from December 31st 2011 from Sanofi-aventis for use with Lantus and Apidra and replaced with SoloSTAR and ClikSTAR pens.
- Lilly’s pre-filled pen used with Humulin and Humalog will be discontinued from March 31st 2011 and the KwikPen will be the pre-filled injection pen for use with Lilly insulins.

The warning on the packaging for testing plasma

In our July and October Newsletters we warned that Roche Accu-chek meters are now measuring plasma blood which results in readings that are about 11% higher than when measuring whole blood. In July we said that the new strips can be identified by a yellow circle with black lines through it. In October our members started reporting

that they were receiving packs with the yellow circle and packs with a green square with lines through it. Thanks to the vigilance of our members, it appears that both the yellow and the green symbols mean that the strips measure plasma blood. However, the strips with the green symbol mean that any interference from maltose has been eradicated and while we may not understand the science behind this, this makes the strips more accurate. It still seems amazing that such changes can come about without any noticeable warnings to patients who have to interpret these results several times a day and make insulin dose adjustments accordingly.

New natural sugar substitute

A new all natural sugar substitute containing no potentially harmful ingredients was launched in the UK and Ireland in September 2010. It contains no calories and is called Zsweet and is aimed at people with diabetes and people who are health conscious.

It does not contain saccharin, sucralose or aspartame about which there is considerable debate. Zsweet is a blend of erythritol and natural fruit extracts to improve the flavour. Erythritol is a naturally derived sugar substitute made from plant sugars that looks and tastes like sugar and is found in grapes, melons and pears.

It can be used for baking or sweetening of hot and cold drinks. It can be purchased on line at www.zsweet.eu or you can write to Zsweet Europe, 50a Leinster Road, Rathmines Dublin 6 IRELAND

US approves metformin/saxagliptin combination tablets for Type 2 diabetes

In the US the Food and Drug Administration [FDA] has approved a once-daily tablet that combines extended release metformin and saxagliptin in one tablet. In the UK both are available separately although saxagliptin is recommended only as a second line treatment and then only to be prescribed by a doctor experienced in the treatment of Type 2 diabetes, according to NICE.

The new combination tablet, called Kombiglyze XR, should not be used for people with Type 1 diabetes or diabetic ketoacidosis and has not been studied in combination with insulin. People with Type 2 diabetes are often taking several medicines, so this combination has the advantage of two their diabetes medicines being given in a once a day tablet.

IDDT News

Thank you from IDDT

The Trustees of IDDT would like to thank all our members for the help and support that has been given throughout 2010. Many thanks to all of you who ordered IDDT Christmas cards, we had an excellent response.

We do appreciate your donations, especially for your donations in this hard economic climate. However large or small all donations help IDDT to continue with its aims of helping people who live with diabetes, so we are very grateful.

As you know, IDDT has always relied on voluntary donations rather than a membership fee because we believe that everyone should be entitled to our information regardless of income and ability to pay. This policy is still one in which we strongly believe so membership of IDDT remains free but of course we do appreciate donations.

The old saying, look after the pennies and the pounds look after themselves certainly applies at the moment, so I would just add that if it is easier for you to make a small monthly donation, just a couple of pounds, then do get in touch and we can send you the forms for a standing order payment. Just contact IDDT on 01604 622837, e-mail enquiries@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS.

IDDT Conference 2010
IDDT's Conference in October 2010 was filmed and by the time you receive this Newsletter, the film should be on our website, so if you have internet access, take a look – see the discussions, the sessions with Dr Gary Adams and Dr Charles Fox.

Date for your diary – Conference 2011
Please make a note in your diary that IDDT's 2011 Conference will be on October 14th 2011, a weekend later than usual. We are also looking at holding somewhere it other than Birmingham, to give members living in different parts of the country the opportunity to join us. There will be more details later in the year, but in the meantime, put the date in your diary, Saturday, October 15th 2011.

