INDEPENDENT DIABETES TRUST
Newsletter
September 2015 Newsletter, Issue 86
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Major review of Type 1 diabetes in children and adolescents

It is not unusual for parents to call IDDT to ask if their child can be 'forced' to change to 4 injections a day when they are doing well on 2 injections a day and don't want the change. A Review in The Lancet suggests the answer is clear – no, because available evidence does not show that any one regime is better than any other. Happiness and quality of life are important!

Fergus Cameron is leading researcher in diabetes in children and adolescents at Royal Children's Hospital Melbourne. His work focuses on the brain as a target for diabetes-related complications. He says, 'Now eye and kidney complications are rare for children with Type 1 diabetes, mental health disorders are now the main complication during Type 1 diabetes in childhood.' Later this year, his team plan to present MRI studies of children showing the effects of both high and low blood glucose on brain activity.

He co-authored a review in The Lancet (Vol 385, May 23, 2015) in which he says that the future must include mental health specialists as part of diabetes teams. He also says that "the ballooning costs of new analogue insulins and technology are not delivering equivalent improvements in outcomes." He warns, "Social media testimonial-driven care, strong presence by pharma and device companies, and 'eminence- based' medicine have the potential to erode evidence-based care." In other words, care must not be influenced by the pharma industry (and financial gain) or the views of senior specialists but must be based on evidence from clinical trials.

What the review says...

HbA1cs

- In the 20 years after the landmark Diabetes Control and Complications Trial (DCCT) changes in the treatment of Type 1 diabetes occurred. In the first 10 years after the DCCT, paediatric clinics reported reductions in HbA1cs from more than 9% (11.7mmol/mol) to 8-8.5% (10.1-10.9mmol/mol). Much or most of this improvement occurred with regular and isophane GM insulins.
- In the past 10 years there has been almost exclusive use of short- and long-acting analogue insulins and more recently, high rates of pump therapy. However, despite increased costs and intensive efforts by health teams and patients, national and multinational databases show that HbA1cs still remain between 8-9% (10.1-11.7 mmol/mol).
- The paediatric HbA1c targets have varied since the DCCT and are still in a state of flux with different targets between international groups although the American Diabetes Association and the International Society for Pediatric and Adolescent Diabetes now agree on target HbA1cs of 7.5% (9.4mmol/mol).

In this issue...

Insulin regime and glycaemic control

The new millennium focussed on the introduction of insulin analogues, insulin pump therapy and smart glucose meters for flexible insulin injections but there were very few randomised controlled trials to assess the efficacy of these changes in children.

- Results from a Cochrane Review comparing pump therapy and multiple daily injections showed in 5 of 7 studies there was only a 0.3% benefit in HbA1cs from using pumps.
- In one of the few studies in adolescents tracking their shift from 2 to 4 injections a day, no change in blood glucose control was noted.
- Analyses of numerous national databases, including the UK, have shown no association between insulin regime and control.

The review concludes that the quality of evidence used in guidelines is inadequate and variable, so there is no support for a dogmatic approach that stipulates that all children and adolescents should be on the same insulin regime.

Continuous glucose monitoring (CGM)

In all the studies looking at CGM the greatest benefits were seen in people who use them 70-80% of the time, only 0.5% in pump and injection users. However, in an observational study of freely provided continuous glucose monitoring in children only 46% on a pump and 33% on injections used the device more than 71% of the time. So acceptability in children and adolescents is the major issue to the future use of CGM.

Carbohydrate counting

For many years carbohydrate counting, in one form or another, was the way Type 1 diabetes was treated, it disappeared but has now returned. A meta-analysis of carb counting in adults and children with Type 1 diabetes has shown that carb counting itself did not improve HbA1cs. A study in 85 children with Type 1 diabetes using an automated bolus insulin calculated showed that HbA1cs improved by only 0.16%.

What does the review conclude?

Undoubtedly, since the DCCT there have been improvements in the outcomes for children and young people so they are less likely to have early complications of diabetes but these appear to be due to goal-setting treatment rather than any particular insulin or dietary regime.

The research to provide evidence-based recommendations for the treatment of children and adolescents with Type 1 diabetes is lacking in many ways. So more research is necessary to provide guidelines for realistic insulin treatment, monitoring, diet, psychosocial care and education of these groups.

What can we conclude?

Regimes should be individualised to those that best achieve the target HbA1cs taking into account the burden on the young person and on their families, quality of life and health consequences.

Diabet
Retin

It's a scary thought that, according to IDF, diabetes affects around 382 million people worldwide and by 2035 is projected to increase to some 600 million. Diabetic retinopathy and macular oedema are both serious complications of diabetes which can impair vision and may lead to complete loss of vision. After twenty years of diabetes, nearly all patients with Type I diabetes and >60% of patients with Type 2 diabetes will have some degree of retinopathy so it is a huge issue, nationally and globally.

Current treatments of pan-retinal photocoagulation (laser) or intraocular injections of anti-VEGF (Vascular endothelial growth factor) drugs are both invasive and uncomfortable for the patient, making them treatments of last resort. They are typically given at a late stage in the development of these eye complications when patients' eyesight is already being threatened. They also have serious side effects.

The Noctura 400 Sleep Mask, has the potential to revolutionise the treatment for diabetic retinopathy. It can be used at all stages through the progression of the disease and could also be used as a preventative treatment. It offers a home-based, non-surgical and non-invasive monitored therapy for people with diabetes who have these serious sight complications. It will significantly change the patient experience compared with current treatments.

The Facts

There is a growing body of research which has found that diseases such as diabetic retinopathy and macular oedema are driven, in part, by lack of oxygen to the retina (retinal hypoxia). The retina uses more oxygen per unit mass than any other tissue in the body due to the fact that photoreceptors have a phenomenally high

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Preventative drug-free relief from diabetes related sight loss

The Noctura 400 eye mask is an effective, non-surgical and non-invasive treatment for Diabetic Retinopathy and Diabetic Macular Oedema.

By Richard Kirk, CEO PolyPhotonix

metabolic rate. That demand for oxygen becomes even greater at night, rising by around 40% as rod photoreceptors dark-adapt. In the healthy eye, this isn't a problem as the eye provides just enough to get by.

People with diabetes commonly have microvascular damage, which can start to compromise retinal blood circulation and oxygen transport and once circulation is sufficiently compromised, the result is retinal hypoxia. The body's natural response to this is to promote new growth of blood vessels to compensate by releasing VEGF but unfortunately these new vessels are weak and suffer from leakage of fluid which results in retinopathy and oedema.

Current Treatments

Laser photocoagulation effectively cauterises the affected and damaged blood vessels in the retina; the treatment is not permanent, delays the inevitable progress of the disease and also irreversibly damages photoreceptors. (This is the visual field loss which can lead to loss of the driving licence.) The laser is the standard of care when the retinopathy and macular oedema become clinically significant. Although laser treatment reduces the risk of moderate visual loss by 50% at this stage, it is not effective in restoring best corrected visual acuity and has significant side effects that can impact on the quality of life. The other treatment,

Intraocular injections of anti VEGF drugs is used for diabetic macular oedema and this treatment that is provided within secondary care to the later stages of the disease.

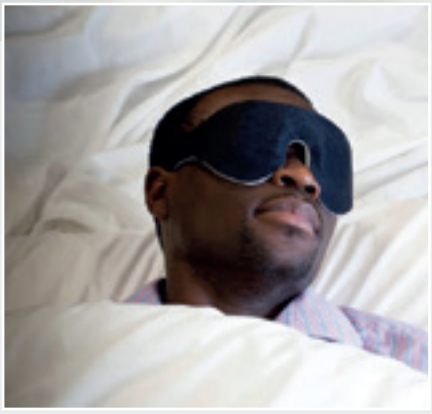
Noctura 400 Sleep Mask

The Noctura 400 is a Sleep Mask which provides a non-invasive treatment for diabetic retinopathy, reducing the need for the invasive interventions mentioned above. It works on the principle of directing low intensity light of a specific wavelength into the rod cells during sleep. It restores the rods to their daytime state, reducing the need for oxygen and avoiding the hypoxic responses and therefore preventing the progression of retinopathy and macular oedema.

