Insulin Dependent Diabetes Trust

April 2010 Newsletter

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Type 1 diabetes the hopeful news

The artificial pancreas

Research funded by the Juvenile Diabetes Research Foundation has shown that an ‘artificial pancreas’ can be used to regulate blood glucose levels at night in children with Type 1 diabetes and reduce the risk of hypoglycaemia. The artificial pancreas combines a real-time sensor measuring blood glucose levels with a pump which delivers the right amount of insulin, so insulin is delivered in response to the blood glucose test.

Seventeen children and teenagers spent 54 nights in hospital and their blood glucose levels were measured using the artificial pancreas and when using their standard pump which delivers insulin at a fixed rate. Different situations were used, such as when the children went to bed after a large evening meal or after early evening exercise, both of which can result in hypos in the night.

The results showed the artificial pancreas

- Kept the blood sugars in the normal rage for 60% of the time compared with 40% of the time with the standard pump.
- Halved the time blood sugars dropped below 3.9 mmols/l [mild hypoglycaemia].
- Prevented blood sugars dropping below 3.00 mmols/l [significant hypoglycaemia] compared with 9 times in those using the standard pump.
- Increased the time blood sugars were between 3.9 and 8.00mmols/l without altering the average rate of insulin infusion.

This is the first study to show the potential benefit of the artificial pancreas. Apart from the potential to offer better overall control of blood sugars and reducing the risk of complications, if the artificial pancreas reduces night hypos, it could greatly improve the quality of life for many people with diabetes and their families who have to cope with worrying night hypos.

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Type 2 diabetes – the surprising news!

Minimum and maximum HbA1c targets for Type 2 diabetes

The results of a 22-year long study at Cardiff University indicate that the safest blood glucose level for people with Type 2 diabetes is HbA1cs of 7.5%. [Lancet, Feb 11, 2010] The study tracked 48,000 people with Type 2 diabetes aged 50 and over from 1986 to 2008. They found that people with highest and the lowest HbA1cs were at greater risk of death from all causes and heart problems than those with average HbA1cs of 7.5% who had the lowest death rates.

The surprise is that this conflicts with the targets recommended by authorities and experts to achieve normal blood glucose levels. This study showed that this policy may increase the chances of early death.

The study also found that people with Type 2 treated with insulin were 49% more likely to die than those using oral drugs, such as metformin and sulfonylurea. This could, at least in part, be because Type 2 patients who need insulin may be more ill than other diabetes patients. However, there is now a tendency for insulin to be prescribed earlier in an attempt to drive down blood glucose levels to meet the low targets set by experts, targets that GPs have to achieve to count as points towards their remuneration.

The Cardiff researchers' conclusions:

Doctors treating people with Type 2 diabetes should try, for as long as possible, to use a combination of diet, lifestyle, and oral medications before shifting to insulin therapy.

Importantly, the Cardiff study supports the findings of the ACCORD study. The ACCORD, sponsored by the US government, was stopped early in 2008 because a significant number of the 10,000 participants who achieved tight control, suffered from heart problems.

In IDDT's January 2010 Newsletter, we questioned why HbA1c targets differed between countries. For example, the American Diabetic Association has long recommended target HbA1c of 7% and has been criticised for this being too high. If targets are based on evidence, should we not expect them to be same? To protect patients' best interests, surely it is time for international experts to examine the present HbA1c targets for people with both types of diabetes and come to a consensus evidence-based view. It may be that there has to be not only a maximum HbA1c but a target minimum HbA1c too.

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Type 1 Diabetes Research - A Chance To Have Your Say…

Do you have an unanswered question or an uncertainty about the treatment of Type 1 diabetes?
Do you think that answering your question through research will help to improve the lives of people with Type 1 diabetes?
This is your chance to make your views known.

The Type 1 Diabetes Priority Setting Partnership has been set up by the James Lind Alliance, the Diabetes Research Network, Diabetes UK, the Insulin Dependent Diabetes Trust, Juvenile Diabetes Research Foundation, NHS Evidence - diabetes and the Scottish Diabetes Research Network.

The Partnership aims to work with people with Type 1 diabetes, their carers and health professionals to identify and decide upon the most important research questions in the treatment of Type 1 diabetes.

The prevalence of Type 1 diabetes is increasing and it is important to get research evidence on the most effective ways of treating it. Research on the effects of treatments often overlooks the shared interests of patients, carers, clinicians and other health professionals. The pharmaceutical and medical technology industries and academia play essential roles in developing new treatments, but their priorities are not necessarily the same as those of patients, carers and clinicians. That's why this project is so important.

IDDT has long believed in the importance of people with diabetes having a say in identifying uncertainties or gaps in research that are important to them, their doctors and health professionals. Both patients and their clinicians are at the sharp end of diabetes – they live with or treat the condition everyday! This is why IDDT is funding this Type 1 Diabetes Priority Setting Partnership which hopefully will influence the future research agenda.

For more background information and to participate in the survey, please go to www.ukdrn.org.uk/JLAsurvey.html or call IDDT on 01604 622 837 to be sent a paper copy of the survey.

IDDT NEWS

IDDT launches a FREE Year Six Lesson Plan and Resources

In an ideal world we would like all children to grow up with a basic understanding of both types of diabetes and how it affects adults and children. IDDT's Lesson Plan is designed to try to improve this situation. At the Education show in March 2010, IDDT launched this new way to improve children's knowledge and awareness of diabetes. The Lesson Plan especially aims to provide children [and perhaps their teachers] with an understanding of how Type 1 diabetes can affect children in their school, to understand about hypoglycaemia and its effects It will also help them to understand more about the different types of food. This is not just to help children with diabetes but to make all children aware of the need for healthy lifestyles and the risks of Type 2 diabetes in later life.

How will it work?

Personal Social Health & Economic Education (PSHE) is currently a non-statutory part of the school curriculum. Many schools choose to teach it because they find their pupils benefit from learning through presentations, creating posters and role play which enables them to manage their feelings and build positive relationships with others. PSHE promotes positive behaviour, mutual respect and self-awareness.

All About Diabetes consists of 5 Lesson Plans and evaluation sheets in a folder for teachers to use in their lessons.

We also provide resources, All About Diabetes, for them or the children to use. This is available as a Powerpoint presentation which an be downloaded on to a memory stick from IDDT's website and used with a white board. The aim is to present the children with questions that they can attempt to answer and then the correct answers can be revealed when the teacher chooses. Another alternative is for children to use the material on the 'All About Diabetes' web page to make a poster or create a presentation.

Who will find it useful?

Clearly the Lesson Plan is aimed at teachers but parents of children with diabetes may also find it useful to take to the school to encourage teachers to use it.

- The Lesson Plans are available free of charge.
- To access the Lesson Plan and Resources on-line visit IDDT's website www.iddtinternational.org and click on 'All About Diabetes'.
- If you would like a hard copy of the Lesson Plan, then contact IDDT by e-mail bev@iddtinternational.org, phone 01604 622837 or write to IDDT, PO Box 294, Northampton NN1 4XS

IDDT has a new website!

Some may say at last! Some of you will have already seen our new website but for those of you who haven't, please take a look. The information has all been updated and we will have much more regular updates from now onwards, so keep an eye on it.

The website address is the same: www.iddtinternational.org

All our publications, the Newsletter, the Parents' Bulletin and Type 2 and You are available to download and for the first time, all our leaflets are now available to download too. In the next few weeks, our publication list will be up there, so you will be able to order hard copies of leaflets, booklets and books online.

If you have any difficulty navigating your way through the site, then give Martin at IDDT a call on 01604 622837 or e-mail him at martin@iddtinternational.org

Animal insulins – IDDT meets Dr Rowan Hillson

It was in 2005 that the then Minister of State for Health issued the statement that some people are better suited to animal insulins than synthetic human insulins, so animal insulins need to remain available. As time has passed, we felt it was time to ensure that this statement still holds true today and so the present Minister organised that IDDT should meet Dr Rowan Hillson, National Clinical Director for Diabetes. The meeting took place on January 20th 2010, also present was Isabel Izzard who has responsibility for supplies at the DoH.

We expressed our concerns at the vulnerability of people who need animal insulin when there is only one supplier, Wockhardt UK. We were assured that there were larger stocks of animal insulins and the raw materials needed for production than for any other drug on the NHS. We continued to explain that it is the fact that there is only one supplier which is the vulnerability eg suppose there was a fire at Wockhardt. We were assured that there are other drugs in a similar situation and there are policies in place to deal with all eventualities. It was agreed that both Dr Hillson and Isabel Izzard would provide written statements to reassure you our members. Once we have these we will publish them.