Improving The Care Of Children And Young People With Diabetes

In answer to a Parliamentary Question, Health Minister, Paul Burstow, acknowledged that it is vital that children with diabetes receive good quality clinical care and that health and education services work in partnership to ensure that children can be supported while living full, active life. [19.10.10]

This is something that we all hope can be achieved and below is what the Minister said is happening – his words not ours:

- NHS Diabetes, described as the national service improvement team for diabetes, has developed a commissioning toolkit which will assist in the commissioning of local diabetes services for children and young people with diabetes. ['Toolkit' seems to be the buzz word in health, so our understanding is that it a list of things that will help local health services to know what they should provide and how to provide it.]
- NHS Diabetes is on the early stages of developing materials for children and young people to help educate them and their families about managing the condition as it progresses.
- The establishment of a Paediatric Diabetes Network in each Strategic Health Authority region to drive improvements in the services delivered to children and young people with diabetes. The aim is to define a clear philosophy of care which incorporates improving outcomes and quality of life for children and young people living with diabetes.
- The running of a task and finish group which is developing work on health care professional training and education and children and young people education. The health care professional work is with the royal colleges and others to influence standards and agree required competencies and new curriculums, which reflect good practice publishing a Commissioning Care Guide, this sets out the appropriate emotional and psychological care interventions for each facet of diabetes care. This is of particular relevance for children and young people to enable them tackle the challenges of their condition and care for themselves effectively from day to day.

I hope the parents of children and young people with diabetes find this encouraging but as a long-standing parent of 35 years, I am afraid I have to ask why these pretty basic issues are still being 'discussed' or 'planned' and why they are not already in place? Or are some of them actually in place but the wheel is being re-invented using modern jargon?

It is action that is needed and has been for many years. In all these discussions and plans let us hope it is remembered that one of the most valuable things is for paediatricians and paediatric diabetes nurses to spend time with children, young people and their families. Time spent means that the needs of individuals are recognised and understood so that the appropriate help and support can be given as and when it is necessary.

AND SCHOOLS……..
In answer to another Parliamentary Question about how many children with Type 1 diabetes have been denied an education in each year since 2000, Lord Hill of Oareford said that the department had

not commissioned any research on the subject but local authorities have a duty to provide education for all children. Here's the reference: *"The School Admissions Code enables admission authorities to give higher priority in their oversubscription criteria to children for medical reasons. However, they must not use this criterion to give a child a lower priority in obtaining a place at a school. The statutory guidance on exclusions also makes it clear that pupils may not be excluded from school on the grounds of their medical need."*

News From Europe

Looks like treatment for diabetic macular oedema may be granted

A drug called Lucentis [ranibizumab] has been approved for use in the treatment of diabetic macular oedema by the European Medicines Agency. Macular oedema is a swelling of the retina in the macula area due to the leaking of fluid from blood vessels. The macula is the central part of the retina which is mainly responsible for seeing colours and fine detailed, such as reading. As macular oedema develops, there is a blurring in the central vision area and focusing becomes difficult. It affects 28% of people who have had diabetes for at least 20 years and is hard to avoid even with the best possible treatment and control. Lucentis has been used for the treatment of age-related wet macular degeneration.

Novo Nordisk's new long-acting analogue not any better than Lantus

Degludec, Novo Nordisk's new long-acting analogue undergoing trials did not perform any better than Lantus [glargine] in people with Type 2 diabetes over a period of 6 months. The company hopes to market the new insulin in 2013.

New regulations on drug safety

The EU Parliament has voted in a new set of regulations on drug safety monitoring. There will be a single accessible database for collection of safety information, new patient information sheets with details of how to report adverse effects and clear labelling of drugs that are undergoing extra monitoring. This will come into effect in 2012. This follows criticism about data secrecy both for the licensing of new drugs and adverse reaction reports.

System to improve current movement of doctors in Europe

In a joint statement to the European Commission, 25 European regulators, including the UK General Medical Council [GMC] have outlined ways to improve the present system of the way doctors can work in European countries, in the interests of patient safety. It includes a call for the GMC to be allowed to test the language skills of European doctors wanting to work in the UK. Regulators are presently not allowed to do this under a 2005 EU Directive which allows free movement of doctors around Europe.