The Noctura 400 Sleep Mask consists of organic light-emitting diodes (OLED's) housed inside a soft cushioned fabric mask, designed to be worn at night, to deliver a precise dose of light therapy during a patient's normal hours of sleep. The mask is programmed to administer the correct dose of light each night as part of a continuing therapy and it also measures patient adherence. At the end of the allocated period (usually 12 weeks), the mask is returned to the clinician for analysis and a replacement mask is provided. The collected adherence information allows the clinician to compare how regularly the mask has been worn, with changes in vision and the condition of the disease.

Availability

The Sleep Mask is currently available to patients privately through approved optometrists as well as through our national provider, The Outside Clinic, who provide a home optician service. It is anticipated that it will be adopted by the NHS in the future.



The Noctura 400 Sleep Mask has been developed by multi-award winning company PolyPhotonix, with a number of UK government and NHS funded research collaborations including Liverpool and Durham Universities. There are a number of clinical trials completed and a number still in progress; it is the data from these trials that has allowed the Noctura 400 to be awarded a CE mark.

On the Noctura website there are a number of patient testimonials included (also at: https://www.youtube.com/watch?v=eKTOvY28WG0) as well as an OCT scan from a patient who has used Noctura 400, showing the before and after scans (during a 6 month period) and the results are incredible.

For further information:

Visit: http://noctura.com/iddt

Twitter: @noctura400 | Facebook: http://tinyurl.com/Noctura400

Freephone 0800 60 50 40

IDDT's Annual General Meeting 2015

As members are aware, we are unable to afford to hold a Conference every year but we do have to hold an Annual General Meeting to comply with charity law. So we are holding an afternoon meeting on Saturday, October 17th 2015 at the Kettering Park Hotel, Kettering Parkway NN15 6XT (Junction 9 off the A14). We hope that as many of you as possible will be able to join us – it is your opportunity to meet the Trustees and staff and of course, each other.

The programme for the afternoon will be as follows:

12 noon – Arrival
12.15 to 1.30 – free sandwich lunch
1.45 - Annual General Meeting
3.00 - Tea and biscuits
3.30 - Dr Gary Adams, 'Sharing experiences'
4.30 - Farewell

The AGM

If you would like to nominate someone for election to the Board of Trustees, then please send nominations to IDDT by October 2nd with a letter of agreement from the person you are nominating and seconded by another member of IDDT.

Please let us know!

For catering purposes, please let us know if you are attending by October 2nd by contacting IDDT, telephone 01604 622837, Rita by email rita@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS. Rita will then send you confirmation and a map to find the Kettering Park Hotel.

Practicalities with

No national restrictions on blood glucose test strips

The problem of people with both Type 1 and Type 2 diabetes not receiving sufficient numbers of blood glucose test strips continues. The position has not changed – the government has no national restrictions on prescribing test strips. These decisions are made by local commissioners and doctors and there are no plans to issue guidance to them on how many they should prescribe.

Clearly this is a cost issue but it is a short-term gain if lack of testing results in poorer blood glucose control. If your test strips are restricted, we can only advise you to argue your case for the number you need, bearing in mind the regulations for driving – that you have to test before you start to drive and every 2 hours on longer journeys.

Winner of the Pomegreat Competition

Over 100 people entered the competition to win a year's supply of Pomegreat juice drink in the June. The answer to the competition was 4 and the winner was Mr J.G. of Seaham in County Durham, so we hope he enjoys his juice!

IDDT Tax disc

Don't throw away your old tax disc holder, use it to show your support for IDDT - ask for your FREE IDDT TAX DISC. It's the same size as the old car tax disc and is even perforated. Just call IDDT on 01604 622837 or email martin@iddtinternational.org

# of living diabetes

Disposal of sharps bins

Sharps bins are available on a GP prescription but there does seem to be a continuing problem for people with different systems in various areas around the country. Local authorities have a duty to collect sharps bins, if you request a collection and some areas make a charge for this, while others don't.

One of our members who lives in Kettering, Northants, has recently reported that in future he will have to travel to Corby or Wellingborough to dispose of his sharps bin, both journeys being a round trip of about 16 miles. He rightly questions what happens to people who can't drive, or can't afford the petrol?

We wondered what is happening in your area? One of our Trustees who lives in Norfolk has his collected every 6 weeks by Fakenham Pet Cemetery – this seems the most bizarre we have ever come across!

GlucoJuice to treat hypos

One of our members rang up to tell us that he has recently been in hospital and was given GlucoJuice to treat his hypos. It worked very well for him and he has continued to use it at home and he finds it much better than glucose tablets that tend to go 'manky'. GlucoJuice is a handy caffeine-free, gluten-free sugar boost that can help to treat mild or moderate hypoglycaemia. The containers are sealed and robust, so they can survive being in carried around.

One pot contains 15g of fast-acting carbohydrate and costs £1.59 per bottle from leading pharmacies. Our member informs us that this is now available on an GP NHS prescription.

The winners of IDDT's lottery draws!

We are delighted to announce the winners of the first draw of our monthly lottery for June 2015. They are as follows:

1st prize of **£339.84** goes to Chris from Bugbrooke
2nd prize of **£254.88** goes to anon. from Amersham
3rd prize of **£169.92** goes to Ronald from Bradford
4th prize of **£84.96** goes to Peter from Nelson

Winners of the July 2015 draw are:

1st prize of **£168.48** goes to Jean from Looe
2nd prize of **£126.36** goes to Evelyn from Stockport
3rd prize of **£84.24** goes to anon from Selston
4th prize of **£42.12** goes to Peter from Nelson (2nd time winner!)

Note: the winners of the draws for August, September and October will be announced in our December Newsletter or will be available on our website.

Thank you to everyone who joined in IDDT's lottery.

If you would like to join in for just £2.00 per month, then give us a call on 01604 622837 or email tim@iddtinternational.org

BAD PRESS for charities

Charities have repeatedly been in the news following the sad death of volunteer fundraiser Olive Cooke. Despite a statement from her family that communication from charities did not cause her to take her own life, the issues raised are very important and charities have been widely criticised for poor or aggressive fundraising calls. In light of this, Sir Stuart Etherington, Chief Executive of the NCVO, has been asked by the Minister for Civil Society, to conduct a review of fundraising self-regulation.

The Trustees would like to reassure our members, and the wider public, that IDDT does not fundraise by cold calling or mass mailings which we consider to be intrusive and as bad as all the other unwanted calls or texts that many of us receive.

IDDT relies on voluntary donations and we are extremely grateful for the help that you our members and supporters give us.

IDDT says thank you!

From left to right in the picture: Adam Jelley, Emily Mayhew, Caroline York, Ben Jelley, Oliver Jelley, Archie Jelley, Claire Jelley, Una Loughran, Tracy Taylor, Tracey Jones-Moses and Renu Elston.

Fundraisers complete challenge for IDDT

A team of runners and cyclists raised almost £300 for IDDT by completing a 14-mile challenge. They ran and biked along the Brampton Valley Way from Market Harborough to Northampton on June 6th in a bid to generate much-needed funds.

The 11 fundraisers included three runners, seven cyclists and 'mascot' Archie Jelley, son of the organiser, who rode in a bike trailer behind his mum Claire's bicycle. Oliver said: "Everyone did brilliantly in completing a tough challenge in hot and dry conditions. We're hoping for more people to take part next year."