Helping out in Haiti

Within a hours of the Haiti disaster, 'Insulin for Life' co-ordinated its associates around the world, including IDDT, to be ready to send insulin, syringes and test strips to Haiti. Like the other aid that was offered, it was difficult to send any supplies until delivery could be guaranteed and a proper distribution system was set up in Haiti. Insulin did get through as soon as possible. The International Diabetes Federation also worked closely with Insulin for Life to help. The insulin manufacturers, Novo Nordisk then relieved the situation by donating 50,000 vials of insulin and 500,000 kroner to support the relief work of the Danish Red Cross in Haiti.

This is just one example of how your help in collecting unwanted, in-date, unopened insulin and other diabetes supplies helps people with diabetes at times of emergency. So thank you to everyone who helps IDDT to help others much less fortunate than ourselves. If you can help, please send your unwanted supplies to IDDT, PO Box 294, Northampton NN1 4XS.

IDDT leaflets help in Ethiopia

IDDT has been contacted by the Ethiopian Diabetes Association who has requested our help. They desperately need basic information in easily understandable language to supply to people with diabetes. Basic information in layman's language is something IDDT believes in, so we have very willingly sent our leaflets for the 27 branches across Ethiopia and given them permission to copy them and translate them as they need.

We have also been approached to do the same for Gambia and so we will help there too.

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'TRUST ME, I'M A PATIENT'

This is the title of IDDT's 2010 Annual Conference. We hope that it intrigues you enough for you to come along and join us! One of the aims is to create a better understanding of our roles and the roles of our doctors and health professionals. The Conference will be held at the Paragon Hotel, Birmingham on Saturday October 9th 2010. We will be sending out the programme details and booking form to everyone in May / June so for now, just put the date in your diary.

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IDDT quarterly publications – your choice

As IDDT has grown so has the number of quarterly free, publications we produce. People who live with diabetes require different information, often according to the type of diabetes they have and the treatment they are given. For example, parents and children with Type 1 diabetes need different information from adults with Type 1 diabetes and people with Type 2 diabetes on diet and/or tablets require different information from people with Type 2 diabetes taking insulin.

IDDT produces the following quarterly publications:

- ► The Newsletter [for people taking insulin, both Type 1 and Type 2 diabetes]
- ► The Parents Bulletin [for parents of children with type 1 diabetes]
- ► Type 2 and You [for people on diet and/or tablets]

The amount of information you may want to receive can change. In addition to the Parents Bulletin, some parents may want to receive the Newsletter for the research and news. People with Type 2 diabetes treated with diet and/or tablets may want to receive the Newsletter in addition to Type 2 and You because their treatment has changed to insulin or may do so in the future.

We are happy to supply any or all of these free publications to you, just let us know if you would like to receive any additional publications to the ones you are already receiving.

Contact IDDT on 01604 622837, e-mail: enquiries@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS

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It's A Sad Day

Under fire from Pharma, Institute may lose its director, Science 22, January 2010

A news item in Science reported on the long-running feud between pharmaceutical companies and the German Institute for Quality and Efficiency in Health Care [IQWiG] which could cost its Director, Peter Sawicki, his job. The post is supposed be non-political but members of Germany's new coalition Government called for him to be replaced with someone who is ‘friendlier’ towards the pharmaceutical industry! Peter Sawicki is a clinical researcher and diabetes expert and readers may remember that his reviews of the insulin analogues caused ‘a fuss’ amongst industry when the reviews recommended that in the majority of cases they should not be used unless their price came down to that of human insulin because they had little benefit over human insulins.

In fact, 600 doctors signed an open letter to the minister of health calling for Sawicki to be kept on but IQWiG’s board of directors decided not to renew his contract. This was also reported in The Lancet where he was described as ‘a hardliner and with him as head, industry and the politicians who support it know they cannot force their products into the market as easily and quickly.’ It is a sad day when the Director of a so-called independent organisation has to go because he is not sufficiently friendly towards the pharmaceutical industry!

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Blood Glucose Testing - New Report

A report commissioned by the National Clinical Director for Diabetes [Feb. 2010] makes recommendations about self-monitoring of blood glucose levels in people with Type 2 diabetes who are not treated with insulin.

An NHS working group requested a systematic review of the evidence from the Health Technology Assessment programme [HTA] to inform their discussions. As a result, their main recommendations for self monitoring of blood sugars in Type 2 diabetes are listed below.

1. Self-monitoring of blood sugars with appropriate structured education should be available to people receiving sulfonylurea treatment to identify low blood sugars. [Sulfonylureas are the type of tablets which can cause hypos.]
2. It should only be provided routinely to people not treated with insulin or sulfonylureas where there is an agreed purpose or goal to testing.
3. It should only be used within a care package, accompanied by structured education which should include clear instructions about the role of monitoring and how the results can be used to reinforce lifestyle change, adjust treatment or alert health professionals. This should include regular reviews to identify and support people who find it useful while discouraging people who gain no clinical benefit from it.
4. People with Type 2 diabetes not treated with insulin who are motivated to monitor their blood sugars and use the information to maximise the effect of lifestyle and medication should be encouraged to continue to monitor.
5. Staff training in the use of self monitoring to support changes in lifestyle and self-adjustment of medications is required.
6. Savings from a reduction in self-monitoring in people should be used to provide both structured education and training of professionals.
7. Future research should focus on how to identify those who will gain most from self- monitoring and establish how they integrate it successfully into their approach to self-management.

Interpretation

Although the recommendations use words like ‘it should only be provided’, they are open to interpretation so that anyone with Type 2 diabetes who wishes to, could be allowed to monitor their blood sugars at home without having to buy strips - it just requires some thought...

- ► Using point 1, recommendations that everyone with diabetes must be offered an educational programme are already in place, in which case everyone should be allowed the opportunity to test their blood sugars at home! If a structured educational programme has not been offered to you, then ask for one then make the choice to test.
- ► Someone on diet only treatment who uses test strips to find out

the effects various types of carbohydrate have on their blood sugars could use points 2 and 4 above.

- Some people test their blood sugars because it gives them a feeling of security but are denied test strips through the NHS, could use point 4. This where Point 5 is essential so that staff look beyond costs and understand the needs of people with diabetes.
- Everyone with diabetes should have a care plan under the National Service Framework and government promised that everyone with a long-term condition will have a care plan in place by 2010 – in which case use points 2 and 3.

So where there is a will there is a way! If you have Type 2 diabetes and don't receive the test strips on prescription that you need, don't be afraid to argue your case using this latest report – it was commissioned by the National Clinical Director for Diabetes so should carry weight.

Common sense approach from Canada

The Canadian Diabetes Association [CDA] 2008 Clinical Practice Guidelines for the Prevention and Management of Diabetes state: "For individuals treated with oral anti-hyperglycemic agents or lifestyle alone, the frequency of SMBG [self monitoring] should be individualized depending on glycemic control and type of therapy and should include both pre- and postprandial measurements." The CDA recently stated "Arbitrarily restricting access to a set limit of strips is contrary to these guidelines and interferes with the ability of physicians and patients to develop an individualised treatment programme."

The important message here?

The frequency of blood glucose self monitoring should be individualized depending on glycaemic control and type of therapy. Of course it should – there are over 2 million people with Type 2 diabetes, they are not all alike and they don't have the same needs, so why keep trying to make a policy to suit everyone? We know the answer is money but any increases in complications as a result of not testing cost money too!

Eu Commission Moves Pharmaceutical Products And Medical Devices To Health, Where It Belongs!

In November 2009, the EU Commission confirmed that the authority for pharmaceutical products and medical devices will be moved from the Directorate-General Enterprise and Industry to the health and consumer-focused, DG SANCO – in other words from industry to health.

The Drugs and Therapeutics Bulletin [Feb 2010] expresses the view that the approach taken by the Enterprise and Industry Directorate appears to have favoured drug companies' profitability and competiveness at the expense of public health. IDDT and health campaigners have long since believed that medicines and medical devices are automatically linked to public health rather than industry which has commercial goals. The hope is that this shift will put patients at the heart of European policy making on medicines and medical devices.

Members of IDDT may remember that the UK Health Select Committee Report on the influence of the pharmaceutical industry at which IDDT gave evidence in 2004, recommended that the responsibility for medicines should be moved from the Department of Trade and Industry to come under the authority of the Department of Health. This was not accepted by the UK government, so we welcome the EU Commission decision and hope that the UK will now come in line with European policy.

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Errors And Failures

A study published in December 2009 and commissioned by the General Medical Council [GMC] has shown that one in 10 hospital prescriptions contains an error. Although the errors ranged from minor to serious, very few would have caused serious harm. The study also showed that newly qualified doctors were no more responsible for mistakes than the more experienced doctors. Consultants made the fewest mistakes.