GPs Could Save Money On Prescribing Costs

NICE recommends that long-acting insulin analogues have a specific but limited place in therapy

In August 2010, a report produced by the National Prescribing Centre [NPC] said that GPs could help to save the £20 million required by the NHS when prescribing drugs for conditions such as heart disease and diabetes by following guidance from the National Institute for Health and Clinical Excellence [NICE].

The report sets out 15 areas where savings could be made, one of which is prescribing low-cost statins and importantly, it raises the issue of prescribing insulin analogues. The report advises that any decision to start a patient on an insulin analogue should be balanced carefully against the lack of long-term safety data and increased prescribing costs. A separate report from the NHS Information Centre shows that the net bill for diabetes drugs is up 42% in the past 5 years – mainly

due to expensive newer treatments such as insulin analogues.

So what does NICE say?

- NICE recommends that long-acting insulin analogues have a specific but limited place in therapy. They are substantially more expensive than conventional insulins, but their use has increased enormously over the past few years.
- People with glycaemic control problems should be properly assessed for underlying causes before these newer, more expensive insulins are considered. This includes education, and checking understanding around how to manage their disease and treatment.

Neil Maskrey, director of evidence-based therapeutics at the NPC, said *"Importantly, whilst the purpose of this piece of work was to identify topics that would increase the efficiency of primary care prescribing, the evidence base for all the topics identified has been carefully examined to ensure that safety and clinical effectiveness would be maintained, or in some cases even improved, if they were incorporated into prescribing practice with less variation than at present".*

IDDT readers have known for some years that evidence shows that insulin analogues are not better than the older insulins for the majority of people and their long-term safety has not been demonstrated. How long have we been saying the extra costs of analogues would be better spent on more diabetes specialist nurses, dietitians and education?

However, while this report advises GPs to look at their prescribing habits, many of us know that the type of insulin prescribed often takes place in hospital clinics and the GP just issues repeat prescriptions. Perhaps hospital clinics should read the report and look at the evidence, or lack of evidence for prescribing insulin analogues.

IDDT Hospital Passport, "the best idea yet!"

- **At any given time 14% of the adult population in England who are being treated in hospital have diabetes.**
- **In 2009, of those treated with insulin more than 33% had medication errors on their charts.**
- **More than 25% of all patients experienced a hypo while in hospital with one in 30 requiring rescue with intravenous glucose or glucagon.**
- **A third of people who inject insulin have an error on their medical chart.**

These are the figures for adults with diabetes - shocking statistics and they highlight the need for greater support for people when they are admitted to hospital. IDDT receives a considerable number of calls and letters from people who experience difficulties while in hospital. The reasons are numerous but often it can be the change in mealtimes, restricted access to their insulin and food, as well as the general stress of being unwell and away from family and friends.

It is not sufficient to just know what care you should expect when in hospital because that alone does not make it happen, so IDDT decided to provide practical help. In October 2010 IDDT launched its 'Hospital Passport' to help people when they are admitted to hospital by providing vital information about their diabetes and how they manage it. It also enables people to include information about all their medicines, their mealtimes, diet and any allergies.

The Hospital Passport is not just for people taking insulin, it is also for people with Type 2 diabetes treated with diet and tablets. It is just as important for people with Type 2 diabetes because so often they are taking a whole host of medications as well as their tablets for diabetes. The Passport provides an opportunity to clearly list all the medications and the timings.

IDDT felt that it was time to try to help and support both adults and children if they have to be admitted to hospital. The Passports are intended to be put with the notes and provide hospital staff with vital

information about the person's diabetes, how it is managed, their likes and dislikes or any allergies. All of this is essential information for hospital staff to help to treat the 'patient' immediately and effectively, minimising the risks of harm.

