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Insulin Dependent Diabetes Trust

March 2012 Newsletter

Ninety Years Since The First Injection Of Insulin

2012 is the 90th anniversary of the first injection of insulin into a young man and what followed made the difference between diabetes being a death sentence and the life people with diabetes have today. Initially there was only 'insulin' and it wasn't until the 1940s that long-acting insulin was developed. Highly purified insulin was not available until the 1970s.

For younger people reading this, 1922 may sound a long time ago, but when my daughter was diagnosed in 1975, it was only just over 40 years earlier that insulin was discovered and lives were saved. I remember feeling a certain amount of shock that if she had been part of her grandparents generation, she probably would not have survived.

During this time, I met people who had been diagnosed just before the discovery of insulin and who had been hanging on by using a horrendous diet to just stay alive. Later, I met someone who as diagnosed at the age of 11, just after World War II, and I found his story unbelievable by today's standards. He knew he had an illness but was not told what it was for several years. He just used to go to the hospital in the mornings on his way to school, have an injection and then go on off to school. The last time I saw him he was a healthy 50 plus year old, so it worked for him!

What about the injections?

They were done with a large glass syringe and a needle that was thick and huge by comparison with today's needles. This whole syringe and needle was stored between injections in industrial spirit

in a plastic tubular container. In our house, Friday night was 'boil-up night' - the syringe and needles were boiled in a pan to keep them sterile! It was a few years before plastic disposable syringes became available but we had to buy them as they were not available on the NHS! Of course, with the introduction of pen injection devices much later, syringes are now classed as 'old fashioned'. Having said this, some people still prefer them – they have greater confidence that the insulin has actually gone in because they can see the syringe is empty and they are smaller than pens. It's all about personal choice...

How did we measure what was going on with glucose levels?
Inaccurate though it was, the only way was by testing urine until the late 1960s when Dextrostix® strips were developed. These were paper strips on to which a drop of blood was placed and timed for 1 minute. The strips changed to a blue colour which was then measured against a colour chart to give an approximate blood glucose level. Although this was much better than urine tests, for most people you generally only knew if you were very high or very low! Again these strips had to be paid for.

Then in 1970, a scientist developed the first meter – a reflectance meter which read the reflected light from the blue colour of the Dextrostix. The darker the blue, the less light would be reflected. The reflected light was sent to a photoelectric cell which gave you a read out, from a swinging needle! The real drawback was not just the cost, about £300 which was a lot of money in the 70s, but it was huge and certainly not something that could be used at home. This was fairly soon followed by small glucose monitors but these were not used at home until the medical profession could be convinced that patients were actually capable of using them without medical supervision. Things have moved a long way since 1922!

Pharmaceutical News

Final Verdict on Actos [pioglitazone]

In January 2012, the EU Commission adopted a positive opinion about the use of Actos [pioglitazone] - containing medicines. After a review, it has been decided that while a small risk of bladder cancer has been associated with taking these medicines, the Committee decided that this risk could be reduced by appropriate patient selection and exclusion, updated contraindications, warnings in the product labels and periodic review of the efficacy and safety of the patient's treatment. It is suitable as a second or third line treatment and the Committee provided clarification for doctors that Actos remains a valid treatment option for Type 2 diabetes, specifically when metformin has not been suitable or worked properly.

So Actos will continue to be manufactured.
Note: On December 22nd a class action lawsuit was filed in an Ontario Supreme Court alleging that the manufacturers knew Actos could cause bladder cancer. The family of a woman who died as a result of bladder cancer are claiming that had she known the risks, she would never have taken the drug.

Still doubts about Tamiflu – Cochrane Review

Tamiflu, manufactured by Roche, is the flu jab that has been the mainstay of dealing with flu in the UK and it is on World Health Organisation's list of Essential Medicines. Millions have been spent on stockpiling it in case of a pandemic but there have been concerns about its safety and how well it works. Its ability to prevent the spread of flu has not been demonstrated in trials and yet Roche has been unwilling to provide information from trials.

Two years ago Roche promised the British Medical Journal [BMJ] full trial reports for independent scrutiny but this has not happened. In a recently published report researchers from the Cochrane Collaboration aimed to find out if Tamiflu prevented complications and reduced the number of people requiring hospital treatment. However, they say that Roche's refusal to provide full access to information and explanations

of how the drug works, leaves critical questions unanswered.

The researchers say that "until more is known about the mode of action of neuraminidase inhibitors, health professionals, patients and other decision makers need to reflect on the findings of this review before making any decision about the use of the drug."

The BMJ can investigation can be found at www.bmj.com/cgi/doi/10.1136/bmj.e458

Levemir [Insulin detemir] added to Victoza for Type 2 diabetes

In September 2011, the European Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion on the use of Novo Nordisk's basal insulin analogue, Levemir®, as add-on treatment to their injectable treatment for Type 2 diabetes, Victoza, in combination with metformin.

The most common adverse effects in trials were common infections and nausea. Novo Nordisk expects approval for this use of Levemir within the coming months.

Is a regime like this too complicated for people who are probably already taking other medications such as statins and blood pressure pills?

Artificial pancreas may be delayed by regulations in the US

As we have written many times before, the artificial pancreas is a complex device that is meant to mimic the function of a real pancreas. It combines a pager-sized continuous glucose monitor and sensor that tracks blood sugar with a pump that automatically delivers the correct dose of insulin at just the right time.

Medical device company, Medtronic, has a very early version of an artificial pancreas on the market called the Paradigm Veo insulin pump. It is sold in 50 countries but not in the United States. The pump has an automated safety feature, called low glucose suspend, which shuts off the insulin flow when glucose falls dangerously low.

The Veo, and the newer devices being developed, are meant to be worn outside the body, but are connected to patients through a tiny catheter placed just under the skin. In the US there are fears that cumbersome FDA regulations requiring proof of safety and effectiveness for low glucose suspend, already widely used elsewhere, will delay it reaching the market, perhaps for years.

Those in favour of the artificial pancreas fear the standards will be set too high in terms of how the devices can be tested in patients, to what lengths companies will need to go to prove they are safe and whether a change in even one of its components will require a whole new round of testing. However, other people are calling for better safety for the new devices.

The artificial pancreas is the dream of everyone with Type 1 diabetes, but the debate is understandable – rapid approval so it can be used now or being as sure as possible about the safety of the device. Without coming down on any side of the debate, recent years have shown the harm caused by fast approval of some drugs, so can the same risks be taken with the artificial pancreas?

On the way - new meter to help with night hypos for pump users...

In January Medtronic received approval in the US for the first remote glucose meter to work with Medtronic's MiniMed Paradigm Real-Time Revel System, an insulin pump with built-in continuous glucose monitoring. It displays blood sugar readings, information on the insulin pump battery life and amount of insulin remaining.

This will enable parents to check blood glucose levels from another room while their child is sleeping.

It is estimated that three out of four hypos occur overnight and some parents get up several times a night to check their child's blood glucose levels. The bedside monitor has an alarm that alerts the parent or carer to changes in blood sugars so that they can take action or go back to sleep if everything is OK. It could easily be used for adults with Type 1 diabetes as they could leave the alarm by their bed so

that it wakes them if the blood sugar levels are dropping. The meter is called the 'mySentry' and it costs about US$3000.

Testing without finger pricks, in the pipeline...

In October 2011 Echo Therapeutics, Inc. announced positive results from its clinical study of its Symphony tCGM System. This is a non-invasive, wireless, transdermal continuous glucose monitoring (tCGM) system. Echo now plans to study this device in people with diabetes followed by a study in critical care patients.

The Symphony tCGM System monitors by biosensor which means without pricking the skin. It is continuous, giving readings 24/7, not just when the skin is pricked like other continuous monitors and it reduces the risk of infection, particularly in hospitals where there is a greater risk. It is expected to receive approval for use in the US in 2013.

Research News

Scientists say they have found a new treatment for Type 1 diabetes

Researchers at John Curtin School of Medical Research in Canberra say they have identified a process that causes the destruction of the beta cells – the cells in the pancreas that produce insulin.

They found that insulin-producing cells need heparin sulphate to survive. Heparan sulphate is a complex sugar. The study identified lack of this substance is a major cause of the death of the beta cells. The autoimmune cells damage the beta cells by producing heparanase, an enzyme that degrades the heparin sulphate in the beta cells.