The vast majority of the errors were picked up and corrected before reaching the patient. More than half involved errors in which the patient's medication was not prescribed on admission, during a re-write of a prescription or when the patient was sent home.

However, 40% were due to writing being illegible or to ambiguous wording. One suggested cause of errors is that paper and electronic prescription forms are different in different hospitals, so errors can occur as doctors move between hospitals. The GMC wants to see standardisation of prescription forms within the NHS – something Wales introduced in 2004!

And in diabetes in particular?

Researchers from Liverpool University looked at 75 hospital prescription charts of people with diabetes and found that in 5% of them, the use of doctors' own abbreviations and hastily written notes could easily be misread by nursing staff. One in six charts had prescription errors, one in three did not have the correct timings for insulin injections, the majority were illegible, a few were not dated and some were not signed by the prescribing doctor. The lack of a signature means a delay in administering the insulin. The lead researcher commented "Our audit has demonstrated an unacceptably high percentage of errors. A misunderstanding from an abbreviation for insulin units could have serious if not fatal consequences. For example, a doctor should prescribe insulin as "10 units" at a specified time, if written as "10 I U" or "10 I units", this could be easily misread as 101 units." Clearly such an error could be fatal."

There are guidelines in place on writing correct prescriptions and after this audit Liverpool hospital undertook intensive training of all their junior doctors.

Medication errors reported to IDDT: one of the disturbing errors reported to IDDT is prescribing the wrong insulin. The most recent was from someone who had been put on to insulin for the first time in hospital and therefore did not know about different insulins. The hospital prescribed Humalog Mix 25 but the prescription he was given by the GP was for Humalog. Only after struggling for 2 years and numerous visits to the GP practice was the error discovered! Eventually 'someone' from the practice phoned him to apologise but after 2 years of difficulties and hypos, an apology on the phone, and not from the doctor, did not seem good enough.

What can you do, to prevent errors happening to you?

Some hospital wards will allow you to do your own injections and manage your diabetes yourself as soon as you are well enough but if the hospital does not give you the opportunity to do this, ask to do it and point out that this is what you do every other day of the year. If you are not well enough or you are really not allowed to do your own injections, ask to see the insulin and injection dose before it is given. If you do your own injections, you can also make sure that your injections coincide appropriately with when the meals arrive – another frequent problem for people with insulin requiring diabetes when they are in hospital.

Research in Australia found one answer to reduce medication errors in hospital was for patients to take their medication with them, so this is worth remembering too.

Recommendations to doctors about errors - Safety Agency says GPs should apologise

According to a report from the National Patient Safety Agency [NPSA] issued in November 2009, if NHS patients receive a prompt apology when mistakes are made it might reduce the number of complaints and legal actions. However, the chief executive of the NPSA is quoted as saying that apologies go against a culture in which "making a genuine apology after an error has occurred is very hard to do for any clinician."

The NPSA runs a voluntary system under which trusts can report mistakes with the aim of learning from them to improve standards of care in the future. In the 6 months before the report, the NPSA dealt with 500,000 mistakes, of which 5,700 were classed as 'serious', resulting in death or permanent harm. Accidents and errors in treatment and medication were the most common.

And the failures?

- **Three quarters of NHS trusts are not complying with safety alerts**

On February 16th a report by Action Against Medical Accidents stated that around 300 health trusts in England have not complied with at least one safety alert by the set deadline. 80 Trusts admitted that they had not complied with 10 or more alerts. The alerts are issued to tackle problems which cause injury or death to patients and NHS Trusts are required to take action. 53 patient safety alerts were issued by the National Patient Safety Agency between 2004 and 2009.

The alerts included one on injectable medicines issued after 25 deaths and 28 cases of serious harm were reported between January 2005 and June 2006. Others included hand-washing to prevent the spread of infections and action to avoid feeding tubes being fitted incorrectly. The Department of Health said it expected all NHS Trusts to comply with safety alerts and record and action them. They will be issuing all NHS organisations with a formal reminder of their obligations to do this and from April 2010, the Care Quality Commission will have increased powers to monitor incidents and ensure compliance with alerts.

- **High value thefts in the NHS**

Health officials have launched an investigation after figures revealed that more than 57 'high-value' thefts have taken place at NHS Trusts in the past 5 years. Apparently a high-value theft is one valued at over £20,000. The 57 include mobile scanner units, ambulance satellite navigation systems and even over 100,000 litres of laughing gas!

News From Nice

Guideline for Type 1 diabetes is not going to be updated

Here is a statement from NICE, the National Institute for Health and Clinical Excellence: "***The review and update of the NICE clinical guideline on type 1 diabetes will not be going ahead as planned. A review of the evidence by an independent expert has shown that only one recommendation (use of aspirin for primary prevention (NICE recommendation 1.10.2.3)) could potentially be affected by new evidence. Following discussion at Guidance Executive, NICE considers that an update is not necessary at this time.***"

So the next review will be in 2013.

The new aspirin recommendation is that people with diabetes over the age of 50, and some younger people, should no longer be routinely prescribed aspirin. Evidence suggests that aspirin can reduce the risk of cardiovascular disease in people with diabetes who have a history of this problem but the increased risk of bleeding associated with the use of aspirin may outweigh any potential benefits in people who have no history of cardiovascular disease. If you are taking aspirin, you should discuss this with your doctor.

Foot ulcer dressings all the same

Research has found that there is no superior type of dressing for diabetic foot ulcers, a result that could save the NHS millions of pounds. About 15% of people with diabetes will get foot ulcers with around half of these taking more than 6 months to heal.

There are a large number of products on the market for the treatment of chronic diabetic foot ulcers and these range from simple inexpensive ones to sophisticated and costly ones. However, in a trial the National Institute for Health Research Health Technology Assessment (NIHR, HTA) found there was no clinical difference between three different types of dressings - a simple dry dressing, a dressing which is impregnated with iodine, and a modern hydrofibre dressing.

Let us hope the NHS takes note of this research and puts the money saved to good use.

NICE issues partial recommendation for Victoza

In it's preliminary recommendations, the UK's National Institute for Health and Clinical Excellence (NICE) is only partially recommending the use of Novo Nordisk's Victoza [liraglutide] for Type 2 diabetes. It recommends use only for very obese patients and not in higher doses. [Feb 15, 2010]

Victoza works by stimulating the beta cells to release insulin only when blood glucose levels are high. It is similar to Lilly's Byetta as both are GLP-1 inhibitors and are injected once a day. GLP-1 is a natural hormone and in people with Type 2 diabetes GLP-1 secretion is often impaired.

The NICE preliminary recommendations state:

- ► Patients who are already taking combinations of tablets to treat their diabetes and still have poor blood glucose control should be offered Victoza in addition, but to be eligible for it, they must also be very overweight, with a body mass index (BMI) of 35kg/m2 and over. [This stipulation is not on Victoza's European Public Assessment Report.]
- ► People with Type 2 diabetes who have a BMI below 35kg/m2 could also benefit from the drug if its use could help to achieve levels of weight loss that could be beneficial in treating other conditions caused by being obese. But even then, Victoza should only be continued if the patient has a reduction in HbA1c of at least 1.0% and a weight loss of 3% of initial body weight after 6 months use.
- ► NICE is not recommending Victoza for use in dual therapy or in the higher 1.8mg daily dosage.

NICE noted a lack of research on patients with lower BMIs which has been requested from the manufacturer and they also said there was a lack of short-term information and research comparing Victoza with other diabetes drugs. In other words NICE felt that there was insufficient evidence to recommend it except under the above conditions.

These recommendations are very similar to those for Byetta.

And abroad……..

Views on Victoza in France

The French prescribing journal Prescrire says that Novo Nordisk's Victoza in Type 2 diabetes "contributes nothing new". They stress that Victoza does not offer advantages in terms of diabetic complications, weight loss, or incidence of nausea at the start of treatment. They also say it does not offer any advantages in terms of risk of pancreatitis and that a few cases of thyroid cancer appeared during the trials, which was not the case with Byetta. They conclude that it is more "prudent" to stick with Lilly's Byetta as Victoza is slightly more likely to cause hypoglycaemia than Byetta.

And in America…….

The FDA, the drug regulatory authority in the US, has given Novo Nordisk permission to market Victoza and it can be used on its own or with other Type 2 diabetes tablets in the basis that the benefits outweigh the risks. However, the FDA is not recommending it as first line treatment until additional studies have been completed as they have concerns about what they describe as complex safety-related issues.