Update from the March Newsletter

Dementia

Following the article about dementia, here is further news. The Government target set in October 2014 that 67% of patients thought to have dementia should receive diagnosis by the end of March 2015 was not met, with GPs being paid £55 for each diagnosis. 59.3% thought to have dementia were given a formal diagnosis and the number on dementia registers rose from 336,445 to 400,707 in England.

GPonline reports that there was strong opposition to the scheme from many GPs who questioned its usefulness and whether it could actively be doing harm to patients, supporting the views of the IDDT member who raised this issue with us. Leading experts told GPonline:

- There's always a grey area when someone has memory problems but doesn't fulfil the criteria for dementia. They're left feeling uncertain and worried that they may develop dementia in the future.
- A diagnosis of dementia can be the start of decline for a patient.
- If you can't remember your grandchildren's names or birthdays, you do need to know what is going on.

Professor Steve Illiffe, professor of primary care at University College London, says the estimate of 676,000 people with dementia is likely to be an overestimate and the Government policy decision was taken in the absence evidence, so without the knowledge of whether it would work or not!

Smart patch can automatically release insulin into the bloodstream

In June, Researchers announced that they have developed smart patch that can automatically release insulin when needed. It can monitor the blood, and when it detects increases in blood sugar levels, it secretes doses of insulin. The patch is a thin square no bigger than a penny and is covered with more than 100 tiny needles, each about the size of an eyelash. These tiny needles are packed with microscopic storage units for insulin and glucose-sensing

Lizzie's Tea Party

Lizzie has Type 1 diabetes and every year she and her Mum organise a big fundraising party where they live, in Ballatar. The children have a great time including fun on a bouncy castle. Their friends and family are very supportive and this year they raised an excellent £1117.

They raise the money to help IDDT with our international activities to help families with diabetes that cannot afford the insulin and other medical supplies they need.

So a huge thank you to Lizzie, her Mum, their family and many friends for their support.

Lucie's Fiver Challenge

Eleven year old Lucie's Mum has Type 1 diabetes so when her school organised a Fiver Challenge, Lucie decided to raise money for diabetes and IDDT. The school children were each given £5.00 to invest to make a profit. Lucie spent £2.50 on dusters and furniture polish, made some flyers advertising her 'Ship and Shape Cleaning Services' and delivered them around her village. Lucie raised an excellent £50.00 towards diabetes research. Well done Lucie!

Martin Hirst, IDDT chief executive, said:

"We, like every charity, are reliant on donations so we are extremely grateful for these vital funds. The money will go towards enabling us to continue to support people with diabetes."

RESEARCH

enzymes and insulin is rapidly released when blood sugar levels rise too high.

In the study using a mouse model of Type 1 diabetes, the painless patch could lower blood glucose for up to 9 hours. Because mice are less sensitive to insulin than humans, the researchers think that the blood glucose controlling effect of the patch could last longer in actual people. The eventual goal is to develop a smart patch that would only have to be changed every few days. More research and clinical trials are required before the patch can be used in people but it is promising.

(Published in the Proceedings of the National Academy of Sciences, June 2015)

Gender differences in Type 2 diabetes treated with insulin

Information from pooling the results of 6 randomised clinical trials involving people with Type 2 diabetes newly treated with Lantus or NPH insulin (intermediate-acting insulin) because their control was not adequately controlled showed that HbA1cs were significantly reduced over time for both men and women, but there was a significantly greater decrease in HbA1c in men than in women.

There were 1,251 females and 1,349 males in the trial for 24 to 36 weeks and the results showed:

- The target HbA1c of less than 7% was achieved by significantly fewer women.
- Women also had a significantly higher insulin dose/kg than men at the end of the study.
- There were higher rates of severe hypos and severe night hypos in women than in men.

The researchers recommended that physicians should be aware of the need to determine and closely monitor insulin doses particularly in women, to try to obtain the best possible balance between glycaemic control and hypoglycaemia risk. (Diabetes, Obesity and Metabolism, June 2015)

NICE News

NICE guidance on alflibercept (Eylea)

Alflibercept (Eylea) injections have received approval for use on the NHS for the treatment of diabetic macular oedema under certain conditions. These are if your central retina is 400micrometres thick or more before treatment and your doctor thinks that alflibercept is the right treatment. The injections should be available within 3 months of the guidance being issued in July 2015. If you are already having alflibercept treatment and your retina is less than the required thickness, then you should be able to continue with the treatment.

NICE advice on Trulicity (deluglutide)

This drug is given once a week by injection to reduce HbA1cs in adults with Type 2 diabetes. Launched in the UK in January 2015, it belongs to the class of drugs known as glucagon-like peptide-1 receptor agonists (GLP-1) – same family as Bydureon and Byetta.

It can be used on its own or in combination with other glucose-lowering medicines, including insulin. The information from clinical trials about it and the other drugs in the same category, is limited.

NICE advice states that when added to metformin, deluglutide once weekly was statistically superior to exenatide (Byetta) twice daily and to sitagliptin (Januvia) once daily and the same as liraglutide (Victoza)1.8mg daily. At present there is no available information which compares deluglutide with other once weekly drugs.

Safety

- The most common adverse events (1 in 10 people or more) are hypoglycaemia, particularly when in combination with a sulfonylurea or insulin, and gastrointestinal disorders.
- There are possible long-term safety concerns of pancreatitis, pancreatic and thyroid cancers, which are the same as with other GLP-1 receptor antagonists.

Patient factors

- The overall effect of deluglutide on weight loss was modest – on average between 0.87kg to 3.03kg.
- Injection site reactions are uncommon (more than 1 in a 1000 people to less than 1 in 100).

Cost

- The annual cost of deluglutide 1.5mg or 0.75mg once weekly is £1182.35.
- The annual costs for other GLP-1 receptor agonists range from £705.75 to £954.84 (excluding VAT and prices in May 2015).

(NICE website www.nice.org.uk Advice (ESNM59), June 2015)

NICE - newer antigoagulants instead of aspirin for stroke prevention

NICE has issued new guidance recommending that adults with atrial fibrillation should be prescribed newer medicines instead of aspirin to prevent stroke. Atrial fibrillation causes the heart to beat irregularly and too fast so blood does not flow properly through the heart and the rest of the body. This means that there may be an increased risk of blood clots which can block blood vessels and a stroke can occur if a clot blocks a blood vessel in the brain.

Aspirin has been used for many years to reduce the risk of strokes but NICE has now decided that the risks of taking aspirin, which can cause stomach bleeds, outweigh the benefits. Hence, NICE recommends that people are offered newer anticoagulants but they said that many adults with atrial fibrillation may already be taking aspirin for other conditions and if so, patients may end up taking aspirin as well as antigoagulants.

NICE also recommends the decision about anticoagulants should be discussed with the patient and if they are prescribed, then doctors should discuss options at least once a year.

Immune System Genes May Change With The Seasons

Researchers at Cambridge University have analysed the genes from more than 16,000 people worldwide, including both the Northern and Southern hemispheres. They found that when the seasons change, the immune system response may also change. Nearly a quarter of the genes differed according to the time of year, with some being more active in the winter and some more active in the summer.

Seasons also affect immune cells and the composition of blood and fat. This could explain why conditions such as rheumatoid arthritis and heart disease are worse in winter than summer. It has been known for some time that there are seasonal variations in autoimmune conditions such as Type 1 diabetes, multiple sclerosis and mental illness. (Nature Communications, May 12th, 2015)

Type 1 diabetes & **metformin**

Following evidence from the Diabetes Control and Complications Trial (DCCT) about 20 years ago, Type 1 diabetes is generally treated by intensive insulin therapy to reduce the risk of long-term complications. However, Intensive insulin therapy does increase the risks of severe hypoglycaemia and weight gain. Despite improvements in glucose monitoring and insulin administration, studies show that many people with Type 1 diabetes have what is classed as 'poorly controlled diabetes'.