The scientists plan to use their findings to develop new drugs to prevent the progression of autoimmune disease and the complications that occur and they have already set up a biotechnology company to do so. [Journal of Clinical Investigation, Dec 2011]

Yet another drug to try to prevent the development of Type 1 diabetes

A compound, once rejected by the giant pharmaceutical company Sanofi, is being transformed into a treatment for Type 1 diabetes. The treatment, DiaPep277 is made from human protein and prevents the immune system from destroying the beta cells that produce insulin. By the time most patients are diagnosed with Type 1, 80% of their beta cells have been destroyed, so the trial included 457 newly diagnosed people with Type 1 diabetes between the ages of 16 and 45 in Europe, Israel and South Africa. They received one subcutaneous injection every three months, on top of their regular insulin injections.

The drug met both the main and secondary goals of a study in the last of three stages of human testing. The people taking the drug had stable C-peptide levels, which meant pancreatic cells secreted insulin on their own, while there was a decline in C-peptide levels among patients taking the placebo.

They also maintained "good diabetic control" compared with those taking the placebo. That means patients need fewer daily insulin doses, delaying or reducing complications from diabetes.

No evidence that intensive diabetes control benefits cognitive function

The first randomised controlled trial has taken place to find out if intensive glycaemic control benefits cognitive function in people with Type 1 diabetes. The results showed no evidence to suggest that intensive control benefits cognitive function. They did find significant improvements in measures of brain atrophy with intensive glycaemic control but these were outweighed by the limitations and harmful side effects of this level of control.

As a result the researchers do not recommend intensive treatment in Type 1 as a way of reducing the effects of Type 1 diabetes on the brain but suggest that further research should be carried out to find out whether different treatment regimes result in different rates of cognitive change.

People over 70 years old with Type 2 diabetes are twice as likely to develop cognitive impairment or dementia as those without Type 2 diabetes of the same age. Until recently no one has investigated whether early treatment can prevent these adverse effects on the brain. Research was also carried out to find out if intensive treatment of Type 2 diabetes [HbA1c of less than 6% or 42mmol/mol] with different drugs reduced the risk of impaired cognitive function. However, intensive treatment was associated with increases in mortality, weight gain, hypoglycaemia and no improvements in heart disease. [The Lancet Oncology, November 2011]

Researchers discover 'normal' function of vitamin E

A team of researchers at Georgia Health Sciences University, USA have found that Vitamin E, a powerful antioxidant found in most foods, helps to repair tears in the membranes that protect cells and also screens what enters and exits the cells.

Lead researcher Dr. Paul McNeil said that whilst we consume enough vitamin E "without any special effort," until now researchers had no idea what its primary function in the human body was but now at least one of its functions is known.

The study showed that vitamin E treatment in an animal model of diabetes restored some membrane repair ability. Also, an analogue of the most biologically active form of vitamin E significantly reversed membrane repair deficits caused by high glucose and increased cell survival after tearing. [Nature Communications, Dec 2011]

A possible new treatment for diabetic retinopathy

Diabetic retinopathy is caused by damage to the blood vessels of the retina and almost everyone who has had diabetes for 30 years or more has some signs of retinopathy. It is generally treated with laser to seal the leaking blood vessels and to try to stop the condition getting worse. The problem with laser treatment is that the tiny burns on the retina leave blind areas on the retina and these may affect the field of vision. This is why people with diabetes who have ever had laser treatment have to have field of vision checks for driving.

Another drug treatment is an anti-cancer drug but the high doses required can damage and harm other tissues. A team of researchers at British Columbia University have come up with a device that can be implanted into the eye so that the drug, docetaxel, can be released slowly and on demand.

The researchers incorporated the ability to trigger the drug delivery system, which is no larger than a pinhead, through an external magnetic field and they sealed the drug reservoir of the device with an elastic magnetic silicone membrane. The magnetic field causes the membrane to change shape to release a specific amount of the drug, like squeezing water out of a flexible bottle. The device worked as it should with minimal leakage over 35 days. [Science Daily, 26.12.11]

IDDT Supported Research Looking At The Actions Of Analogues

IDDT has been supporting research at Tel Aviv University into insulin

analogues and their effects and we have received a message to IDDT from Professor Haim Werner who has led the various studies. He writes:

On the eve of the New Year we would like to extend our very best wishes to the wonderful people of IDDT and to thank you once again for your continued support. We would like to take this opportunity to give you a brief summary of our progress and to update you on our ongoing work and future plans.

The biological role and the mechanisms of action of insulin analogues have been the main theme of our research. In already finished work we have shown that:

1. Long-acting analogues glargine and detemir, and short-acting analogue lispro exhibit an IGF-I-like proliferative activity in colon, breast, and prostate cancer cell lines. Native insulin, on the other hand, was devoid of mitogenic activity. [Cell multiplication]

2. Glargine and detemir, but not regular insulin, display an IGF-I-like antiapoptotic activity. These results are consistent with the concept that insulin analogues may provide upon cells an enhanced survival capacity (i.e., a typical feature of tumor cells).

3. Insulin analogues exhibit atypical signaling capabilities, including the ability to phosphorylate and activate the IGF-IR in a very potent fashion. The clinical impact of these differential signalling abilities is still unknown.

4. Glargine, but not native insulin, induce internalization of the IGF-IR, as revealed by confocal microscopy analysis.

5. In most of the actions, glargine is more potent than detemir.

When combined, our studies are consistent with epidemiological data showing that certain insulin analogues might confer upon diabetes patients an enhanced cancer risk. Our results were published in:

- Weinstein, D., Simon, M., Yehezkel, E., Laron, Z. and Werner, H. (2009) Insulin analogues display IGF-I-like mitogenic and antiapoptotic activities in cultured cancer cells. Diabetes Metab. Res. Rev. 25:41-49.
- Yehezkel, E., Weinstein, D., Simon, M., Sarfstein, R., Laron, Z. and Werner, H. (2010) Long-acting insulin analogues elicit atypical signalling events mediated by the insulin receptor and insulin-like growth factor-I receptor. Diabetologia 53:2667-2675.
- Laron, Z. and Werner, H. (2010) Est-ce-que les nouveaux analogues d'insuline a actionlongue ont une action mitogenique? Journal d'Endocrinologie Pediatrique (Paris) http://www.sfedp.org/jep/2010/02/26.
- Werner, H., Weinstein, D., Yehezkel, E. and Laron, Z. (2011) Controversies in the use of insulin analogues. Expert Opinion Biol. Ther. 11:199-209.

Our work was extensively cited in the scientific literature and we truly feel that our efforts had a significant impact in the field. We are currently working on two main projects:
(1) the role of long-acting analogues on endometrial cancer cells, and
(2) the involvement of short and long-acting analogues in the skin.
We believe that these studies will further substantiate the universal nature of the atypical biological events elicited by insulin analogues. Two new manuscripts are in preparation. In addition, we are planning to present our results at the next meetings of the European Endocrine Society (May 2012, Florence, Italy) and USA Endocrine Society (June 2012, Houston, Texas).

Two graduate students at the Sackler School of Medicine (Mr. Daniel Balas-Aizen and Mrs. Ravid Solomon) are fully involved in these projects. On their behalf, we would like to thank IDDT for the generous support.

Again, thank you very much from all of us. We look forward for a fruitful continuing collaboration.
Haim Werner, Efrat Wertheimer and Zvi Laron

Note: An analysis of research in 2009 suggested Lantus might

pose an increased risk of cancer but two other studies found no links between the long-acting insulin and cancer risk. The US and European regulators reviewed the findings and decided that they could not confirm on deny the cancer risk. Sanofi then announced it would conduct its own study into the risks, although independent research would have been preferable.

Recently Sanofi announced the results of its own meta-analysis covering 80,000 patients using Lantus and which assessed the cancer risk using different insulins. The lead researcher said, “In the context of all available information, the current evidence supports that insulin glargine is associated with no increased risk of cancer as compared to other insulin therapies. These findings are reassuring for patients and their physicians.”

A recent study by Swedish researchers looked at medical records of 23,000 patients, including 2,724 women who developed cancer and 20,542 who did not. The analysis showed that having diabetes and being overweight increased cancer risk but it also found that patients taking Lantus had twice as many cancers as those using the diabetes drug metformin. Needless to say Lantus manufacturer, Sanofi, have questioned various aspects of the quality of the study.