- ► In animal studies, the medicine in Victoza caused rats and mice to develop thyroid tumors, some of which were cancerous. The FDA states that it is difficult to extrapolate studies in animals to humans so they have exercised their authority and require additional studies in animals and the establishment of a cancer registry in humans to monitor the annual incidence of medullary thyroid cancer over the next 15 years. This is in addition to a cardiovascular study to evaluate the cardiovascular safety of Victoza in a high-risk population,.
- ► They warn that Victoza should not be used if 'you or any member of your family has a type of thyroid cancer called medullary thyroid cancer or if you have Multiple Endocrine Neoplasia syndrome type 2', a disease where people have tumors in more than one gland in their body. They also advise

that you should tell your healthcare provider if you are taking Victoza and you get a lump or swelling in your neck, hoarseness, difficulty swallowing, or shortness of breath.

- The FDA also advise that you tell your health professional if you have had pancreatitis, gallstones, a history of alcoholism or high triglyceride levels and you should stop taking Victoza immediately if you have severe pain in your stomach that will not go away as this may be the symptoms of pancreatitis.
- The risk of hypoglycaemia is higher if you take Victoza with another diabetes medicine, such as a sulfonylurea and the most common side effects with Victoza include headache, nausea, and diarrhoea. Nausea is most common when first starting Victoza, but decreases over time in most people.

As with all new drugs, it seems a cautious approach to Victoza is the best way forward and the FDA advises doctors to carefully review the prescribing information to decide on its suitability for each individual patient.

Psychological And Emotional Needs Of People With Diabetes

Although people cope with living with diabetes, it is estimated that 40% have what is classed as poor psychological wellbeing – depression and anxiety being the most common. Eating disorders are also a fairly common problem.

There has been a lot of research into depression and anxiety in people with diabetes and it has been assumed that this is much more likely to apply to people with Type 1 diabetes. However, a recent study [Practical Diabetes Int, Jan/Feb 2010] suggests that nearly half of people in a hospital clinic who completed several questionnaires reported some level of psychological disturbance.

It is worth noting that when the people in the clinic were asked to enter this study, those with retinopathy were twice as likely to respond, 20% of respondents returned an incomplete questionnaire and nearly half of those sent the questionnaire did not respond at all. So the study cannot be seen as a measurement of the numbers of people with some psychological disturbances but more a measure of the types of problems people with diabetes experience. Indeed, living with any chronic conditions incurs problems such as depression, anxiety and simply being tired of living with the condition.

Please forgive some of the expressions used in writing about this study but they are used by the researchers and may well not be used by those of us who live with diabetes.

Some of the findings in the study were contrary to previous thinking:

- The numbers with some form of psychological ‘disturbance’ were about the same for people with Type 1 and Type 2 diabetes.
- The only exception to this was that the number of people with Type 2 diabetes with eating disorders was 22%, nearly double that of the group with Type 1 diabetes – again not expected.
- Overall, 36% of the study participants had moderate to severe levels of depression, anxiety or both.
- Although previous studies have shown an association between depression / anxiety and poor glycaemic control and diabetic complications, this study showed only a weak relationship between anxiety and HbA1cs in people with Type 1 diabetes. No other significant relationships were found in patients with either Type 1 or Type 2 diabetes.

Living with diabetes is not simply a matter of knowing how to manage your diabetes, or your child’s diabetes, sometimes the stresses and strains of everyday life and managing diabetes are just too much and support or sometimes just a listening ear is needed.

As the findings of this study show a significant frequency of psychological disturbances, the authors recommend that their findings be used to support applications for funding diabetes-specific psychological services for people with diabetes.

An excellent recommendation but we know that help and understanding is not always available so just when will we something happen? It has been recognised for many years that diabetes-specific psychological support is essential for some people with diabetes.

Health Minister, Ann Keen answers a Parliamentary Question by Mark Hunter MP [300860, November 2009]
"We have not made any recent assessments into the adequacy of either psychological support or education for people suffering from (i) Type 1 and (ii) Type 2 diabetes. It is for primary care trusts to commission comprehensive diabetes services that meet the needs of the local population.

We recognise the important role emotional and psychological support has in enabling people with diabetes to self-manage their condition on a day-to-day basis. The Department is working with NHS Diabetes and Diabetes UK to identify what needs to be done to enable the National Health Service and local care services to meet the psychological and emotional needs of all people with diabetes." She goes on to add that the Department of Health and Diabetes UK have been working with NHS Diabetes since 2005 'to find ways to increase the spread of patient education programmes.'

IDDT comments:
There are two points that need making. Firstly, wasn't it a brilliant idea on the part of politicians to make local Primary Care Trusts [PCTs] responsible for providing services, whether for psychological or any other services. It's a form of divide and rule - every time we raise important issues about a lack of some service, the government gets a way with the answer that it is down to PCTs to commission them according to the need of the local population! It's impossible to campaign nationally to bring about improvements and very difficult for local people to get together locally to fight their PCT. So nothing much happens!

The second point that just has to be made is the admittance on the part of a Minister that the Department of Health and Diabetes UK have been working since 2005 to find ways of increasing availability of patient education programmes. That's 5 years! It is time that a fresh look was taken as it seems they are finding this an impossible task.

Benefits – The Green Paper Becomes A White Paper

In our IDDT's October Newsletter we informed members that we had joined with other charities to raise serious concerns about the Government's green paper which revealed plans to abolish Attendance Allowance [AA] and leaves the way clear to end the care component of the Disability Living Allowance [DLA]. This will affect millions of people including some with diabetes and so we asked members to write to their MPs to let them know that they, and we, are unhappy with the proposals. We are grateful to all our members who took this action as without it, MPs would have been unaware of the strength of feeling amongst people when the proposals went before Parliament as a White Paper.

A great deal was achieved and sufficient pressure was raised so that Health Secretary, Andy Burnham announced, "I can state categorically that we have now ruled out any suggestion that DLA for under-65s will be brought into the new National Care Service."

However, while this appears to have forced the government to rule out the option of taking away DLA for the under-65s, it has also put them in a position of admitting, albeit by omission, that DLA for those over 65 and AA is still under threat.

It is now a question of waiting to see what happens.

Should We Go Back To Basics - Do We Need

A Re-Think?

There have been two recent press releases about children with Type 1 diabetes that have to give rise to concern – the incidence of retinopathy in young people and the numbers of hospital admissions with diabetic ketoacidosis. Then an article in the British Medical Journal discusses how the treatment of Type 2 diabetes has been over medicalised, over diagnosed and influenced by the pharmaceutical industry without looking at the long-term effects of such policies. So is it time to go back to basics?

Figures for children with Type 1 diabetes must raise some questions

► Retinopathy

Surgeons in Wales are having to give laser treatment for retinopathy to patients in their late teens and their 20s who are 'struggling to control their diabetes'. Retinopathy, damage to the blood vessels in the eye, is normally seen in older people and/or those who have had diabetes a long time. Doctors are worried that patients are developing retinopathy at a younger age.

Consultant Ophthalmologist at Cardiff University Hospital, Dr Roger McPherson, told the BBC: "We are seeing it in younger and younger patients and I am getting a steady stream of people in their 20s and even their late teens." The Diabetic Retinopathy Screening Service for Wales also said that they have seen a worrying rise in children developing problems.

It is thought that poor management of diabetes and/or ignoring advice on diet and lifestyle are the main reasons for the rise in retinopathy. In addition, young people may ignore the symptoms if they only affect one eye. While this may be a partial answer, there are some very pertinent questions that need to be asked.

If poor management is the cause of the increase in retinopathy why is this happening now?

In years gone by, there was less knowledge, less help and support from specialist nurses, no home blood glucose monitoring and no HbA1c test. Diabetes control was largely guesswork, so why is there more retinopathy in young people now?

Are the present daily multi-dose regimes and frequent testing too much for this age group?

Conforming to all that is required of young people with Type 1 diabetes has always been a problem for them, but is conforming to today's more complicated insulins and multi-dose regimes just asking too much of young people? Are they giving up trying, do they not understand what to do or does it simply take too much time out of their busy lives that could be spent with their friends?

Is aiming for tight control and the resulting increase in serious hypos the cause of 'poor' control?

It is well proven that tight control as required by today's target blood sugars leads to more hypos and it is well known that treating hypos often results in high blood sugars. So is the increase in hypos, and subsequent highs, responsible for more erratic blood sugars which is classed as 'poor control'?

Raising the age-old question, but it has to be asked, are we seeing the effects of the long-term use of the human, synthetic insulins?