Various drugs have been suggested to try to improve this situation and some people with Type 1 diabetes have been prescribed metformin (a drug for Type 2 diabetes) in addition to their insulin, although the evidence for this has been limited. A review for the use of metformin for Type 1 diabetes found only 9 relevant trials which showed:

- A significant reduction of 6.6units per day of insulin.
- A non-significant reduction in HbA1c of 0.11%.
- A weight reduction of 1.7 to 6.0kg in 3 of 6 studies.
- A reduction in total cholesterol of 0.31 to 0.41mmol/L in 3 of 7 studies.
- Metformin may have beneficial effects on the cardiovascular system.

The most frequently reported adverse effects of metformin are gastrointestinal symptoms in up to 30% of people but these subside over time in many people. Metformin has been associated with a rare but serious condition, lactic acidosis. Separate studies showed increased rates of hypoglycaemia.

Currently there are studies taking place to assess the effects of metformin for people with Type 1 diabetes. In the meantime, NICE draft guidance recommends the addition of metformin to insulin treatment in adults with Type 1 diabetes with a BMI greater than 25 who wish to improve their glucose control while minimising their insulin daily dose.

More about metformin – it may prevent open-angle glaucoma in people with diabetes

A new study found that people with diabetes who took metformin had a lower risk of developing open-angle glaucoma. Glaucoma, usually a painless condition, is where the pressure inside the eye increases because fluid doesn't drain from the eye. Open-angle glaucoma is one of several types of glaucoma and may cause blindness. It is thought that more people with diabetes have glaucoma than in the general population, especially in older people.

The researchers looked at information from more than 150,000 people with diabetes between 2001 and 2010 who took a variety of common tablets for Type 2 diabetes. Open-angle glaucoma developed in 4% of these people but the risk was lower in those taking metformin and did not change in those taking other tablets. If the standard dose of 2 grams of metformin was taken every day for two years, the risk of open-angle glaucoma dropped by almost 21%. (JAMA Ophthalmology, May 2015)

And more - neuropathy due to Vitamin B-12 deficiency in Type 2 diabetes, not diabetes

Metformin is often the first line of treatment for people with Type 2 diabetes and it has been linked to a deficiency in vitamin B-12. People who have been on metformin have shown a malabsorption of vitamin B-12 and some tend to have a lower B-12 level and worse diabetic neuropathy than people on other oral treatments.

Vitamin B-12 has several important roles and the signs and symptoms of B-12 deficiency can easily be mistaken for diabetic neuropathy. Several studies have shown that B-12 supplementation, alone or with other agents, has improved aspects of diabetic neuropathy, such as skin sensitivity, pain, paresthesia, nerve conduction, and autonomic symptoms. The researchers recommend that patients and health professionals should be ware of the possibility of Vitamin B12 deficiency in people taking metformin and how to remedy this. (Clinical Diabetes. 2015; 33(2): 90-95)

NEW high strength insulins

Several new insulins have come to the market recently; three high strength insulins which have concentrations greater than the previously standard strength of U100 and biosimilar insulin.

The Trustees of IDDT have discussed the introduction of different strengths of insulin in depth and strongly expressed their concerns about the risks of errors by people with diabetes, health professionals and hospitals. These concerns come from their experiences of the introduction of the first genetically modified human insulin in the 1980s when there was a dearth of evidence of benefit and many people with diabetes were not informed of the differences from their previous natural animal insulin.

These new stronger insulins have been largely developed for people who require large doses of insulin to reduce the volume injected and the number of injections.

New term – the 'dose step'

The 'dose step' is a new term to define how to dial up the required dose on the prefilled pen.

For Lantus, Toujeo and both strengths of Humalog:

- one dose step on the prefilled pen is equivalent to one unit of insulin.

In contrast, for Tresiba:

- one dose step on the U100 pen is equivalent to one unit of Tresiba
- one dose step on the U 200 pen is equivalent to 2 units of Tresiba.

Dose conversion when switching between standard and high strength insulin products

For all the insulin products in the table below, the required dose is displayed in the dose counter window of the prefilled pen.

- For Humalog 100 and 200 units/mL KwikPens, and for Tresiba 100 and 200 units/mL FlexTouch pens so there is no need for dose conversion when transferring patients from the standard to high strength version or vice versa.
- However, Toujeo is not bioequivalent to Lantus so dose adjustment is needed when patients are switched from Lantus or other basal insulins to Toujeo or vice versa.

If you are being changed to a different strength insulin, the MHRA advice to health professionals is worth noting.
Before starting treatment with a high strength, fixed combination or biosimilar insulin::

- consult the summary of product characteristics and any educational material,
- ensure that patients read and understand the patient leaflet and any patient education material,
- ensure that patients receive appropriate training on the correct use of the product,
- give patients a patient booklet and Insulin Passport (or safety card),
- warn patients only to use insulin as they have been trained because using it any other way may result in a dangerous overdose or underdose.

Their advice to people with diabetes is obvious - monitor glucose levels closely after starting a new treatment and in the following weeks. You may need to adjust doses and timing of concurrent rapid acting or short acting insulin products and other antidiabetic treatments.

Here are the details of the new insulins:

Key feature	Active substance	Brand name	Strengths	Injection device
High strength	Insulin degludec	Tresiba	U100: U200	FlexTouch prefilled pen
	Insulin	Humalog	U100: U200	KwikPen prefilled pen
	Insulin glargine	Lantus Toujeo	U100 U300	SoloStar
Fixed combination	Insulin degludec & liraglutide	Xultophy	Degludec and 3.6mg/mL of liraglutide (Victoza)	Prefilled pen
Biosimilar	Insulin glargine	Abasaglar	U100	Lilly reusable pen

The European Medicines Agency is consulting on safety advice and the MHRA in the UK has stated that it is important that patients and health professionals are aware of the different strengths and how to use them to minimise the risk of medication errors, such as the wrong dose of insulin being injected.

Information on another new insulin TRESIBA

Tresiba (insulin degludec) - no hint of added benefit in children and adolescents

Severe side effects more frequent in girls with Type 1 diabetes and no data for Type 2 diabetes

Tresiba has been approved since January 2015 for adolescents and children from the age of one year with Type 1 or Type 2 diabetes. In an early assessment, the German Institute for Quality and Efficiency in Health Care (IQWiG) examined whether this new insulin, alone or in combination with other blood-glucose lowering drugs, offers added benefit over the appropriate comparative treatments.

The findings show:

There was no added benefit of Tresiba for adolescents and children with Type 1 diabetes. The manufacturer (NovoNordisk) only presented one study investigating children and adolescents with Type 1 diabetes. The results showed no differences between the treatment groups regarding mortality, symptoms and complaints, most side effects such as severe and symptomatic hypoglycaemia and ketoacidosis. Health-related quality of life was not investigated. Hence, there was no suggestion of an added benefit of Tresiba.

In girls there is a suggestion of greater harm regarding serious adverse events. Neither positive nor negative effects were determined for boys but in girls with Type 1 diabetes treated with Tresiba, serious adverse events occurred more frequently than in the comparator group. Within 52 weeks, there were severe side effects in around 15 of 100 girls who received Tresiba compared with 3 of 100 girls who received standard treatment. Hence the suggestion of lesser benefit of Tresiba in girls compared to the appropriate comparator treatment.

Novo Nordisk presented no data for adolescents and children with Type 2 diabetes. Therefore there is no suggestion of an added benefit of Tresiba..

Why did IQWiG come to these conclusions?