These uncertainties are the reason IDDT has supported the Tel Aviv research.

Calling All Smokers!

Did you know that smoking can raise HbA1cs by 34%? Recently scientists have reported the first strong evidence which shows a strong link between nicotine and the development of the complications of diabetes. This is as a result of persistently raised blood glucose levels in people with diabetes who smoke. The researchers also point out that this could have implications for people with diabetes using nicotine replacement therapy for long periods of time – they are intended only to be used for short-term health.

Apparently, it has been known for a long time that people with diabetes who smoke have higher blood sugars than non-smokers with diabetes but nobody knew the exact substance that caused this. [Presented at the 241st National Meeting of the American Chemical Society]

IDDT News

Don’t forget!

IDDT has a CONFIDENTIAL Helpline to offer support to anyone affected by diabetes. This includes people with diabetes and their families, health professionals, teachers, employers and others.

Our aims are to offer understanding and empathy in a non-judgemental way to support people in making the decisions that are right for them.

The IDDT helpline offers callers:
A respectful listening service.
Information.
Emotional support.
Written information, as appropriate.

What the IDDT helpline does not offer to callers:
It does not offer medical advice.
It does not offer the opportunity to speak to medically trained staff.
It does not offer professional counselling.
We are here to help where we can!

A Date for Your Diary

It may seem like a long way off but we thought we would take this opportunity to let you know about IDDT’s 2012 Annual Conference. Once again we will be holding the Conference at the Kettering Park

Hotel and the venue has been booked for Saturday 13th October.

As usual there will be talks from a range of speakers on a variety of subjects that will be of interest to people living with diabetes, as well as both formal and informal opportunities to meet other people who live with the condition and to share knowledge and experiences.

We had some really positive feedback after last years' event, so we hope that you will be able to come along and make this years' event even more of a success.

Leaving a Legacy

Although it is a very sensitive subject, leaving a gift to IDDT in your Will is one way to make a real difference to the lives of people living with diabetes. We are very grateful to all the people who have left legacies to IDDT and enabled us to continue with our work.

We have a leaflet "Your Reasons for Making a Will" which explains about the various ways you can leave a gift to IDDT and how vital this type of legacy giving is to ensuring that we can go on helping and supporting thousands of people who live with diabetes. So, if you are thinking about making or updating your Will we hope you will consider leaving a gift to IDDT.

If you would like a copy of the leaflet, just contact IDDT on Tel: 01604 622837, email martin@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS.

IDDT helps developing countries

As the UK arm of '*Insulin for Life*', last year IDDT continued to collect unwanted, unopened and in-date insulin and diabetes supplies and to distribute these to clinics in developing countries where adults and children die for lack of affordable insulin. Thanks to you, in 2011 we managed to collect and distribute over 8,000 pens, cartridges and vials of insulin all of which came to a value of over £25,000. Without your help, it would simply have gone to waste.

We also continued to co-ordinate our Sponsor a Child Scheme. This scheme allows people to sponsor a child that is cared for by the Dream Trust Hospital in India. By making regular monthly donations, sponsors can support the hospital to purchase the insulin and diabetes supplies that are so desperately needed for children with Type 1 diabetes to just stay alive.

Similarly the support for the Dream Trust has gone from strength to strength with over 75 sponsors supporting 28 children to provide the £17 a month needed by each child to buy life-saving insulin. For more information about how we help developing countries visit: http://www.iddt.org/here-to-help/helping-developing-countries/ or contact IDDT on Tel: 01604 622837, email martin@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS.

Children from the Dream Trust celebrating World Diabetes Day 2011.

How YOU can help:

There are three ways in which you can help.

- Perhaps you have recently changed your insulin or equipment and now have supplies that you no longer need – then send them direct to us and we will ensure that they are sent to those that need them.

- Ask for one of our “Look in Your Fridge” posters to give to your doctor and/or nurse and ask them to send us any unwanted insulin that they have.
- Consider sponsoring one of the many children whose diabetes is cared for by the Dream Trust in India. It costs as little as £2 a month to sponsor a child.

For more information on the Dream Trust visit www.dreamtrust.org or contact IDDT.

The Latest On The Health And Social Care Bill

It is almost impossible to keep you up-to-date on what is happening with the Health Bill in Newsletters because by the time we go to print things can have changed yet again! It is complicated and certainly makes us, the taxpayers, feel somewhat impotent in the whole decision making process about our healthcare. Maybe it even seems boring, nevertheless, we are an organisation for people with long-term conditions, arguably the group of people who will be most affected by the changes. So it is important that we are all aware of how the changes will affect us.

Calls for the Health Bill to be withdrawn

- The Royal College of Nursing [RCN] has called for its withdrawal, claiming that the government has largely ignored its concerns expressed during the consultation. The RCN is on record as saying that withdrawing the Bill would create confusion and it believes that the turmoil of proceeding with these reforms is now greater than the turmoil of stopping them.
- The Royal College of Midwives has also called for the Health Bill to be scrapped. They say that they support many aspects of the Bill but believe that these can be achieved “without the need for this divisive and costly Bill”. The main thrust of their argument is government failure to produce evidence that the upheaval will benefit patients.
- The British Medical Association has also called for the Bill to be ditched.

There is a view that ditching the Bill at this late stage would cause even more chaos than if it goes through. The cynics amongst us would say that this is exactly what the Government intended when they encouraged the changes in the NHS such as the formation of Clinical Commissioning Groups and dismantling of PCTS, to start long before the Bill was approved and even before it went out to what appears to be the cosmetic consultation! Does the future of the NHS depend on which option is going to cause the least amount of chaos – keeping it or ditching it?

The amendments

On February 8th the Bill started its way through the House of Lords by which time the government had. made 136 amendments which Mr Lansley says will strengthen the future of the NHS and maintain the modernisation plans of ‘No decision about me, without me’. The key amendments include:

- **Secretary of State accountability**: putting beyond doubt the Secretary of State’s responsibility and accountability with respect to a comprehensive health service.
- **Greater patient involvement**: patients will have a greater say in their health, with the NHS Commissioning Board and Clinical Commissioning Groups having stronger duties to promote patient involvement in their own care.
- **Education and training**: the NHS Commissioning Board and Clinical Commissioning Groups will have new responsibilities to support education and training, strengthening the links between workforce planning and education and training.
- **Health inequalities**: a new duty on the Secretary of State, NHS Commissioning Board and Clinical Commissioning Groups to report annually on their progress in tackling health inequalities.
- **Strengthening integration**: Making clear that the health regulator Monitor will have the power to require healthcare providers to

promote integration of NHS services.

There is little doubt that if the Government Whips do their job and MPs vote along Party lines, the Bill will go through, although there are coalition MPs and if the papers are to be believed, even Cabinet Ministers, who have grave concerns about the future of our NHS.

And the costs?

It is estimated that Clinical Commissioning Groups [CCGs] made up of local doctors, nurses and other health professionals could control £65 billion of NHS funding on commissioning services [from any willing provider]. The NHS Commissioning Board will be responsible for £21 billion.

Details of CCG and local authority spend estimates for 2012-13 can be found at:
http://www.dh.gov.uk/health/2012/02/baseline-allocations/

What will happen to diabetes in the NHS changes?

On January 25th 2012, Health Minister, Paul Burstow gave the following answer to a Parliamentary Question along these lines. Here is what he said:

"The National Audit Office is due to publish its report on "The management of adult diabetes services in the NHS" this summer. Dr Rowan Hillson, the national clinical director (NCD) for diabetes, will consider the report before making recommendations to Ministers on the next steps in providing consistent, quality healthcare for people with diabetes.

In the meantime, the Department continues to encourage current commissioners to use the national diabetes information service tools to ensure that all their patients are receiving the care processes and outcomes required by the National Institute for Health and Clinical Excellence Quality Standard for diabetes, and to take action if this is not so."

MHRA Issue Statement About Statins

In 2010, a clinical trial meta-analysis reported that statin therapy overall was associated with a slightly increased risk of new onset diabetes. Although a small risk, given the extent of prescribing even a relatively small increase in the risk of new onset Type 2 diabetes could potentially result in a significant number of additional cases of diabetes per year. Treatment of 255 people with statins for 4 years resulted in one extra case of diabetes and while this may not sound very much, between 2002 and 2008, statin use doubled for people over 40 and quadrupled for those older than 80.