The early trials of human insulins did show an increase in risks of hypoglycaemia and in some cases, in retinopathy. These findings were never really independently explored, so are we now seeing the effects of long-term use of synthetic, human insulins?

► **3,300 emergency admissions of children with diabetes**

Latest figures for England show that there were 3,300 cases of children with Type 1 diabetes admitted to A & E departments with diabetic ketoacidosis [DKA] during the year beginning in April 2008. DKA occurs when blood sugars are too high and it is a serious condition that needs immediate treatment to prevent coma.

During the year, children and young people under 18 accounted for about a quarter of the 13,465 emergency admissions for DKA. The number of admissions with DKA has risen by nearly 9% since 2006. Of course, there is an increase in the numbers of children being diagnosed and it could be that Type 1 diabetes is not being diagnosed early enough, but neither of these factors would account for so many cases. Thus, there must be an increase in children already diagnosed who are being admitted for DKA. Why?

As is frequently said, it could also be the result of diabetes specialist nurses staffing levels being reduced but as stated earlier, people managed years ago without all the present systems, so this gives rise to many of the questions raised for retinopathy:

Are the regimes too complicated and hard to understand?
Do children get fed up of the amount of testing and injecting and simply not do it?
Do multi-dose regimes lead to more erratic blood sugars?
Are the synthetic human and analogue insulins really working for this age group?
Is there an increase in unaware hypos and therefore more erratic blood sugars?

These are some very basic questions but they actually do need answering. It is not sufficient to simply make demands for more NHS resources without looking at all the possible causes. Studies may show that tight control, multi-dose regimes and frequent testing improve blood glucose control but do they in real life? Should we look at more basic facts about what is acceptable to children and young people, what they feel they can cope with and what gives them the best quality of life?

Treatment of Type 2 diabetes raises some questions too

'Bad medicine: Type 2 diabetes' by Des Spence, a GP from Glasgow, was published in the British Medical Journal [March 3, 2010]. While describing diabetes as 'industry's golden goose', he raises basic issues with an honesty to be admired.

In saying that the numbers of people with Type 2 diabetes is predicted to double over the next 20 years, he quotes the much used expressions that diabetes is a 'ticking time bomb' with GPs berated for the undiagnosed 'missing millions' [expressions no doubt developed for advertising campaigns].

He says that the rationale for detection and treatment of Type 2 diabetes is to prevent cardiovascular and microvascular disease and that these studies promote aggressive control of blood glucose levels [HbA1cs], blood pressure and cholesterol with the belief of 'the lower the better'. This in turn means that people with Type 2 diabetes are potentially prescribed 3 drugs to control blood sugars, 3 drugs to control blood pressure, two drugs for cholesterol, aspirin and ultimately insulin.

This is polypharmacy [when numerous drugs are prescribed] and is rarely a good idea as there appears to be little research into complications or possible interactions of a lifetime of treatment with so many drugs. He makes the following points:

- Polypharmacy is the "expressed state policy for treatment of Type 2 diabetes, ruthlessly enforced through national decrees" and he questions whether this is good medicine.
- Marketing of new drugs exposes patients to unknown adverse effects and that despite having no information about mortality rates, new drugs are widely prescribed on an unscientific extrapolation of lowering HbA1cs. [Where have we heard all this before – yes, it is what IDDT said about human insulin over 15 years ago!]
- The culture of targets is too restrictive and reduces patients to little more than numbers.
- There has been a creeping towards over-diagnosis with terms like "prediabetes" and "impaired glucose tolerance," resulting in many patients who don't have diabetes being treated as

> if they did. Diabetes isn't just poor medicine for these reasons but because of the anxiety that it causes millions of people.

His view is that diabetes is the industry's golden goose: a large population, lifelong treatment, and a bonanza of drugs. He cites the recent Diabetes UK Professional conference as a platform for "sponsorship from big drug companies, whose logos emblazon the official literature for a mere £50,000. Also, NHS consultants are oiled by pharma's money to educate others about diabetes."

His suggestion? It's time to address the issue of obesity and for doctors to advocate for health rather than be paid advocates of big pharma.

BMJ 2010;340:c1216

* * *

More About Eyes

Eye drops after a cataract operation and blood glucose levels

Here is a letter from one of our members, Mrs J.T. which raises an issue that may well be important for other people who have cataract operations.

"I have a query about Betnesol eye drops I was given after a cataract operation. I had my first cataract operation 4 years ago and had no adverse reaction whatsoever to the eye drops prescribed after the procedure but the drops were different. However, this time I was given Betnesol [4 times a day for 4 weeks] and I have found that I had to up my insulin intake by at least a quarter to maintain anything like reasonable blood sugar levels. The first two days after the op my blood sugars were up at 17 but on speaking to the helpline, I was told this could be a reaction to the trauma of the operation. However, 6 days later I have virtually had to double my insulin dose at each daytime dose. There is no mention of raised blood sugars on the Patient Information Leaflet but when I went on the internet, I did find that Betnesol increases blood sugars but on making another call to the Helpline, I was told that the strength of the drops should not cause this problem. I am supersensitive or have other people experienced similar problems?"

The explanation

Betnesol contains the active ingredient betamethasone sodium phosphate which is a corticosteroid and is being used, in this case, as an anti-inflammatory to decrease the risk of inflammation in the eye after the cataract operation. In fact, all steroids can and very often do affect blood sugar levels and it is surprising that Mrs J.T. was not advised of this. Using a very reliable website, www.netdoc.co.uk gives the following information about Betnesol:

- ► Raised blood sugar levels are at the top of the list of side effects and this can apply to anyone using Betnesol.
- ► Diabetes, or a family history is in the list entitled 'Use with caution'.
- ► People with diabetes may need to increase their dose of insulin or antidiabetic tablets.

Clearly Mrs J.T. is going to have to be very careful when she stops taking the drops drops because she is on nearly double her normal dose of insulin and when stopping Betnesol, her blood sugars are going to change and she runs the risk of having low blood sugars and unexpected hypos. It would be advisable for her to talk to her doctor about what to do.

So if you are having a cataract operation be aware of these possibilities if you are prescribed Betnesol.

By the way….do you have to use eye drops?

Most people who have glaucoma [raised pressure in the eye] require life-long treatment with eye drops to lower the intra-ocular pressure and prevent further vision loss. It can be quite difficult to put in eye drops so that they don't run down the cheeks but there is a product called Autodrop to help. This is attached to the eye drop bottle to ensure that the bottle is held over the eye at the correct angle so that the dose is delivered in the right place. The cost is £2.92 [incl VAT] and they are available from Owen Mumford's Medical Shop, to order contact: 0800 731 6959 or order online at www.medicalshop.co.uk

New treatments for treating diabetic macular oedema on the horizon

Implant for treatment of diabetic macular oedema - macular oedema [fluid retention] is a form of retinopathy which affects the part of the eye that provides the fine vision. It is difficult to treat with laser but recent research has shown that an implant which delivers microscopic doses of fluocinolone acetonide can make significant improvements that last for up to 30 months when the drug runs out.

The implant is about the size of a grain of rice and is inserted into the vitreous, the jelly-like substance in the centre of the eye, where it is delivered in tiny doses every day.

In the study, more people who had implants had a 3 line improvement in their visual acuity compared with usual treatment. However, the implant had side effects – a high proportion of those with implants required a cataract operation and over 60% developed raised pressure in the eye. Nevertheless, the researchers say that the implant is effective at treating diabetic macular oedema. [Presented at the Retina Congress 2009, Dean Eliott, MD, Doheney Eye Center, California]

Drug possibility for diabetic macular oedema - Lucentis [also known as ranibizumab injection] is presently used to treat age-related macular degeneration. Research carried out in people with Type 1 diabetes suggests that it may be effective in treating diabetic macular oedema. The drug works by blocking the effects of a protein called VEGF which causes the tiny blood vessels to leak and new vessels to grow. Applications for approval for use in the treatment of diabetic macular oedema have been sent to the European Medicines Agency [EMA] and the Food and Drug Administration [FDA] in the US and if the drug is approved, it could be a major step forward.

Steroids may slow progression of proliferative retinopathy but…
Proliferative retinopathy is the development of new, unwanted blood vessels on the retina which can leak and damage vision. Researchers have found that injecting corticosteroid into the eye may slow the progression of proliferative diabetic retinopathy and macular oedema but they increased the risk of glaucoma and cataract, so laser treatment still remains the best option. [Archives of Ophthalmology, December 2009]

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Weight Loss Drug Should No Longer Be Prescribed

22.01.10 The European Medicines Agency [EMA] has recommended that the weight loss drug Reductil [silbutramine] should no longer be prescribed by doctors or dispensed by pharmacists as its risks of causing heart attacks and strokes outweigh its benefits. One of the advisory committees has recommended suspension of the marketing authorisation for the drug in all countries in the EU. The Agency is recommending that doctors should not issue any new prescriptions and pharmacists should not dispense Reductil. People already using Reductil should see their doctor to discuss an alternative but it is safe to stop taking the drug before their appointment if they so wish.