In this latest dossier for the use of Tresiba in children and adolescents the manufacturer, Novo Nordisk did not differentiate between Type 1 and Type 2 diabetes in the analysis of the study data. This is in contrast to its dossier for the benefit assessment of Tresiba in adults in summer 2014, which did differentiate between Type 1 and Type 2 diabetes. Novo Nordisk justified this by claiming that the therapeutic indication was not differentiated in the Summary of Product Characteristics, which generally recommended intensive insulin therapy for adolescents and children.

However, IQWiG did differentiate between Type 1 and Type 2 diabetes in its assessment because these are two different diseases. This results in different treatment recommendations for the two diseases in the Summary of Product Characteristics, from which children and adolescents are not exempt.

What happens now in Germany?

IQWiG's dossier assessment is part of the early benefit assessment according to the German Act on the Reform of the Market for Medicinal Products (AMNOG) supervised by the Federal Joint Committee (G-BA). After publication of the dossier assessment, the G-BA conducts a commenting procedure and makes a final decision on the extent of the added benefit.

We hope that the MHRA in the UK will be equally diligent in its assessment of Tresiba in children and adolescents.

WARNING

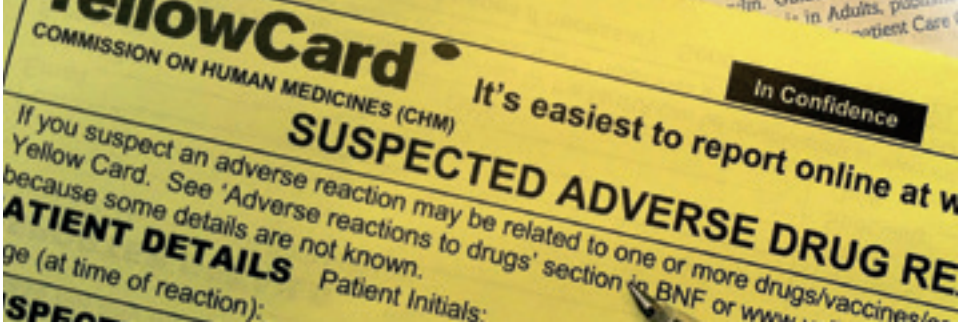
review of three Type 2 drugs

SGLT2: canagliflozin (Invokana), dapagliflozin (Farxiga), and empagliflozin (Jardiance)

The European Medicines Agency (EMA) has started a review of canagliflozin, dapagliflozin and empagliflozin, which are diabetes medicines known as SGLT2 inhibitors. This was requested by the European Commission following several reports of diabetic ketoacidosis in patients on SGLT2 inhibitor treatment for Type 2 diabetes. EMA will now review all available data on the risk of diabetic ketoacidosis (DKA) with SGLT2 inhibitors and consider whether any changes are needed in the way these medicines are used in the EU. They advise: "*Patients who have any concerns about their diabetes medicines should consult their doctor or pharmacist. It is important that patients with diabetes continue to take their prescribed treatment and do not stop treatment without first discussing with a healthcare professional*".

And in the US – a similar review is being carried out by the FDA in the US. They are warning health professionals to evaluate for the presence of acidosis, including ketoacidosis and if confirmed, patients experiencing these signs or symptoms should discontinue SGLT2 inhibitors and take appropriate measures to correct the acidosis. The signs and symptoms listed included difficulty breathing, nausea, vomiting, abdominal pain, confusion, and unusual fatigue or sleepiness.

The FDA database of adverse event complaints about these drugs from March 2013 to June 2014 contained 20 reports of DKA, most of them with Type 2 diabetes. All cases required hospitalisation and the median time to onset was 2 weeks after starting the drug. The FDA said that the cases they analysed were atypical because glucose levels were only mildly elevated at less than 200 mg/dL (11mmol/l in the UK) in some reports.



MHRA News

New website for Yellow Card scheme

European citizens can now obtain information on suspected side effects of medicines approved in the European Union through the European Medicines Agency (EMA), website, www.adrreports.eu.

In the UK, the Yellow Card Scheme collects suspected adverse drug reactions (ADRs) to provide early warnings of possible hazards. There is now a new single reporting website for suspected problems with all healthcare products including medicines, adverse incidents with medical devices, defective and counterfeit or fake medicines or medical devices.

Suspected ADRs can be reported by health professionals and the public and are also collected from drug companies. You only have to suspect a problem, not prove it. The website can be found at www.mhra.gov.uk/yellowcard and here is how to make reports:

- by email to yellowcard@mhra.gsi.gov.uk
- by freephone on 0808 100 3352 (available weekdays 10:00 - 14:00)
- by writing to Yellow Card Scheme, Vigilance and Intelligence Research Group, MHRA, 3.O, 151 Buckingham Palace Road, London SW1W 9SZ

In July a Yellow Card smartphone app was launched for reporting ADRs. This supplements the existing website and is the only app that allows patients, carers and healthcare professionals to report side effects directly to the Yellow Card Scheme. Users can select specific medicines or vaccines to track and receive news and alerts about them. You can download the app from the iTunes App Store and Google Play for your IOS or Android device.

Closing of websites illegally advertising and selling medicines

Last year the Medicines and Healthcare products Regulatory Agency (MHRA) closed down more than 1,600 websites for illegally advertising and selling medicines that were falsified, counterfeit or unlicensed.

Medicines worth more that £3 million were seized which included erectile dysfunction medicines, slimming products, sleeping pills and antidepressants, the majority of which originated in India and China. The MHRA in collaboration with sites such YouTube, Amazon and eBay also seized nearly 19,000 online videos for illegally advertising medicines.

The MHRA advises that buying medicines online is a risk as you have no idea what you are getting or how it will affect you. If you are ill, you should see your GP and use prescribed or pharmacy medicines from a legitimate high street or online pharmacy.

Transparency in research challenged by judicial review

May 2015

The Health Research Authority (HRA) authorises trials and works to ensure the safety of patients taking part. It has proposed that all drug trials in future must be registered to prevent companies from 'hiding' bad results, which has happened in the past. This can then result in a drug appearing to work better and more safely than it actually does.

The HRA proposals also included a requirement on the people running trials to ensure that all previous studies in which they were involved have also been registered. This is to try to bring historical information to light that perhaps has never been published. Another advantage of registering all trials is that to prevent scientists from repeating a trial that may have failed and not been published, as well as giving them important information.

Our longstanding readers will remember our campaign to maintain animal insulin and may also remember that one problem was that we did not have access to the trials of the then new 'human' insulin. So we were unable to demonstrate from the research carried out, that some people did have adverse reactions to 'human' insulin as strong anecdotal evidence suggested.

AllTrials Campaign

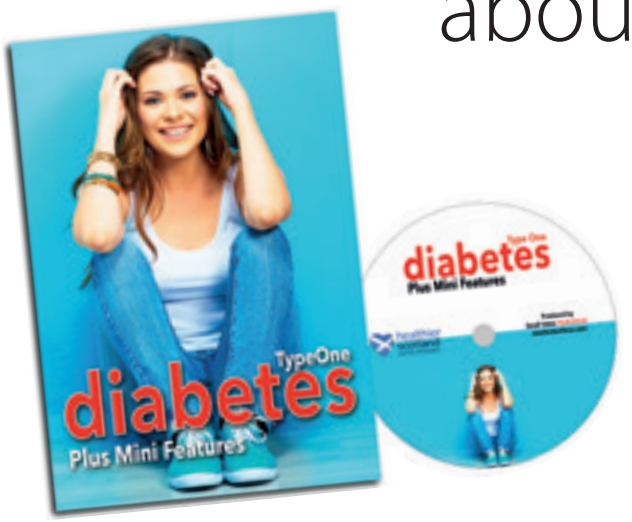
A campaign for transparency in human drug trials was launched in 2013 - the AllTrials campaign. One of the organisations behind this is Sense About Science along with support from many researchers including the Cochrane Collaboration, the Wellcome Trust, the Medical Research Council as well as the public, patients, doctors and pharmacists. If patients have been willing to take part in research, then they deserve to have the findings published whether these results are negative or positive or put another way, whether the results are to the liking of the drug companies or not.