The risk appears to depend on individual risk factors and is greater in people already at risk of developing diabetes, those with high blood pressure, raised triglycerides and raised body mass index.

While the evidence from studies is variable due to the differences in the studies themselves, none of the statins can be excluded as a cause of newly diagnosed Type 2 diabetes. However, the MHRA state that the overall benefits of statins strongly outweigh any risks, including those at risk of diabetes and those with diabetes when they start statin treatment. The MHRA go on to recommend that health professionals monitor at risk patients both clinically and biochemically. [January 2012]

Driving And The DVLA Regulations

Update January 2012

Driving licence application forms for people with diabetes are to be rewritten after complaints that the EU rules on the fitness to drive are both confusing and being interpreted too harshly by the DVLA.

As we have previously reported, one of the difficulties under the new regulations is that people treated with insulin are to be barred from

driving if they have two severe hypoglycaemia attacks within a period of a year. At the moment, the definition of a severe attack is 'one which requires the assistance of another' but this does need clarification.

It is also not clear why nocturnal hypoglycaemia is included in the two severe hypos, especially as the Minister of Transport admitted in a letter to IDDT, that there is no evidence that night hypos affect the ability to drive during the day. News reports suggest that the EU Commission has already told MEPs that its experts are looking further at the issue of "waking" and "nocturnal" severe hypos.

The DVLA has agreed to rewrite the forms to clarify how severe a hypo has to be before it needs to be declared, and set out a timetable for redrafting the guidance by the end of January.

The DVLA has also stated:

- ***"We are awaiting clarification from the European commission to confirm our understanding of the interpretation of the minimum standards required by the directive."***
- ***"We must apply European medical standards but we consider every case individually and only refuse licences where absolutely necessary."***

The DVLA does not yet know how many people have been affected by the changes. It hopes to have figures in the 'new year' and has agreed to issue monthly reports about how many people with diabetes have been prevented from driving.

IDDT comments...

We have had only a very few calls where people have had their licence withdrawn as a result of 'two episodes of severe hypoglycaemia'. Each person has received no warning from either their doctor or the DVLA, just a letter in the post telling them to stop driving immediately. On each of the occasions the severe hypos were at night time and would not interfere with driving the next day.

Our fears are that the result of this legislation is that people are simply not going to discuss their hypos with their health team for fear of being reported to the DVLA, yet these are the very people who can help them with regime change in order to minimise the risks. So the problems with hypos will not be resolved! As you will see below, the American Diabetes Association does not recommend mandatory reporting by doctors for this very reason – that it may keep people from discussing these issues with their doctor.

How do they do it in the US?

- The American Diabetes Association [ADA] is against blanket bans or restrictions. It recommends that patients who have issues that might pose a driving risk be assessed by a physician who normally cares for people with diabetes [and therefore understands the condition].
- The ADA doesn't recommend mandatory physician reporting, because it may keep people with diabetes from discussing these issues with their doctor.
- It also recommends that people who take insulin test their blood sugar before driving and retest at regular intervals if they're driving for longer than one hour.
- For those at risk of serious hypoglycaemia, the ADA recommends not starting an extended drive with low normal blood sugar levels [between 3.9 and 5.0 mmols/l] without consuming some carbohydrates to prevent against a drop in blood sugar while driving. Naturally the ADA also advise having fast-acting carbohydrate (fruit juice, hard candy or dextrose tablets) available in the car and keeping an extra snack, such as cheese crackers, handy, too.

The evidence the ADA cite from the analysis of 15 previous studies on people with diabetes and driving, found that overall people with diabetes have between a 12% and 19% increased risk of a motor vehicle accident compared to the general driving population. However, they do adopt a different approach from the DVLA in terms of risk, pointing out that society tolerates riskier driving situations all the time such as:

- People with attention-deficit hyperactivity disorder (ADHD) have about 4 times the car accident risk of the general public.

- Those with sleep apnoea are about 2.4 times more likely to crash.

Perhaps this is one occasion when the EU and the DVLA should take a look at the US approach! [Published Diabetes Care, January 2012]

NICE News

Lucentis not recommended for the treatment of diabetic macular oedema

Despite appeals from charities and the Royal College of Ophthalmologists against the National Institute for Health and Clinical Excellence [NICE] recommendations that Lucentis [Ranibizumab] should not be used for the treatment of diabetic macular oedema, NICE issued its final guidance on November 30th 2011 confirming this decision. However, NICE has also made clear that people who are already receiving treatment on the NHS with Lucentis should have the option to continue treatment until they and their clinician consider it appropriate to stop.

The Royal College of Ophthalmologists expressed their regrets at this decision saying that laser treatment does not help all patients and works less well in people with more severe macular oedema. They feel that this group of people ought to be offered treatment with Lucentis. The hope is that there will be further discussions between the manufacturers of Lucentis, Novartis, and NICE about lowering the cost to a level that the NHS can afford so that a patient access programme can be set up to avoid unnecessary loss of sight. We will keep you posted...

The final guidance is available at: http://guidance.nice.org.uk/TA237

Bydureon - weekly injections for people with Type 2 diabetes

Byetta [exenatide] has been available for some time as a treatment for type 2 diabetes instead of going on to insulin. As well as offering blood glucose control, it has the advantage of weight loss in many people. Now a version is available that is a once a week injection and it is called Bydureon. It has the potential to significantly improve quality of life.

NICE has recommended Bydureon for use in the NHS in people with Type 2 diabetes when it cannot be controlled with tablets alone.

Injection Techniques

As it is the 90th anniversary since the first injection of insulin, we thought we should take a more in depth look at injection techniques as they are important to help to give the best possible control of blood glucose levels. As many as 800,000 people are injecting either insulin or the new injectable drugs for Type 2 diabetes, incretin mimetics - Byetta [Exenatide] or Victoza [Liraglutide]. For insulin and injectable Type 2 drugs to work, correct injection technique is essential.

We don't yet know the long term effects of injecting Byetta or Victoza but we do know that incorrect injection technique using insulin, including incorrect needle length, can lead to the poor absorption of the insulin. This can lead to:

- Low blood sugars [hypoglycaemia] because of a sudden rush of insulin.
- High blood sugars [hyperglycaemia] because of slow or delayed absorption,
- Lipohypertrophy, an accumulation of fat under the skin caused by injecting too often in the same area. The advances in injection devices, injection pens and thinner needles of varying lengths, have helped people to reduce this and improve blood sugars but they have all been associated with lipohypertrophy. The same applies to insulin pump cannulae if they are repeatedly inserted into the same place.
- Lipoatrophy, dips in the injection area also caused by injecting too

often in the same area but this is less common as all insulins are now highly purified.
- Bruising or bleeding at the injection site.

Rotating injection sites

Simply changing the injection site for every injection is not sufficient as this can often lead to a small area within specific sites being repeatedly used so it is better to use a rotation scheme. The following one has proved to be effective.

- Divide the injection areas into quarters [say for stomach] or halves when using the legs or buttocks.
- Use one quarter or half per week and always move in the same direction [either clockwise or anticlockwise].
- Injections within each quarter or half should be spaced at least 1 cm from each other to avoid damaging the skin tissue.

Injections into lipohypertrophic tissue may make it worse and insulin absorption may be delayed or erratic, potentially worsening diabetes management. Switching to areas without lumps and bumps could result in significantly smaller doses of insulin being needed.

Do not remove the needle immediately after injecting

Once the insulin has been injected, it is advisable to leave the needle in place for a few seconds to ensure that there is no leakage on removal of the needle from the skin.

Changing the needle

Repeated use of the same needle leads to the needle tip being damaged and a loss of lubricant on the needle. Not only does this make injections more painful but it can affect glycaemic control. It also means that the needle is no longer sterile.