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The Safety Of Analogues And Lantus

Launch of major research programme

In September 2009, the manufacturers of Lantus, Sanofi-aventis, announced the company's action plan to provide methodologically robust research that will contribute to the debate over insulin safety, including insulin analogues and Lantus [glargine]. The research programme is designed to provide more information on whether there is any association between cancer and insulin use and to assess if there is any difference in risk between Lantus and other insulins. The plan is designed to give short- and long-term results.

Subsequent comments…

Publication of research in Diabetologia resulted in statements from drug regulatory authorities in Europe and the US that a link between insulin glargine [Lantus] and cancer cannot be confirmed or denied, largely because there is a lack of evidence – in other words, the research has not been carried out.

Regular readers will remember that IDDT was one of the few organisations that sent all this information about the studies and advice from the editor of Diabetologia to our members so that they could make an informed choice of treatment. Having said this, the fact that there is insufficient evidence to be able to conclude that Lantus and the other analogues are safe, is hardly an informed choice but the best we could do!

So we are left wondering why research has not been carried out and why the Sanofi-aventis failed to publish all their information to answer what appears to be the key question - does Lantus promote growth of pre-existing tumour cells compared to human insulin? According to an article by Stumvoli and Nawroth [Diabetologia 2009 52:1987-1989], the answer is simple:

- ► This research was not required to gain marketing approval for Lantus.
- ► It was considered not necessary because opinion leaders have been willing to recommend it and doctors to prescribe it on the basis of circumstantial evidence data showing that it improved quality of life and reduced hypoglycaemia.

So no one was bothered about other important outcomes – like morbidity and mortality. This is reminiscent of the 1980s and the introduction of human insulin when studies to compare mortality or morbidity rates with human and animal insulins were not done. These are very important issues for patients!

However, today this is even more surprising given all the recent disputes and settlement claims over various ‘blockbuster’ drugs that have turned out to cause harm. The lesson that evidence rather than assumption is necessary does not seem to have been learned!

Stumvoli and Nawroth say that “companies must ensure that early stage preclinical testing should include safety aspects over and beyond the legally required toxicology studies. They point out that the problems that have arisen with Lantus apply across the field of drugs and healthcare once more leaving the patient alone. Physicians are caught between conflicting forces of suspicion and company interest, emotions and personal relationships with drug company reps, colleagues and scientific associations. At the same time, shareholders lose money and confidence while companies lose trust, image and money.”

They also point out that the problem now occurring with Lantus is of the company’s own making and one that the scientific community has failed to prevent. They suggest that there should be a rethink and reorganisation of the various relationships mentioned above in drug development and marketing to achieve better patient care and safety.

Praise for the editors of Diabetologia

There was a great deal of criticism levelled at Diabetologia and the editors for publishing the studies about the risk of cancer and Lantus on the basis that they caused alarm. As readers know, IDDT praised them for informing patients and doctors of possible risks so that they could decide whether or not to take those risks. However, they were accused of causing unnecessary alarm.

How can alarm be unnecessary when the facts speak for themselves – as the regulatory bodies acknowledged that the risks cannot be confirmed or denied. In other words they don’t know.

It was pleasing to see an editorial in the journal Diabetes [Vol 58, November 2009] praised the editors of Diabetologia for taking the extraordinary steps of soliciting additional studies from several countries when they received the initial paper reporting an increased incidence of cancer in people using Lantus. The editorial refers to ‘harshly worded statements published rapidly after the Diabetologia articles’ citing “Insulin glargine and malignancy: An unwarranted Alarm” in The Lancet and “Insulin Glargine and Cancer – An Unsubstantiated Allegation” in Diabetes Technology & Therapeutics.

We have to agree with the views of Diabetes and give praise for the careful way that this issue was handled. It is an unanswered question that should not be swept under the carpet simply because it is uncomfortable, embarrassing to those who sing the praises of Lantus or because it is likely to cause alarm. If science had done this over the centuries where would we be today?

Protecting Insulin Producing Cells

Rituximab is a drug used to treat non-Hodgkin’s lymphoma and rheumatoid arthritis but research in the US has shown that it can protect the insulin producing cells in new onset Type 1 diabetes. This could help people with Type 1 diabetes to keep producing some of their own insulin.

In phase 2 trials, 87 people with newly diagnosed Type 1 were give rituximab or a placebo [dummy] at one week intervals for 4 weeks. C-peptide levels are an indicator of how much insulin the body is making and after a year C-peptide levels were higher in people taking the drug compared to those taking the placebo. Those taking the drug also needed smaller doses of injected insulin.

From Our Own Correspondents

Related issues - dry skin and cholesterol treatment

Dear Jenny,

Thank you for the newsletter, as always it is interesting.

I’d like to comment on two separate but related issues you mentioned. The first is dry skin. This used to be a problem for us, Colin’s skin had become extremely dry especially on his feet and legs. We tried emollient creams etc but the benefit was very short-lived and the underlying problem continued. However, since we increased his dose of fish oils to 4 large capsules a day of a brand that’s particularly high in omega 3 fatty acids, the problem has disappeared. He hasn’t had dry flaky skin for a couple of years now – and he’s into his 60th year of insulin-dependent diabetes.

The high dose of fish oil has other benefits too. He was unable to tolerate statins and his cholesterol levels had begun to rise alarmingly. Now, he takes a nutritional supplement called Sytrinol (Solgar) to reduce his cholesterol without side-effects, and because of his high omega 3 intake, the ratio of good to bad lipids has improved to such a level that both his GP and his consultant are happy! He now requires no medication whatever to control cholesterol.

I think your readers should be aware that any product that reduces cholesterol by inhibiting absorption of fats will tend to reduce the fatty acids they need for good health and therefore could do more harm than good – even if they do control cholesterol levels. It is much more beneficial overall to correct these problems by nutritional means; the good fats are essential for healthy skin, joints, connective tissue, cardiovascular function and to protect against depression. I recommend avocado, olive oil, nuts, seeds and fish as well as fish oil supplements.

Arabella Melville

More children become clinically diabetic during winter

Dear Jenny,

I take the liberty to comment on “more children diagnosed in winter” IDDT, January Newsletter, page 11 – citing Diabetic Medicine, Aug. 2009.

What is meant is “that more children become clinically diabetic during winter” due to infections which give the last blow to the beta cells, i.e. reaching 80% destruction. I would write “more children are diagnosed with clinical diabetes”.

It is also true that many children had their first trigger to start the autoimmune disease of Type 1 diabetes during autumn and winter by virus epidemics, years before the diagnosis is made, but this was not meant in the above article.

Professor Zvi Laron
Israel

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Statins will not go away!

Dear Jenny,

My diabetes is controlled by diet only and until recently I was taking a statin, Pravastatin, as a precaution against heart attacks. Looking back, I had early signs of problems in August 2008 but then in June 2009 a review identified an enzyme upset and cholesterol levels 3.4. So my Pravastatin was removed but this set in motion some serious side effects – severe loss of appetite, weight loss of 8pounds, bouts of shivering and shaking lasting about 4 hours and the vision in my right eye became impaired. Two ultrasound scans show a slightly enlarged liver and three gallstones – the consultant is of the opinion that having stopped the Pravastatin, normality will resume.

What bothers me is that the literature for patients on the downsides of statins never seems to mention specific problems such as the effects on the liver and enzyme upset. It is one thing to reduce cholesterol levels to avoid heart attacks but not at the expense of causing other problems that may be serious. I think that statin use should be carefully monitored over several months to highlight side effects that may be serious.

In my opinion Diabetes UK and IDDT should publish a major article on the possible dangers of statins and their adverse effects. It seems negligent for doctors and Government to blanket advertise statins as a universal remedy to avoid heart attacks without giving equal publicity to the side effects that can affect some people. Doctors must not regard a pill as a remedy without careful follow up procedures, especially in older people.

Mr W.M.
Midlands

■ ■ ■

I felt I must return to animal insulin

Dear Jenny,

My grateful thanks to you and Beverley for your help during the past years when I felt I must return to animal insulin. I had originally, in 1971, been put on animal insulin but was informed in 1982 that as animal insulin would no longer be available after the end of that year, I must change to human insulin. I did not like the idea but was told there was no choice, so while waiting for a major operation in hospital I was changed over to human insulin and given the operation the next day. What a risk!