Richmond Pharmacology Ltd receives permission to bring a judicial review

The battle for greater transparency in human drug trials has faced a serious setback with a legal challenge. Richmond Pharmacology, a company that conducts clinical trials on behalf of major drug companies has received permission to bring a judicial review of the HRA's proposals. If the judicial review goes against the HRA, the drug companies will be able to continue their secrecy in clinical trials.

At the time of writing, the HRA is preparing its defence and has confirmed that it will continue to act in line with its statutory duties to protect and promote the interests of patients and the public in health research.

A new video about Type 1 diabetes



A new video about Type 1 diabetes is now available and well worth watching. It covers the many aspects of diabetes including an Introduction to diabetes, the clinic, insulin including pumps, healthy eating, exercise, hypos, hypers, sick day rules and complications. There are also mini-features which include travel, Ramadan, sex, smoking, alcohol, emotions and many more. The medical team involved was headed by Professor Andrew Collier from Ayr hospital. The video was made by Small Video Productions and was funded by Healthier Scotland but is appropriate for the whole of the UK.

The price of the DVD is £15 plus £3 postage and packing and is available from smallvideo@mac.com

From our own correspondents

I might be forced to move to Canada

Dear Jenny,

I am 44 years old and was diagnosed with diabetes when I was 3. I can't stand using synthetic insulin – it should be DNA (DO NOT ADMINISTER) insulin. I was on the natural animal insulin for a long time then switched to synthetic /GM insulin. It was horrible.

I live in the US and was able to acquire the natural pork insulin from Canada but then they stopped allowing people from the US to purchase it. My doctor reluctantly signed the papers so I can import it from Europe. The DNA insulin for me is poison. If I can't purchase natural insulin from Europe I will probably try to move to Canada. We should have better treatment options. It's funny how we are told to eat more natural foods but natural medications are bad for you. Unfortunately, I'm certain you have heard or read many stories like mine.

By email

Specsavers or not?

Dear Jenny,

I have read in the June Newsletter about the DVLA saying that you should go to Specsavers to have your eyes tested by one of their optometrists. I would not tell anyone to go there.

You may ask why, they don't have the equipment to fully check your eyes the proper way. I go to an optometrist in Birmingham for my eye examination and it takes 2 hours. I have had Type 1 for 50 years and know that to check your eyes properly, you should have a photo of your eyes so you can see for yourself if there is anything wrong. You should also look into a machine which shows dots which you have to find to check your visual fields.

If you feel that the DVLA have got it wrong, you have to put to paper and tell them so. The more of us that do something about it, the greater chance they will listen to us. If you feel your optometrist is better equipped and does a better job than Specsavers, tell the DVLA so. You need the best care of your eyes. I moved and my eyes have improved.

Mr H M, Birmingham

Note: This is one of several complaints we have received. Our understanding is that the DVLA 'employ' Specsavers to screen visual fields for driving, not to do a full eye examination. The problem we see is that people who want the full eye exam will have to go to their own optometrist as well as Specsavers and what then happens if there are conflicting results?

Reducing added sugar in drinks

With all the publicity about sugar, we cannot avoid a discussion in this Newsletter. Harvard University research has shown that sugary drinks are implicated in 184,000 deaths worldwide and added sugars, such as those in fizzy drinks are 11 times more likely to cause Type 2 diabetes than regular sugar. In addition, it showed that products high in sugar and fat have contributed to record child obesity and bad teeth.

A report by the British Medical Association, 'Food for Thought' (13.07.15) calls for a 20% tax on sugary drinks to subsidise the sale of fruit and vegetables to try to tackle the increasing level of obesity and diet-related health problems in the UK. This was followed by a report from the Scientific Advisory Committee on Nutrition which, for the same reasons, advised the government to halve the current recommended intake of 'free sugars'.

Keith Vaz MP has called on Government to expand the Responsibility Deal and set mandatory limits on sugar and fat content, particularly in products that target children. However, the campaign group, Action for Sugar, maintain that a gradual reduction in calories and sweetness is the best way to cut sugar in the general population.

In the meantime, Tesco has committed to reduce added sugars by 5% in all own label soft drinks so after 4 years, about 2 teaspoons of sugar will have been removed from a can of fizzy drink. Tesco's classic cola contains 9 teaspoons of sugar, so plenty of room for improvement!

Public Health England said other drinks brands should follow Tesco's lead but some companies have already been reducing calories in their soft drinks:

- Sainsbury's has reduced the sugar content of its own brand high juice squashes by between 4% and 10%.
- The Co-Operative Group has removed 1.5 billion calories from its range of own brand squashes.
- ASDA is reducing added sugar by 22% on its own brand soft drinks.

Alternative sites for testing

Dear Jenny,

I write in response to your article on blood glucose testing sites, in your Newsletter of June 2015. When I was diagnosed in 1962, at my hospital appointments blood was taken from my ear lobe(s) to obtain my blood glucose at the time. Since then I have used my ear lobes constantly and it is a completely PAIN-FREE site, unlike fingers which are the most painful site imaginable. I simply cannot understand the obsession that medics seem to have with fingers, which we are using all the time. I have NEVER used my fingers, and my consultant is quite happy with this - indeed he says he has other patients who use their ear lobes. I notice in your article that no mention is made of ear lobes - why is this? I hope, through your Newsletter that you will feel able to remind people that ear lobes are an option. For me, any other site is completely out of the question.

Mrs B. E., South Yorks

Glucose-containing wrist bands

Dear Jenny,

Thank you so much for the article about the wrist bands containing glucose I have designed and thank you to the Newsletter readers. I have had some really nice and helpful replies from it and will put them to good use. I will keep you all informed on the progress.

Adam Booker

More on continuous glucose monitoring (CGM)

Dear Jenny,

I think some of the information about CGM in the June Newsletter is slightly out of date. I've got Medtronic CGM - mainly because despite having an assistance dog I still managed to have several long unconscious episodes.

I've had the CGM for a couple of years and at first it was about 20 minutes behind my blood sugars, and the life of the sensors did mean slight inaccuracy at the end. My old blood testing machine that ties in with the insulin pump was immensely and criminally inaccurate, causing calibration errors and inaccuracy. Then they brought out new sensors, and a new, much more accurate blood testing machine that ties in with the pump.

Since then the sensors have been uncannily accurate up till the end. For people like me with no hypo warnings and who drop low quickly, the CGM is a life-saver. It cuts off the basal if you drop too low, which helps a great deal, and the new Medtronic pump even cuts back in as soon as you start to rise again (at the minute this is manual on my pump). So at night I am at last safe - it also sirens when you are dropping.

As I have my assistance dog, I am often stopped by people in the street (several times an hour when shopping) and at least one person every week admits on behalf of themselves or a relative that they have no low blood sugar warnings, and I always ask if these people drive and they always do - they haven't told anyone of their problems because they are scared their license will be taken away. If the benefits of having CGM could be advertised, and the money found to put people on it, there would be a lot fewer people driving dangerously.

By email

Recommended maximum daily amount of sugar

The present target for the maximum daily amount of sugar is 25g for women (5 to 6 teaspoons) and 35g for men (7 to 8 teaspoons). So some of these drinks contain the daily recommended allowance of sugar! Take a look…

- Old Jamaica Ginger Beer - 50.2g or 13 teaspoons
- 7Up - 36.3g or 9 teaspoons
- Tesco classic cola - 36g or 9 teaspoons
- Coca-Cola and Pepsi - 35g or 9 teaspoons
- Barr's Irn Bru - 34g or 8 teaspoons
- Tesco original cola - 32g or 8 teaspoons
- Fanta Orange - 22.8g or 6 teaspoons.