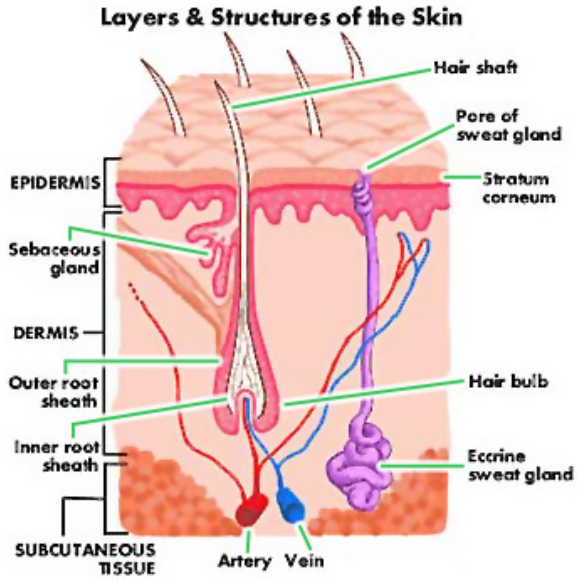
The pen needle should be removed between injections

- If you leave the needle on your pen between injections, the insulin could crystallise and create a blockage making the next injection impossible.
- It also means that there is an open passage to the insulin which allows the insulin to leak out of the cartridge and/or air to be drawn in.
- Pre-mixed insulin, such as 30/70, contains a short/rapid-acting insulin and an intermediate-acting insulin and the short/rapid-acting insulin is more fluid and will leak out more readily than the longer-acting insulin. This means that this leakage will alter the proportions of the mixture which will, in turn, affect your glycaemic control.

Subcutaneous injections

For insulin and the Type 2 injectable drugs to be effective they have to be injected into the subcutaneous tissue. This is the layer of fatty tissue marked on the diagram below.

The muscle is underneath the subcutaneous tissue and if you inject into the muscle it is painful and the absorption of insulin can



accelerate its effect so increasing the risk of hypoglycaemia. This can also be followed by hyperglycaemia because the insulin runs out more quickly. So injecting into the subcutaneous layer enables the insulin to be absorbed at a more predictable rate giving better control of blood sugars.

Needle length

For the injected insulin or drug to reach the subcutaneous [fatty/adipose] tissue it is necessary to have the appropriate needle length for the syringe or pen. This is determined by the skin thickness and the thickness of the subcutaneous tissue. Research in the US measured both of these at four injections sites [thighs, buttocks, abdomen and arms] in an ethnically mixed adult population with diabetes. [Current Medical Research and Opinion, June 2010] There were some interesting and perhaps surprising findings.

Skin thickness

The skin thickness at the 4 injection sites is thinnest in the thigh and thickest in the buttocks, with a difference of 0.57mm. The arms and abdomen have an intermediate thickness.

- A change in body mass index of 10 only makes a skin thickness difference of less than 0.2mm.
- Age made no difference to skin thickness, so the statement that your skin gets thinner with age may not be true.
- People with Type 2 diabetes taking insulin have similar skin thickness at all four injection sites to those not treated with insulin.
- People with Type 1 diabetes have thinner skin thickness by 0.1mm compared to those with Type 2 diabetes.
- Males have a slightly thicker skin, by 0.3mm, than females.

Subcutaneous tissue thickness

The arm and thigh had similar thickness with the thigh being slightly thinner by 0.4mm. The abdomen was more than 3mmm thicker than the arm. The subcutaneous tissue of the buttocks was the thickest injection site, almost 5mmm thicker than the arm.

The range of subcutaneous tissue thickness varied much more than for skin thickness in terms of gender and injection sites.

- Females have 5.1mm more subcutaneous tissue than males.
- Age was not related to any significant differences in thickness.
- The type of diabetes, insulin use or not and injection site did show differences. In Type 2 diabetes the abdomen tissue was about 5mm thicker than in people with Type 1 diabetes and at the buttocks those with Type 2 diabetes had about 2.3mm less subcutaneous tissue than those with Type 1 diabetes.

Conclusions about needle length

This research shows that skin thickness varies very little between different adults but subcutaneous tissue varies considerably in particular areas, injection site, BMI and gender with very little variation according to age and race.

People who have been injecting for many years will remember that needles were much thicker in diameter and also much longer than today – up to 16mm! The need for shorter needles became clear when investigations showed that more than 80% of non-obese children were at risk of injecting into muscle with the 12.7mm [½ inch] needles. 8mm needles partly reduced this but still carried a risk of injecting into muscle in children, adolescents and thin adults. 5 and 6mm pen needles were then introduced to further reduce the risk of injecting into muscle and many people need to use specific injection techniques such as angling the injection [45 degrees instead of 90 degrees] and/or injecting into a raised fold of skin. 4mm pen needles have alo been shown to be safe and effective. The main points to come out of measuring skin and subcutaneous fatty tissue in this research are:

- Shorter length needles will deliver insulin and other medications into the subcutaneous tissue at all injection sites and in nearly all adults with diabetes.
- It is estimated that with shorter needles, a 90 degree injection will deliver the insulin or drug into the subcutaneous tissue 99.5% of the time.
- The belief that longer needles are necessary for people who are overweight or obese does not appear to be the case. Two further studies have shown that shorter needles in obese people are just as effective at maintaining glycaemic control as longer needles and of course, are preferred by those having to inject.

The injection must go into the subcutaneous layer of tissue, if it goes too far it will go into muscle and result in pain and erratic blood glucose levels and if it doesn't go in far enough, then the insulin, or other medication, will not be effective. It is always worth checking your injection technique with your nurse and you should discuss:

- site and site rotation,
- needle length,
- the angle of the injection and whether to raise the skin or not.

Note: Becton Dickenson who carried out the above research, have launched the BD Micro-Fine™+ 4mm pen needle and thin gauge (32 G) - the world's smallest pen needle.

Devices to help with injections

There are various devices to help with injections and for people with particular difficulties. For further advice you should discuss these with your health professional. Here are some examples.

Needle removers

It is important that needles are removed from pens and syringes safely without doing anyone any harm - this can be particularly difficult for people who have dexterity problems.

Clip'n'store is a device to safely and easily remove pen and syringe needles as it cuts the needles and stores them in a reservoir. It also means that you don't need a sharps disposal bin. These are available from Arctic Medical, call 01227 832400 for more information.

An almost identical product is made by Becton Dickinson called the BD Needle Remover. Novo Nordisk make a NovoFine Needle Remover which is a cap that fits over the needle on the end of the pen and grips so that you can twist off without having to use your fingers. You then press a button on the device to eject the needle straight into a sharps bin. This is available on prescription but there is a similar pen needle remover that comes free inside every box of Unifine needles from Owen Mumford.

Fear of needles

Needle-free injections

No one actually likes needles but true needle phobia [a fear of needles] is rare. It is generally recommended that needle free injections systems should be reserved for people with true and severe needle phobia [Royal College of Nursing, 2006].

- The needle free injection Mhi-500 and SQ pens were available in the UK on an NHS prescription but in June 2010 it was withdrawn from the Drug Tariff.
- There is a needle free system available on prescription and this is the Injex. The Injex accessories are also available on prescription.

Injex works by delivering the insulin as a fine stream of fluid under pressure so that it penetrates the surface of the skin. This means that there may be differences when compared to injections with needles:

- There may be faster absorption of the insulin so it will take effect more quickly.
- The high pressure may cause bruising of the skin.

A *User instruction manual (PDF)* and an *online training video* are available from the manufacturer's website (www.injex.com).

Not seeing the needle

Some people with a fear of needles can be helped if the needle is not actually seen.

Novo Penmate, which can only be used with Novopens, replaces part of the Novopen with a larger body to hide the needle before injecting. A button is then pressed and the needle is inserted automatically.

For people who use syringes, there are devices that cover the needles which are automatically inserted into the skin at the press of a button – these are called the Autoject 2 and the Inject-Ease

Injections for people with visual impairment

The advantage of using a pen to inject is that when dialling up the dose, there are clicks to count the number of units being dialled.

However, some people are still injecting with syringes, mainly those people using pork or beef insulins and the markings can be difficult to see. Syringe magnifiers are available and they enlarge the numbers and the markings on the insulin syringe. They also make the vial and syringe easier to hold and help to guide the syringe needle into the rubber stopper.

Do You Sometimes Forget When You Took Your Insulin?

If this is the case, you are not alone – it maybe that you simply forgot or you have one of those moments when you can't remember if you have actually done your injection or whether you are remembering yesterday morning.