I managed on this for some years but seemed to lose control. I was then put on analogue insulin but was not really happy with it from the start, with loss of hair, higher cholesterol levels and dangerously low blood glucose levels. So I asked my doctor for a change to animal insulin. He was reluctant to allow this, but after persevering and good advice from Beverley I succeeded in persuading him to allow me to make the change.

At my last clinic visit my cholesterol had come right down to 4.3, my blood pressure was 130/70 and my hair is increasing again. I then had to help my sister to allow her doctor to change to make the change as she had similar problems. Having been allowed to do so, she too is feeling much better.

Thank you for all the work you have done to keep animal insulin available in this country.

S.M.

Misinformation at its worst

Dear Jenny,

I read the letter title “Misinformation at its worst -- type 1 becomes type2!” with interest. I know that it is possible for type 1’s to develop some of the characteristics of type 2 including insulin resistance; however, I too have had a conversation with a nurse who told me that I, who am type 1 diagnosed in 1958 before my 11th birthday, could change into a type 2 and would need their expertise in handling type 2 problems.

As far as I can tell my insulin requirements are consistent with my weight [no insulin resistance] and I have never had a detectable C-peptide, whenever a C-peptide test has been done.

I also have an ophthalmologist who insists on putting type 2 on his reports mainly because of my current age. There is a danger in growing old with type 1 diabetes - you are not readily distinguishable from type 2’s who are in the vast majority. And while in the case of my eye doctor this makes very little difference, it does make a big difference if in treating an emergency or a surgical procedure insulin is withheld for too long.

By e-mail
USA

Diabetes National Service Framework – Six Years On

By Martin Hirst

The Department of Health (DoH) has released its report “Six Years On: Delivering the Diabetes National Service Framework”, which updates on the progress made since the National Service Framework (NSF) for Diabetes was developed in 2001. The NSF lays down twelve national standards of care that people with diabetes should expect. The standards include prevention, education, active self-management, health monitoring, care of children and young people with diabetes, emergency treatment, support through pregnancy and detection and management of long-term complications.

The report states that the NHS continues to make good progress in identifying people with diabetes and is able to identify earlier people with undiagnosed diabetes. This process has been aided by an increased focus on prevention through initiatives such as the NHS Health Check Programme and Change4Life.

Education

The report also highlights the shortfalls in the provision of a structured education programme for every person with diabetes through the delivery of Dose Adjustment For Normal Eating (DAFNE) and Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) courses, as recommended by the National Institute for Clinical Excellence (NICE). There are an estimated 300,000 people in the UK with Type 1 and yet there are only 15,301 people who have successfully graduated from a DAFNE course. With the basis of the NSF being active self-management then surely the failure to deliver structured education is not allowing people to have the opportunity to self-manage in an informed way. It also acknowledges that only 60% of people have an agreed care plan and that although this is an increase on previous years, further improvements are necessary.

Clinical Care

With regard to clinical care the National Patient Safety Agency (NPSA) recorded over 13,000 incident reports relating to insulin-related errors in hospitals and inpatient facilities between November 2003 and March 2009. The report, while not directly saying that this is unacceptable, acknowledges that improvements need to be made in this area.

Looking at the clinical care of children and young adults the National Diabetes Audit (NDA) showed that only 17.73% of this group achieved the NICE recommended HbA1c target of <7.5%. The report calls for all those involved in the care of this vulnerable group to urgently review how best to deliver these standards.

There also needs to be improvements in the quality of care that people with diabetes receive while in hospital with a view to improving the patient experience and reducing length of stay. Currently there is work being undertaken to develop best practice guidelines for ketoacidosis, hypoglycaemia and care before operations.

Complications

Similarly there need to be improvement in the detection and management of long-term complications, with particular focus on diabetic foot problems and diabetic retinopathy.

In summary

There continues to be year on year improvement in service delivery but increasing rates of diagnosis mean that increasing levels of resources will need to be allocated to diabetes care and service delivery will need to become more effective. If this were my school report then the headmaster's final comment would be "Does enough to get by but could do better".

The Impact Of The Recession

The recession has far-reaching consequences and affects not only those who are made redundant but also their families. People who keep their jobs may be on shorter working hours, have pay cuts or pay freezes. In addition to all this, families may have debts and house prices may prevent them moving house to try to alleviate the situation in some way. All of this can affect family relationships and so the recession is likely to cause more people to be anxious or depressed. People with diabetes are no exception to the effects of the recession but they are at greater risk of anxiety and depression affecting their diabetes and their blood glucose control. Among other things, stress tends to raise blood sugars and depression tends to lead to less motivation, lack of energy and loss of appetite, all of which can affect blood sugar control.

Seeking help

Ignoring the problems and hoping they will go away is not the answer, nor is just hoping they will go away. It is far better to seek help at an early stage and there are ways to do this.

- If any of the above symptoms occur then seeking help from your GP is probably the first thing to do. He/she will be able to offer you help with anxiety and depression and it may be that talking to him/her will clarify the most important concerns and enable you to take some practical steps. Your GP may be able to point you in the right direction.
- Calling the NHS Stressline is another option. Health advisors will listen, offer practical advice and put you in touch with people who can help, such as debt, housing and employment advisors or counselling and talking therapy services. Direction. The number is 0300 123 2000 and is open daily from 8am to 10pm.

- ► If you prefer not to phone, the Stressline website gives links to organisations that offer advice and help - visit the NHS Choices website www.nhs.uk and search Stressline.

IDDT has two free leaflets – ‘**Stress and Diabetes**’ and ‘**Diabetes and Depression**’. If would like copies, please contact IDDT on 01604 622837, e-mail enquiries@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS.

Benefits – if you need to know about state benefits and have access to the internet, then an excellent source of information is available at: http://www.benefitsandwork.co.uk/

And while talking about the recession – thank you
The Trustees at IDDT would like to thank everyone who is donating to IDDT during these difficult financial times. We know that it is hard and so we are particularly grateful for the help and support you are giving to IDDT.

The income for many charities has reduced by 10%, partly due to the fact that a proportion of their income comes from industry, which is making cut backs too. As readers know, IDDT has never accepted industry funding, so we have not lost anything! Many thanks for your continued generosity which enables IDDT to continue to grow and develop new ideas while maintaining prudent management of our funds. A big thanks also go to IDDT’s small staff who work exceptionally hard and with great enthusiasm to see that IDDT moves forward to help and support people with diabetes.

Diagnosing Diabetes With The Hba1c Test

Research [New England Medical Journal, March 2010] has shown that the best way to diagnose diabetes may be by using the HbA1c test, which is a measurement of blood glucose levels over the previous few weeks. People who had HbA1cs of 6% or greater were at higher risk of developing diabetes. [HbA1cs of 5.00 to 5.5% are considered normal.]

The study involved over 11,000 people with no history of diabetes. The HbA1c test identified more people who later developed Type 2 diabetes than did the fasting glucose test presently used. It also was a better predictor of the risk of stroke, heart disease and death from Type 2 diabetes. The HbA1c test also had advantages over the fasting glucose. Blood sugars can vary from day to day and hour to hour so the HbA1c test is more reliable, as it allows doctors to track average blood sugars over time, such levels are not affected by stress or illness. From the patient’s perspective, with the HbA1c test they do not have to fast.

In January 2010 the American Diabetes Association switched to using the HbA1c test for diagnosing and European authorities are considering a similar change.

HbA1cs are also a reliable way of diagnosing Type 1 diabetes in children and adolescents

Research has also investigated whether the HbA1c test was a reliable method of diagnosing Type 1 diabetes in children and adolescents. [Pediatric Diabetes, Feb 8, 2010] 184 children and adolescents with blood glucose levels over 11.1 mmols/l were included in the study – 84% had newly diagnosed Type 1 diabetes and 15.2% had transient hyperglycaemia.

The results showed that those with newly diagnosed Type 1 diabetes had HbA1cs between 6 and 14% and all had typical symptoms of high blood sugars – drinking and peeing a lot. In the group with transient hyperglycaemia HbA1cs were between 4.5 and 6.2% and none of them had typical symptoms of diabetes. All patients with HbA1c values greater than 6.35% had new onset of type 1 diabetes. In patients with HbA1c values less than 6.35%, the diagnosis of type 1 diabetes could be excluded. So the researchers concluded that childhood Type 1 diabetes can be diagnosed and excluded with high reliability using HbA1c testing.

Doctors express concerns
Pulse, the weekly GP magazine, reports that another study suggests that changing to diagnosis using HbA1cs could almost double the number of people classed as having diabetes [presented at Diabetes UK Conference in March]. Pulse comments that this would considerably increase the workload of GPs.