Artificial sweeteners may cause spikes in blood sugars

Research suggests that consumption of artificial sweeteners such as saccharin, sucralose and aspartame might trigger higher blood sugar levels in some people. This may be adding to the problems they were designed to combat, such as diabetes and obesity. However, the researchers stress that their findings are preliminary and people should not take this to mean that they should consume sugary drinks instead.

The reasons behind blood sugar changes remain uncertain but it is suspected that artificial sweeteners could be disrupting the system of bacteria in the gut present in all of us from birth.

Experiments showed that the most widely used sweeteners in food and drink, saccharin, sucralose and aspartame, caused mice to have a quite dramatic increased risk of glucose intolerance, which can lead to Type 2 diabetes.

The same scientists also monitored what happened to 7 people who did not normally use sweeteners - when given regular doses of saccharin for a week, 4 of them developed significant glucose intolerance.

They also looked at 400 people and found that the gut bacteria of those who used artificial sweeteners were noticeably different from people who did not.

There has been much debate over the years about the risks and benefits of artificial sweeteners and as these additives are consumed by hundreds of millions of people across the globe, this research should open up the debate again. (Nature, Sept 2014)

NHS news

Fit for work changes

This initiative funded by the Department of Work and Pensions is designed to help employees and employers to manage sickness absence or a return to work. It will also help GPs to support their patients with what is described as free, expert and impartial advice from occupational health advisers rather than placing the responsibility with GPs.

Patients who meet certain criteria and have had 4 weeks sickness absence can be referred by their GP to an occupational health adviser who will carry out an assessment and draw up a 'return to work' plan, during which time GPs do not have to sign fit notes. Patients cannot self-refer but employers will be able to do so once the GP referral service has been rolled out nationally. The scheme is voluntary – GPs are not forced to refer and patients have to give their consent..

The scheme was first piloted in 7 areas in 2010 and went 'live' in March in two areas in England and Wales with plans for nationwide coverage this autumn. A similar scheme is being introduced in Scotland.

Apologise to patients directly

New guidance from the General Medical Council (GMC) and the Nursing Medical Council states that all nurses, midwives and doctors in the UK must apologise and explain mistakes to patients face-to-face.

If something goes wrong with a patient's care, it is expected that they, or someone close to them, will receive an explanation of what has happened and what can be done if they have suffered harm. As part of this, health professionals will need to report errors early and not try to prevent colleagues from raising concerns about patient safety. In turn, managers must ensure that anyone who raises concerns will be protected from unfair criticism, detriment or dismissal.

Prescription facts

Information for the calendar year to April 2015 from the Health and Social Care Information Centre showed that:

- 1,064.6 million prescription items were dispensed in 2014, a 55.2% increase since 2004.
- The total net ingredient cost of prescriptions dispensed in 2014 increased to £8.9 billion, a 9.6% increase on 2004, when the total cost was £8.1 billion.
- For 8th year in succession, the highest cost was drugs used in diabetes.
- In terms of therapeutic area, the greatest increase in the volume of prescribing in 2014 was antidepressant drugs.
- 89.9% of all prescription items were dispensed free of charge, with 60.0% dispensed free to patients claiming age exemption (aged 60 and over).

Some people who are obese are to be denied bariatric surgery

NHS England is imposing restrictions on bariatric surgery that go beyond NICE guidance. The present guidance (November 2014) recommends the option of bariatric surgery for people who are obese if they have a BMI of 40 or more, or 35 to 40 and other significant disease eg diabetes. However, NHS England's commissioning policy stipulates that the patient must have 'received and complied with' a tier three or four weight loss management service for a duration of 1 to 2 years to qualify for bariatric surgery. Many local weight loss programmes don't last this long so it would be impossible for people to qualify for surgery! It also stipulates that the patient must have been morbidly obese for at least 5 years to be eligible.

Such rationing and cost cutting appears to flout the NHS Constitution which gives patients the right to receive treatments recommended by NICE.

If NICE is going to be ignored as and when the Department of Health choose, why are we wasting money developing NICE Guidelines?

Welsh government to improve NHS care for major health conditions

At the end of June, it was announced that the Welsh government will invest £10million to improve major health conditions such as cancer, diabetes, heart conditions and several others. Each condition has its own delivery plan.

The £1m for diabetes will go towards

- improving self-management through structured education programmes,
- driving up care standards,
- recruiting new staff to support the transition between child and adult services,
- improving clinical podiatry,
- investing in community diabetes specialist nurses.

Jeremy Hunt Watch

Jeremy Hunt will prioritise diabetes and childhood obesity

At a conference (May 21st 2015), Jeremy Hunt said that his first priority is going to be a national strategy on diabetes and childhood obesity. So for those of us living with Type 1 and Type 2 diabetes, we eagerly await improvements as a result of his first priority…

Mr Hunt announces responsible use of NHS resources

Mr Hunt is clamping down on the £300 million a year the NHS spends on wasted drugs. In June he announced that we, as patients and taxpayers, should know the costs of the medicines we take so that we don't waste them! The price of medicines costing more than £20 will be put on the packs along with 'funded by the taxpayer' by 2016. Apparently, this will reduce waste and will improve patient care by boosting adherence to drug regimes. Will it work and has it been piloted to show it works?

If we look at diabetes alone, which no one chooses to have, this suggestion is not only insulting but could make people feel guilty for needing high cost drugs or insulin.

For people with Type 1 diabetes, insulin is the essential lifesaver – whatever it costs. We might become aware of the high prices drug companies charge for their products, so maybe they will not be too happy, especially if they have to pay for all the new packaging. We would like to remind Mr Hunt that there are other ways in which medicines' waste can be reduced.

When someone's type of insulin is changed, unless it is urgent, then why don't doctors and health professionals advise patients to use up their previous insulin first instead of having to throw it away (or send to IDDT for developing countries)?

Evidence from well respected experts suggests that many of the expensive analogue insulins are not superior to the previous insulins. (Politics of affordable insulin, BMJ 2011:343) So why are vast amounts spent unnecessarily on expensive insulins with no proven benefit? Should he tell prescribers to look carefully at evidence and costs before prescribing or just to look at NICE guidance?

7-day GP opening is not evidence-based

Mr Cameron's pre-election promise of 7-day and evening opening of GP surgeries will now not apply to all practices, according to a statement from Mr Hunt (GPonline, 29th June 2015) - hardly surprising as there is a shortage of GPs to cover existing services.

Pilot areas set up under the Prime Minister's Challenge Fund have shown that that 7-day opening is not necessary everywhere. For example, an area covering 21 practices in NHS Hambleton, Richmond and Whitby CCG has shown a lack of patient demand, so 7-day opening is closing down.

7-day working for hospital doctors

On July 16th Mr Hunt made a speech which included the following: "*…But we will reform the consultant contract to remove the opt-out from weekend working for newly qualified hospital doctors. No doctors currently in service will be forced to move onto the new contracts, although we will end extortionate off-contract payments for those who continue to exercise their weekend opt-out. …As a result of these changes by the end of the Parliament, I expect the majority of hospital doctors to be on 7-day contracts.*"

"*I will not allow the BMA to be a road block to reforms that will save lives. There will now be 6 weeks to work with BMA union negotiators before a September decision point. But be in no doubt: if we can't negotiate, we are ready to impose a new contract.*"

Interesting that Mr Hunt refers to the British Medical Association (BMA) as a union! But of greater interest is that he omits to say that all the other hospital staff are going to have to work 7 days too – support staff, nurses, diagnostics etc. Is he going to impose new contracts on them too?