The response……..
The Hospital Passport has received widespread acclaim and gratitude from people with diabetes – hence the comment "The best idea yet!". But GPs, practice nurses and diabetes specialist nurses have also praised the idea and see it as very useful for their patients. One GP has ordered one for all his patients with diabetes and one hospital has ordered 1000 and intends ordering more so that every patient in 3 hospitals will eventually have a Hospital Passport. Many people have suggested other uses for the Passport, so we will be looking at these and hopefully putting some of them into practice, as ever to meet the needs of adults and children with diabetes.

The Passport is FREE and available to anyone with diabetes and to health professionals to provide to their patients. Copies are available from IDDT by contacting martin@iddtinternational.org phone 01604 622837 or write to IDDT, PO Box 294, Northampton NN1 4XS.

Byetta - Good News

The manufacturers of Byetta [exenatide] have released the results from a 4 year evaluation of nearly 375,000 people in the US with Type 2 diabetes. 22,000 of them were taking Byetta over 4 years. The findings show reduced incidence of cardiovascular disease and hospitalisation due to all causes with Byetta. The incidence of cardiovascular disease and all-cause hospital admissions was lower than with insulin, thiazolidinediones [eg Actos] and sulfonylureas and the same as for metformin and Januvia [sitagliptin].

Snippets

Guess who's advising the advising the government on public health?
We all have our thoughts on ways to deal with the increase in obesity and alcohol misuse, whether this is through pricing or tougher regulations about marketing. But never in a million years would most of us think of inviting representatives of McDonald's, PepsiCo and other large food and drinks manufacturers to submit their policy proposals on how to deal with these major public health issues. Well that's what Health Secretary, Andrew Lansley has done! These are the very companies that have profited out of the obesity and alcohol misuse epidemics and it is hard to see how big business is going to offer suggestions that cut their profits and adversely affect their shareholders. Like all big business, their shareholders interests will come first – perhaps they'll just give money for playing fields again to increase children's exercise after they have eaten their unhealthy foods!

Don't keep fit at work
It is well recognised that physical activity can stave off depression but a study in the British Journal of Psychiatry, suggests that this is the case only if it is fun and not done while at work. It suggests that those who exert themselves at work are no less likely to suffer depression than those in desk jobs.

Drug companies and gifts
The Association of British Pharmaceutical Industry has announced an amendment to its code of practice – from 2011 branded items to health professionals such as stationery containing advertising will no longer be allowed. "Inexpensive items" will be permitted as part of a formal patient support programme.

Standards for laparoscopic surgery
A UK national audit of theatre equipment in 474 hospitals found that only 11% of them had the highest standards of equipment considered necessary for safe laparoscopy surgery. 28% of hospitals were using obsolete and potentially unsafe equipment with 25% not having a maintenance contract to replace broken equipment.

Another use for insulin

Insulin is best known for treating diabetes and bringing down blood sugar levels. However, insulin injections are now being given to stop or reduce the formation of excessive scar tissue after surgery. Tests at the University of California showed that cuts treated with insulin healed faster – 4 days faster than wounds treated with saline solution. It is thought that insulin reduces the amount of fibroblasts, the scar-producing cells, that collect after a wound has healed.

Probiotic drinks – no proof of health claims

The European Food Safety Agency has ruled that more than 800 health claims made by the probiotics industry are unproven. The claims relating to the products' ability to improve digestion and immune system functioning were ruled to be either too general to be tested or unsupported by scientific evidence. Needless to say, the industry is appealing against the rulings.

Interestingly a Cochrane Review has shown that probiotics can improve the symptoms of diarrhoea and reduce the chances of repeat episodes. The usual standard treatment for diarrhoea is rehydration with fluids but this does not reduce the length of the illness. The Cochrane Review found that giving probiotics in addition to these fluids can cut down the duration of diarrhoea and reduce the likelihood of it lasting more than four days.

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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Name: ——————————————————————————

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——————————————————————————

Postcode: ——————————————————————————

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From Your Editor – Jenny Hirst

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