Assuming the research evidence shows that a move to diagnosing using HbA1cs is the most effective, the workload of GPs cannot be a reason for not making the change. However, as a patient organisation, we know that many people are now not receiving the recommended standards of care, so we are bound to express our concerns about the future care of people with diabetes. Planning to meet the demand for future services must take place - we cannot have a system where standards are lowered for everyone because of increasing numbers of people being diagnosed.

* * *

New Devices On The Market

MyGlucoseLevel.co.uk
MyGlucoseLevel.co.uk is a system for recording and charting blood glucose levels and is designed to help people to understand and manage their diabetes. A user of this system can record their test results any time and any place where there is internet access. Access can be given to nominated health professionals, such as diabetes specialist nurses, allowing them to view the results without the need for a hospital or GP appointment.

My Glucose Level is a secure, web-based recording system with no software to download or install. It was designed by someone with Type 2 diabetes who tests 4 times a day and decided he wanted to have something simple that would show his results in a way that was useful and made sense to him.

Arctic Medical supplies My Glucose Level in the UK. It is available from www.MyGlucoseLevel.co.uk from as little as £1.50 a month. **Arctic Medical have kindly offered IDDT members a two week free trial, all you need to do is include the code IDDT10 when ordering.**

Hypo-Fit
Hypo-Fit is another product supplied by Arctic Medical. It is a syrup that can be used to treat hypos and comes in three flavours - orange, tropical and mint. It is available on NHS prescription. If you would like to try Hypo-Fit, contact IDDT for a free Hypo-Fit Brill box – phone IDDT on 01604 622837, e-mail enquiries@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS.
More information about these products can be obtained by visiting www.arcticmedical.co.uk

One man's experience of road testing of hypoglycaemia symptoms monitor alarm [Model HAS-01]

By Johnny Prescott

I purchased one of these alarms in July 2009. I have had Type 1 insulin dependent diabetes for over 50 years and try, with mixed success, to keep my HbA1cs below 7mmols/l and I felt that anything that would warn of a pending night hypo must be advantageous. Thanks to this watch-like device we may have found a way of having a little more peace of mind at night.

On too many occasions in the past, I have been known to have had too many night hypos where I have fitted and blacked out – the trials and tribulations of being a type oner! However, these are very stressful occasions for my wife and family, in addition to the well-known risks of hearts attacks, choking and even death…and that's before the paramedics arrive….all a very nasty business!!

The ‘Hypoglycaemic Symptoms Monitor Alarm’ is about the size of a watch and is worn on the wrist at night. It is designed to indicate the symptoms of low blood sugars whilst sleeping. It does this by sensing the increased perspiration along with a drop in body temperature – the classic cold sweat symptoms of hypos. It does not detect or indicate blood sugar levels as there is no probe or anything that scratches or pierces the skin on the underside of the monitor – only 2 bevelled smooth sensors.

For the majority of people experiencing a hypo there is a drop in body temperature with increased perspiration but if you do not suffer from these hypo symptoms, the makers say that the monitor may not be for you.

I have worn the monitor on my right wrist nightly for the last 2 months and while it has gone off a few times because I was too warm – no bad thing as it has allowed me to do a check blood test anyway – it has actually gone off twice when my blood sugar had dropped to 3.3mmols/l and 3.9mmols/l at around 4.00am on both occasions – thus avoiding a hypo. So it does work!

The alarm itself sounds a continuous series of 4 beeps and vibrates as well in alarm mode. This is enough to awake up most deep sleepers. It wakes me up in time to do a blood test before a serous hypo sets in and I am still compus mentis enough to do it!

Therefore in conclusion, although I am no Jeremy Clarkson, I can say that I have rallied and raced this little device over the past 2 months and feel that it is worth the £69.00 asking price. [The manufacturers, Medpage offered to refund the cost in full after one month if I found it unsuitable, so you can’t be fairer than that.]

I believe that what this night time monitor gives is peace of mind, not only to myself but to my family. Of course it has limitations – it may not work every time so it cannot be relied on entirely and therefore the usual precautions of testing etc must be taken, but it has saved me twice to date and no doubt will do so again in the future. What price peace of mind for you and your family?
If you would like more information about the HAS-01 Alarm, the details are as follows:
Manufacturer: **Giant Biosensor www.giantbiosensor.com**
Distributed by: Medpage Ltd, www.medpage-ltd.com or phone 01536 264 869
NOTE: **IDDT is not advertising or endorsing these devices.**

Europe Takes Action Against Ageism In Drug Trials

A group of geriatricians in Europe has produced a charter against ageism in clinical trials. The EU funded project, PREDICT, says treatments are less likely to be tested on older people despite the fact that the elderly take the most medication.

Trials in younger people cannot always be extrapolated to the elderly – drugs may have different effects in various age groups and in different states of health. PREDICT wants older people to have access to drugs which have been shown to be safe and effective for their age group. A spokesman for the British Geriatric Society said that it is easier for drug companies to carry out trials [testing] on younger people but this means that the trial group is not representative. If treatments are not evaluated for elderly people, it is difficult for doctors to balance the risks and benefits in this age group.

PREDICT has found clear evidence that the elderly are underrepresented in trials eg the average age of patients in clinical trials for blood pressure treatment is 63 but 44% of patients are over 70 when they are diagnosed.

Results Of First Ever National Audit For Diabetes

A report in the Daily Telegraph [23.01.20] on the first ever national audit for diabetes says that one in five hospital patients have diabetes. The Telegraph reports that this demonstrates the ‘devastating impact’ of changes in British lifestyles.

The audit of NHS hospitals has found that 20% of patients on hospital wards now have diabetes, twice the proportion previously estimated which therefore, has a very significant effect on NHS resources.

The figures will be officially published later this year but it appears that there are 2.6 million people in the UK with diabetes and of these, 2.3 million have Type 2 diabetes in which nine out of ten cases are related to lifestyle causes, such as obesity, low exercise levels, smoking and alcohol use. Cases of Type 2 diabetes have doubled since 1996, in line with the rise of obesity and if rates of obesity continue to spiral, by 2025 treatment costs for more than 4 million people with diabetes could be a quarter of the NHS budget.

Dr Rowan Hillson, the National Clinical Director for Diabetes, who is leading the audit of 200 hospitals made the following points:

- All patients admitted to hospital with diabetes should be given access to specialist advice, whatever the reason for their admission, so complications are not missed.
- 20% of diabetes patients in hospital were not given their medication at the right time while 30% said staff had been unaware they had diabetes.
- There is evidence that the appointment of specialist nurses can reduce re-admissions of patients with diabetes, as well as reducing drug errors, and length of stay. However, only just over half of people with diabetes in hospital are seen by a specialist nurse.
- The best standards for foot care are where everyone with foot problems is referred to a team of specialists to ensure complex problems were not missed. However, this is not standard practice and foot care varies across the country. The number of people undergoing lower limb amputations because of ulcers caused by diabetes has doubled in the last 10 years to around 5,000. Vascular surgeon Professor Roger Greenhalgh, from Imperial College Healthcare Trust, told the Telegraph “The numbers of amputations are going up partly because of the increased prevalence of diabetes, but we are also finding that too many cases are not referred to specialists early enough”.

Is there anything we can do as patients in hospital?

Yes, we have to be vigilant and perhaps courageous enough to speak up. As patients or as carers we have to ask to see a specialist or a specialist nurse. If we have foot or leg problems, it is important to ask to be referred to a specialist.

Snippets

Coughs diagnosed by smartphone

Researchers have suggested that iPhones could be used for immediate diagnosis of coughs. A company has designed software that can identify respiratory illness from the sound of a cough and their researchers believe that the programme could be developed for use with a smartphone.

Australia adopts novel way to combat climate change

Australia is selectively breeding ‘green’ sheep that burp less. The Australian Sheep Cooperative Research Council reports that as 66% of greenhouse gases consists of methane from livestock, there is a need to study breeds that produce fewer emissions!

Plastic packaging revisited

Some years ago there were concerns that plastic packaging on foods caused harm but nothing much more was heard about it. Now a study by researchers at the universities of Exeter and Plymouth has shown that a chemical, Bisphenol A [BPA], commonly used in plastic packaging is associated with a 42% increased risk of heart disease and a 34% increased risk of Type 2 diabetes.

Affording food in the US

A survey by the Dept of Agriculture in the United States suggested that 49 million Americans could not afford the food they needed at some point during 2008. The severity of this situation has increased to a point where more children are now being exposed to malnutrition.

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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Tel No: ____________________

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From Your Editor – Jenny Hirst

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