There is now a new product on the market to help with just this situation. It is called the Timesulin and it measures the time that has passed since the last dose of insulin.

It is a cap that fits on to most types of injection pens. It has a small LCD screen which displays the amount of time since the last dose was taken. Once the insulin is injected, the timer automatically resets and begins again. The cost is around £25 for two caps. More information is available at www.timesulin.com

Oral Thrush

Oral thrush is also known as oral candidias and is a yeast infection in the mouth caused by a type of fungus called Candida albicans. It cannot be passed on to other people.

Oral thrush is more common in certain groups of people.

- People who wear dentures - 7 out of 10 people who wear dentures will develop oral thrush at some time.
- People with a weakened immune system, such as those with HIV and AIDS – 9 out of 10 people with AIDS have oral thrush.
- People with Type 1 and Type 2 diabetes. Oral thrush is 5 times more common in people with Type 1 diabetes than in the general population.
- Oral thrush can sometimes affect newborn babies. If the mother has vaginal thrush, it can be passed from mother to baby during labour.
- Certain antibiotics or corticosteroids can cause oral thrush, if this is thought to be the case, then the medicine may need to be changed or the dosage reduced.

There are several other types of thrush that can affect various parts of the body – inside the vagina, the nappy area of babies, the cuticles, the skin and the head of the penis.

Symptoms and treatment for oral thrush
If not treated, oral thrush can cause soreness and discomfort in the mouth. However, it can usually be treated with antifungal treatment which are available as tablets, lozenges, powders, creams and rinses for people who are unable to swallow tablets.

Note: some anti-fungal medicines should not be used during pregnancy, breast feeding or with certain other medicines. Your GP or pharmacist will be able to advise on this.

Bits And Pieces

Low gastroparesis rates are found in diabetes patients

Researchers have said that gastroparesis may be less common than previously thought. Information on 587 diabetes patients showed that only 5% of those with Type 1 diabetes and only 1% of those with Type 2 diabetes developed gastroparesis over a 10-year follow-up. Gastroparesis is when neuropathy affects the nerves of the stomach and digestive system so that food is not digested properly. This in turn can cause blood glucose levels to be erratic. [The American Journal of Gastroenterology, Dec 2011]

Higher daily B-12 intake is needed for diabetes patients on metformin

According to recent research people with Type 2 diabetes who are treated with metformin should increase their daily intake of vitamin B-12. Information collected in the US National Health and Nutritional Examination Survey showed that 5.8% of people treated with metformin had a deficiency in vitamin B-12, compared with 2.4% of those who were not on metformin and 3.3% of those who did not have diabetes.

Vitamin E has a function after all!

Although it has been known for years that Vitamin E deficiency caused muscle problems, until recently researchers had no idea what the main function of Vitamin E was. However, a team of researchers has found that it helps to repair tears in the body's cell membranes that protect cells from outside forces and it also screens what goes in and out of the cells.

The study showed that Vitamin E treatment in an animal model of diabetes restored some membrane repair ability. Also, an analogue of the most biologically active form of vitamin E significantly reversed the inability for membranes to repair caused by high glucose and increased cell survival after tearing. Vitamin E is in many foods and we consume enough in the food we eat.

Using the HbA1c for the diagnosis of Type 2 diabetes

The Canadian Diabetes Association is recommending the use of the HbA1c test for diagnosis of Type 2 diabetes in adults. A result of greater than 6.5% is the level for diagnosis. Type 2 diabetes has traditionally been diagnosed by fasting plasma glucose [FPG] or a 2 hour oral glucose tolerance test [OGTT] at a given moment in time but the HbA1c test reflects the average blood glucose over the preceding few weeks.

The change does mean that some people may not be identified as having Type 2 diabetes with the HbA1c test compared to the glucose test but equally, some people are not identified with the glucose test.

The HbA1c test has several advantages - it can be taken at any time of day, it is more convenient than the FPG or OGTT with no fasting for the patient and it avoids the day to day variability in glucose levels. It also has disadvantages in that it can be misleading in certain ethnic groups and is not recommended for diagnosis in children, adolescents, pregnant women or people with Type 1 diabetes. Age also affects HbA1cs in that the results can increase by up to 1% per decade but further studies are required for diagnosis in the elderly.

The World Health Organisation is recommending the use of the HbA1c for diagnosis of Type 2 diabetes and America is also using this method but the UK does not appear to be going down this route, yet.

News About Diet

Don't be disheartened by Yo-yo weight loss

We know that all too often when trying to lose weight, there is a swift weight loss in the first 4 to 6 months but this is then followed by no further weight loss or even weight gain despite continuing to diet. This can be disheartening and people sometimes give up on weight loss diets but recent research should give us encouragement to continue

to diet.

Researchers at Ben-Gurion University found that perhaps we have been too blinkered in our attitude to healthy diets and they say that although maintaining ideal body weight is linked to better health, when it comes to mild or moderately obese people, adopting healthier dietary habits gives benefits beyond weight loss, such as decreasing inflammatory tone and increasing 'good' cholesterol [HDL]. This means that as long as the dieting continues, the risk of cardiovascular disease is reduced, even despite weight gain.

The researchers say that their study gives a strong message to the public, "Switching to a healthy lifestyle is a long-term strategy that should be done moderately but persistently." [Health News, 23.12.11]

Low carbs two days a week - another piece of interesting news

Researchers from the UK looking at breast cancer risk, have found that women using a low carb diet [about 650 calories] for just 2 days a week but eating normally the rest of the time, on average lost 9 pounds after 4 weeks compared to women who cut back to 1500 calories everyday. As well as having greater reductions in weight, they also had reductions in insulin and leptin levels, both of which are implicated in the risk of cancer.

Clearly to change to a low carb diet for just 2 days a week is not possible for people with diabetes because it would mean changes in insulin or medication doses according to which diet day of the week but yet again, this study demonstrates that a low carb diet aids weight loss.

What did the women eat? Protein and healthy fats and one piece of fruit a day but they avoided bread, pasta, root vegetables like potatoes, carrots and parsnips. Other foods they could eat were nuts and green, leafy vegetables, peppers, mushrooms, tomatoes, broccoli, eggplant and cauliflower.
[Presented at the CTRC-AACR San Antonio Breast Cancer Symposium Nov. 2011]

Prescriptions or diet pills rise by 65%

Diet pill prescriptions increased by 65% in the last year and sales of over-the-counter slimming products went up by 20%. According to the press, depression and stress account for 12.5% and are the main triggers for people putting on weight. Slimmers also feel extra pressure to be thin and many are falling victim to obesity -discrimination. National Obesity Forum head Professor David Haslam said: "Discriminating against the obese is deplorable, with the psychological aspects of obesity often overlooked." The Department of Health stated "Clinical Guidelines on obesity make it clear that drug treatments should be prescribed if diet and exercise have been tried and after discussions about risks and benefits."

From Our Own Correspondents

Listening to the patient being treated

Dear Jenny,
In December I had to go into hospital and have an operation on my back. I took the IDDT Hospital Passport with me and displayed it in a prominent place. Several doctors and nurses picked it up and looked at it but I don't know if it made any difference. They took all my medicines away and locked up my insulin which I protested about. Fortunately every time I needed it, I just had to press a button and a nurse got it out for me. It is after all dangerous stuff to be left unguarded.

When I had my operation they put me on what they called a sliding scale in the form of a glucose drip solution with human actrapid insulin attached in a syringe. They regularly took blood tests and adjusted the insulin dose accordingly. After the operation at bed time a male nurse came and tested my blood. He said it was 3.8 mmol so I asked him to take the insulin away but he just replied "the doctor has prescribed it." There was still glucose going into my vein so I just ate a biscuit and tried to sleep. At about 5 am he tested my blood and said it was

2.3 mmol so I asked him to get me some milk with sugar in it which I drank and he test my blood again. It was then down to 2.0 mmol, so he went into panic mode and removed the insulin syringe and rushed out to find me a GlucoGel [Hypostop].

It's a great shame they prefer to listen to an absent doctor's advice instead of the patient being treated. Anyway I recovered from it and am safely home now on my pork insulin.

Mr H.M.
By email

I really do need pork insulin!

Dear Jenny
I live outside the UK and with your help, 10 years ago I started to use pork and I have been doing well for many years. Last year I had a lot of problems with my blood sugars. Nothing seemed to work, I thought it had something to do with the nights but was not sure. Then my doctor said I had to try analogue insulin instead of pork insulin.

I was only prepared to use Novorapid and I refused to start with the long-acting Levemir. For 10 days I used the combination of Novorapid and Pork Isophane. I got worse every day, I really didn't recognise myself. I saw my husband looking at me but he didn't say anything. Everyday I mailed with the internist. He said that it was not possible yet to say if Novorapid was OK for me. Most stupidly I did not stop taking NovoRapid right away, it was as if my brain did not work.

Then my doctor asked in an email how my body was reacting on the Novorapid. That very moment I knew I was getting harmed and I stopped the Novorapid and within 10 hours I felt myself coming back. I recognised my feelings and my thoughts again but I also realised that all my joints were hurting and I was feeling very sick. Next morning all these complaints had disappeared.

My real problem was indeed the nights with serious hypos. Now I don't use any insulin in the late evening and wake up at 4.00 am to see what insulin is necessary.

S.D
Europe

An Inspiration To People With Type 1 Diabetes, Young And Old – John Lumb

John died of lymphoma in December 2010 after living with Type 1 diabetes for 50 years. He had no complications of diabetes often present in people with long-term Type 1 diabetes. He was diagnosed at the age of 15 in 1960 and always followed a regime of insulin, diet and exercise as attaining as good fitness levels as possible was his main aim because at 15 he was already recognised as a gifted cricketer.

Indeed, he went on to play 2nd XI County Cricket for Yorkshire with distinction. He also achieved professional coaching awards in cricket and football and academically a BSc in Economics.

His wife has recently written to IDDT as John was a supporter of IDDT and other organisations which championed Type 1 diabetes as he always felt it was marginalised and its implications on daily life never fully understood or publicised. His record shows what can be achieved with Type 1 diabetes but he always maintained and said: "You can do normal things but it is not a normal life. You always play on an uneven playing field – yours is always uphill yet you are judged on the level so actually your achievements are the greater."

And from John's wife: "I hope John's achievements are of interest to your readers and act as an inspiration to budding sportsmen [and women] with Type 1 diabetes".

Stevia – A New Sweetener

Stevia is a natural herbal sweetener that is 200 to 300 times sweeter than table sugar by weight but has no calories or carbohydrates. It contains substances called “glycosides” which are responsible for its sweetness. The stevia extract is taken from the stevia rebaudiana plant was originally native to South America where it has been used for sweetness for hundreds of years. Produced as a sweetener, it can be found in most of the major supermarkets under the name of ‘Truvia’. It is also made in pure powder extract form, soluble tablets, sachets and even liquid extracts.

Pork And Beef Insulins Continue To Be Available

Statement from Wockhardt UK

As many of our readers will know the original reason for the formation of IDDT was to maintain supplies of animal insulins, not only so that this choice of natural insulin remains available for everyone, but especially for the people who have adverse reactions to the synthetic insulins. We never forget that this need still exists and we know that many animal insulin users worry about the continued availability of the animal insulin they need. Many are often wrongly told that animal insulins are no longer available. In order to give reassurance to those people who need animal insulins, we have received a statement from the Managing Director of Wockhardt UK.

7th February 2012

Supporting insulin-dependent diabetic patients

Wockhardt UK has been committed to the provision of porcine and bovine insulins for many years, recognising the medical needs and preferences of each individual person with diabetes.

The Department of Health fully accepts that some people are better suited to porcine or bovine insulin and that these insulins should continue to be made available. Because Wockhardt UK firmly believes in maintaining freedom of choice for those needing insulin, we can offer reassurance that Hypurin® porcine and bovine insulin will continue to be available for the foreseeable future.

Sirjiwan Singh
Managing Director, Wockhardt UK Ltd

Changes in the Packaging – statement from Wockhardt UK

February 9th 2012

Hypurin® (Insulin Ph Eur) Porcine and Bovine packaging announcement

You may notice some changes to your Hypurin® insulin product packaging, please be assured that there has been no change to the insulin itself, nor the way in which it is made.

Changes in regulatory requirements have meant the size of the text within the patient information leaflet included in the pack has now increased, making it clearer and easier to read. This has also resulted in the size of the vial pack being made bigger to accommodate the larger leaflet.

When implementing these changes, Wockhardt took the opportunity to make some further improvements to the pack design, listening to comments from patients and pharmacists e.g. clearer/easier to read insulin type through use of darker fonts on cartridge packaging and whitened background on cartridge labels to enhance visibility of text for easier reading.

Your new pack will also now show a Wockhardt logo in place of the old CP Pharmaceuticals logo. Wockhardt, previously known as CP Pharmaceuticals have continued the manufacture of Hypurin® animal insulins for over 40 years, recognising the medical needs and preferences of patients with diabetes and maintaining patient choice. If you would like any further information regarding the new packaging

change, please contact Wockhardt on 01978 661 261 or email hypurin-insulin@wockhardt.co.uk
Note: you can also see the new packaging on IDDT's website home page www.iddtinternational.org

Just to remind you...
IDDT's survey of people with diabetes and their family carers about their experiences with synthetic GM insulin showed the following:

- On average the adverse effects did not appear until 13 months after treatment with 'human' insulin began and most people complained of 3 or 4 of the following adverse reactions.
- 41% - loss of warnings of hypos or 'I function on automatic pilot'.
- 34% - extreme tiredness or lethargy
- 9% - sleeping all the time
- 32% - weight increase of 1.5 stones [21 pounds] and above
- 28% - feeling unwell all the time
- 24% - memory loss or confusion
- 9% - blood glucose levels dipping and peaking erratically
- 8% - described by their families as 'not the same person'
- 5% - mood changes, described as difficult to live with
- 7% - pains, especially ion the legs and joints
- 4% - irregular or late periods

Sadly so many years later, we are still receiving similar reports from people using human and analogue insulins.

Public Health Outcomes Framework

'Helping People Live Healthier Lives'

This new public health outcomes framework was published in January this year and it sets out the desired outcomes for public health and how these will be measured.

The framework concentrates on two high-level outcomes to be achieved across the public health system.

- increased healthy life expectancy,
- reduced differences in life expectancy and healthy life expectancy between communities.

The second group of outcomes focus attention on reducing health inequalities between people, communities and areas. Some of the measures to be focused on include:

- fewer children under five will have tooth decay,
- people will weigh less,
- more women will breastfeed their babies,
- fewer over 65s will suffer falls,
- fewer people will smoke and
- fewer people will die from heart disease and stroke.

It is also going to tackle causes of ill health, so the new measures will also look at school attendance, domestic abuse, homelessness and air pollution.

Mr Lansley intends that from April 2012 about £5.2 billion will be ring-fenced to be spent on public health services by local authorities. They will be able to choose how they spend it according to the needs of their population and those who make the most improvements will be rewarded with a cash incentive.

How will public health be measured? There will 66 health measures against which councils and government will be able to measure improvements and if there aren't any, take any action needed.

Is this just another shift in responsibility for the health of the nation – from government to local authorities? It seems that yet again the changes mean that the government cannot be blamed for any failures to meet the targets and nor can they take any credit either – something to be remembered when the next general looms!

The Public Health Outcomes Framework will be published on the

Department of Health website – http://www.dh.gov.uk/health/2012/01/public-health-outcomes/

The Burden Of Treatment Of Diabetes – Do We Talk About It?

A study carried out in the US has shown that although people with diabetes routinely discuss what is described as the burden of the treatment of diabetes during clinic visits, many people do not have their concerns addressed at the time. [Diabetes Care, Nov 28, 2011] So are patients being listened to?

It is important to recognise that this study was about the burden of treatment, not about the burden of living with diabetes, which is a different issue. For the study the burden of diabetes treatment was defined as treatment-related effects that limit a patient's ability to participate in activities and tasks that are crucial to quality of life and that are not attributable to underlying disease.

- The researchers looked at 46 videos of GP visits and found that 93.5% of visits contained discussions about the burden of treatment with 55% of the discussions being started by patients.
- 12 involved conversations that were about compliance with the monitoring required for effective or safe use of the medications,
- 19 concerned patient efforts or difficulties in obtaining treatment in a timely, convenient or affordable manner.
- 24 covered unwanted or unintended symptoms as a result of the prescribed medication,
- 28 concerned the burden of correctly delivering or taking medication.

However, despite the high rate of discussions, only 30% were addressed in an unambiguous manner. The researchers suggest that these findings show that opportunities are being lost to prevent non-adherence to treatment and improvement in the quality of life for patients with diabetes and other chronic conditions. They also suggest that doctors and health professionals may need education on ways of addressing and discussing issues relating the concerns of patients about their treatment.

NHS News

Is the future of public health policy in the hands of big business?

The Department of Health has awarded the public health campaign contract to just one company, Freud Communications, and it is said to be worth several millions a year. In the past various aspects of public health work have been handled by different agencies but now the entire PR on public health is with Freud Communications.

Other Freud clients include Pepsi, KFC, Walkers Crisps and the drinks company, Diageo. Public health experts expressed scepticism about the government's real commitment to public health and expressed anxieties about the reliance on PR people with deep links to the food industry.

Matthew Freud, owner of Freud Communications, is the son of writer Sir Clement Freud and is married to Rupert Murdoch's daughter Elisabeth.

Doctors say cuts will adversely affect patient care

A survey carried out by the Guardian in December 2011, showed that at least 4 out of 5 doctors believe that the NHS cuts will adversely affect patient care. They feel that patients are waiting longer for hospital beds and for treatment. The majority of them feel under pressure to prescribe slower working drugs because they are cheaper. There have been cuts in occupational health support services and a reduction in community health services and ambulances regularly face delays

when they hand over emergency patients at hospitals. It is hard to see how David Cameron's claim to "cut the deficit, not the NHS" actually stands up!

The Debate About Daily Aspirin Goes On

The connection to age-related macular degeneration

Daily aspirin is often prescribed in older people to protect the heart but research seems unclear about the risks and benefits. A survey carried out by Portsmouth Hospitals NHS Trust also showed that health care professionals varied greatly in whether or not they prescribed aspirin for people with diabetes and also in the doses they prescribed.

Research into the connection between aspirin use and age-related macular degeneration has given conflicting results but a recent study carried out in the Netherlands found that late-stage 'wet' macular degeneration was more than twice as likely among aspirin users than those not taking aspirin.

Macular degeneration affects the macula at the back of the eye and impairs central vision. The macula is a small area on the retina where detailed central vision takes place eg reading. The cells in the macula deteriorate and the central part of vision becomes blurred but what is seen around the blurred area is relatively clear because the peripheral area of the retina is not affected.

Macular degeneration accounts for about 50% of all visual impairment in developed countries. It usually affects people over 50 years and so is known as Age-related Macular Degeneration [AMD]. There are two types of AMD – dry which develops very slowly over a number of years and wet, which develops more rapidly.

The recent study took place in seven European countries and involved 4691 people aged 65 or older most of whom reported at least some aspirin use, monthly, weekly or daily. More than a third showed early age-related macular degeneration and the late stage showed in 3.3%. The most significant finding was that 33% of the participants with the 'wet' form took daily aspirin compared with only 16% of those who did not have the condition.
[Ophthalmology 2012; DOI: 10.1016/j.ophtha.2011.06.025.]

Note: If you would like a copy of IDDT's leaflet 'The Eyes and Diabetes' call 01604 622837, write to IDDT, PO Box 294, Northampton NN1 4XS or visit our website http://www.iddt.org/wp-content/uploads/2009/10/the-eye-and-diabetes.pdf

NHS To Be More Transparent – 'Duty Of Candour'

In October 2011, under plans set out by Andrew Lansley, the NHS is to be more transparent, apparently to make a safer NHS for us as patients.

Over a million patient safety incidents are reported every year and for 2010 these were:

- Almost 790,856 (69%) resulted in no harm to the patient;
- 270,114 (24%) resulted in low harm;
- 69,154 (6%) resulted in moderate harm;
- 9,650 (0.6%) resulted in death or severe harm.

It is therefore the Government's intention that NHS providers will be more open and admit when things go wrong. There will be a contractual 'Duty of Candour' in healthcare which will be an enforceable duty on providers to be open and honest with patients or their families when things go wrong.

How will the 'Duty of Candour' work?
It is proposed that the requirement will be inserted into the NHS Standard Contracts, which set out standard terms and conditions which all organisations providing NHS-funded secondary or community care must agree to. Therefore this will include the providers of NHS acute hospital, community, ambulance and mental health services and will apply across NHS Trusts, NHS Foundation Trusts, the independent, charitable and voluntary sectors and social enterprises where NHS funded care is being provided.

Can it work?
There already is a fear of whistle-blowing within the NHS – this is where NHS staff are fearful of reporting colleagues when they feel there may have been inadequate or even wrong treatment, so how does the 'Duty of Candour' overcome these fears?

How is it enforceable? What are the penalties when the duty is breached [when there is a cover up]? How will patients and health professionals be supported if they feel the NHS is not being open about an incident? We wait and see...

Note: there is so much information about the changes in the NHS it is difficult to take in, so in the next Newsletter we will discuss the new organisations that are to be developed – Health and Wellbeing Boards, HealthWatch, Monitor and the Care Quality Commission.

Snippets

Go for a walk to reduce chocolate cravings
A study of 78 people who regularly ate chocolate showed that those who had a brisk 15 minute walk before being given an easy or a difficult desk task ate fewer chocolates than those who rested before working. The researchers also found out that the difficulty of the workload was not associated with increased carvings for chocolate. [Appetite December 2012]

The colour of your plates
We have known for some time that one of the ways to help with weight loss is to use a smaller plate. Now research in Canada has shown that not only does a smaller plate help but the colour of the plate also has a big impact on how much someone eats!

If the food is on a plate that is similar in colour, people will serve themselves about 22% more than if the colours of the plate and food are in sharp contrast. Not only this, but people who eat in front of the TV, computer or even while listening to music tend to eat more than people without these distractions. Children will eat 20% more if they are eating in front of the TV than if they are not and this happens more in boys than girls.

Overweight doctors less likely to talk to patients about weight loss!
Normal-weight doctors were more likely than overweight doctors to diagnose obesity in some patients and discuss weight loss with them. Doctors with a normal BMI were also more confident in providing diet and exercise advice and their weight-loss advice was perceived as trustworthy, compared with obese or overweight doctors. [Obesity, January 2012]

Europe doesn't match up
A survey carried out by the European Food Information Council shows that most Europeans don't consume the recommended daily amount of fruit and vegetables. The World Health Organisation recommends 400 g a day but only in Poland, Germany, Italy and Austria was this target met. The worst country was Iceland where the average intake was 196g a day.

Smart pills – or big brother?
Proteus Biomedican and Lloyds Pharmacy have joined to together to launch a new digital pill to check whether patients are taking the drugs

they were prescribed. It is called Helius and is a sensor tablet that is swallowed with the patient's other medication. A chemical reaction in the stomach then sends a signal detected by a patch worn on the body.

One Thing For Sure – The Care You Receive Depends On Where You Live!

One of the many concerns that people have expressed over the changes in the NHS whereby funding decisions are made at local levels by Consortia, is that treatment and care will vary according to where you live. This is a shift which does cause some worries and rightly so. We looked at just three Parliamentary Questions asked by Adrian Sanders in November and December 2011 of the Secretary of State for Health:

1. What steps is he taking to ensure that the NICE recommendation that insulin pump therapy s available to 12% of people with Type 1 diabetes?
2. What steps he is taking to ensure that social and psychological support services are available to young adults and adolescents with diabetes?
3. What assessment the Department of Health has made of the health and social needs of this group?

The answer to all three of these questions is basically the same: "These are matters for the national health service locally."

As Primary Care Trusts are due to disappear in 2013, this means that the Consortia will be making these decisions. This means the doctors and health professionals in your area will be making the decisions and it appears that the NHS nationally is able to opt out of ensuring that much needed services are supplied.

IDDT's Leaflet 'Know Your Rights' will help you to know your rights and help you to ensure that you receive the care you need and deserve. If you would like a copy, call IDDT on 01604 622837, email enquiries@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS.

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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PO Box 294
Northampton
NN1 4XS

Name: ——————————————————————————

Address: ——————————————————————————

——————————————————————————

Postcode: ——————————————————————————

Tel No: ——————————————————————————

From Your Editor – Jenny Hirst

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