Jeremy Hunt announces a Carers Strategy

On July 1st 2015, Jeremy Hunt announced a 'Carer's Strategy' to look into support for current and future carers. Wasn't this covered in the Care Act last year? No, Mr Hunt is calling for a "*new national conversation that urges the public to take more responsibility for the care of the elderly*". He argues that "*personal responsibility needs to sit alongside system accountability*" and "*if we are to rise to the challenges we face, taking care of older relatives and friends will need to become part of all of our lives*".

While he praises existing carers, he is calling for a change of attitude. Family planning must be as much about care for older generations as planning for younger ones and there must be "*a wholesale repairing of the social contract so that children see their parents giving wonderful care to grandparents – and recognise that in time that will be their responsibility too*". It seems that we are now being told how to behave!

Driving News

HGV licence applications process improved by the DVLA

The Driving and Vehicle Licensing Authority (DVLA) has made some improvements in the way people treated with insulin apply for their annual renewal to drive vehicles over 3.5 tonnes. This is to reduce the unreasonable delays people have been experiencing when renewing their licences.

- The DVLA Drivers Medical Group has increased capacity to assess applications from people with diabetes.
- The application form (D4) is being simplified so that it is easier to complete and will reduce the number of rejected applications.
- The response time will be speeded up for any vocational drivers chasing up the whereabouts of their First Vocational Licence Application with the DVLA Contact Centre.

There are also plans to improve the whole process which includes:

- Updating all DVLA literature to advise drivers not to send in their driving licence when applying for a renewal.
- Changing legislation to allow drivers to apply for their licence 90 days before it is due to expire.
- Recruiting and training more staff and medical professionals.

You can contact the DVLA Contact Centre about Vocational Medical Enquiries on 0300 790 6806

No change in your visual fields but your car driving licence is revoked

If you have had laser treatment and have not been told to stop driving by your eye specialist (ophthalmologist) but the DVLA has revoked your driving licence, then you should question the DVLA decision because your eye specialist and your own optometrist have a professional duty to inform you if you shouldn't drive. IDDT's advice is that you immediately contact the DVLA and inform them that you are appealing the decision. Keep a note of the date of the telephone call or if you send a letter, keep a copy.

Have another field test with a different optometrist or ideally with your ophthalmologist and ask him/her to write a letter stating that you are fit to drive and submit all this to the DVLA as your appeal. Your ophthalmologist is more highly qualified than an optometrist (from Specsavers) so this should carry weight with the DVLA.

It's a good idea to plan ahead

If you have a regular check with the eye department at your hospital, try to organise this before your driving licence is due for renewal and ask for a copy of your chart and the above letter. Submit the originals to the DVLA with your application form, but keep copies. Assuming that you are fit to drive, it is hard to see how the DVLA could ignore the evidence you present to them.

Adherence with the driving rules

The regulations state that people taking insulin must carry out blood glucose tests before driving and every 2 hours on longer journeys. However, an article in Practical Diabetes (Vol 31 No 9) points out that one recent survey found:

- up to a third of insulin-treated drivers were not fully aware of the driving regulations,
- over half (53%) admitted failure to test before driving and at intervals on long distance travel (59%),
- 56% reported some degree of hypoglycaemia with symptoms each month, including 13% while driving.

Another survey showed that in the UK only 52% routinely check their blood before driving, not good but better than France at 43% and Germany at 27%.

In this same article, Professor Ken Shaw suggests that the barriers to complying with the driving regulations are the inconvenience and discomfort of finger prick testing for people with busy lives but says, "Education on the principles of safe driving and recognition of responsibilities still remains fundamental to achieving improved outcomes".

Driving, hypos and the truth

A study was carried in Denmark after the implementation of the new EU driver's licence regulations stating that anyone who has 2 severe hypos in a year (defined as requiring the help of another) is not allowed to drive. The study investigated the rate of self-reported and anonymous reported severe hypos.

What a surprise!

After implementation of the EU regulations, the reporting of severe hypos by people with Type 1 diabetes went down significantly.

What did the EU expect to happen when this decision was made? The answer is not rocket science! The loss a driving licence is a major problem, especially for those whose jobs depend on driving or those who live in rural areas. No one, including IDDT, would suggest that people should drive if they are not safe to do so, but when more than one hypo a year includes night hypos, one has to question the wisdom of the regulations. (http://care.diabetesjournals.org/content/early/2014/10/02/dc14-1417.short)

For people newly diagnosed with Type 1 or for those with Type 2 who become insulin treated, it is important that driving regulations are discussed as part of the education process.

Pharmaceutical NEWS

Switzerland – animal insulins will cease to be distributed

Some years ago, CP Pharmaceuticals (now Wockhardt UK) set up a company in Switzerland to supply Hypurin porcine insulin. This supply is now ceasing on October 31st 2015. People who have been using this insulin will now have to obtain the same insulin by personal importation from Wockhardt UK.

Novo Nordisk to cease distribution of Tresiba® in Germany

On 1 July 2015 Novo Nordisk announced that they are ceasing distribution of once-daily basal insulin Tresiba® (insulin degludec) in Germany. This follows a failure to agree price negotiations with the GKV-Spitzenverband, the German national association of statutory health insurance funds. The 40,000 people using Tresiba® have until September 2015 to change to a different insulin. The decision to cease distribution of Tresiba® in Germany has no implications for the other countries.

Update advice on high-dose ibuprofen

The European Medicines Agency has updated its advice on the use of high-dose ibuprofen, high doses being at or above 2,400mg per day. A review has confirmed a small increased risk of cardiovascular problems, such as heart attacks and strokes with high doses but no such risk in doses of 1,200mg per day. This is the highest dose generally used for over-the-counter preparations taken by mouth.

The advice is:

High doses of ibuprofen (2,400mg per day) should be avoided in people with serious underlying heart or circulatory conditions or in those who have already had a heart attack or stroke.

Doctors should carefully assess a patient's risk factors for heart or circulatory conditions before starting long-term treatment with ibuprofen, especially if high doses are required. Risk factors include smoking, high blood pressure, high cholesterol levels and diabetes.

Note: The risk with high-dose ibuprofen is similar to the risk with some other non-steroidal anti-inflammatory drugs (NSAIDs), including Cox-2 inhibitors and diclofenac.

These recommendations also apply to dexibuprofen, a similar medicine where a high-dose is at or above 1,200mg per day.

This makes it the time to think about the seasonal flu jab

It is offered first to people in 'at risk' groups and this includes people with diabetes, pregnant women and the elderly. It gives good protection [70-80% reliability] against all strains of flu and lasts for a year. Flu viruses are spread rapidly by coughs and sneezes from infected people.

The pneumo jab

What has become called the pneumo jab is a vaccination to protect against pneumonia [inflammation of the lungs]. Pneumococcal infections are caused by a bacterium with many different strains and can lead to serious health conditions. They can affect anyone but some groups of people have a higher risk of the infection developing into a serious health condition. These include:

- children who are under two years of age – they are vaccinated as part of the childhood vaccination programme,
- adults who are 65 years of age or over,
- children and adults with certain chronic [long-term] health conditions.

How pneumococcal infections spread

They are easily spread from person to person by close or prolonged contact with someone who has the infection. The bacteria are present in tiny droplets that are expelled when someone who is infected breathes, coughs or sneezes. You will also be infected if you breathe in these droplets or if you touch any droplets that might have landed on a surface and then transfer them to your face. Once the bacteria have entered your body, usually through your nose or throat, they can either lie dormant or they can multiply and cause health problems such as pneumonia.

When you see your GP for a seasonal flu jab, ask whether you also need the 'pneumo jab' to protect you. It's available to everyone aged 65 or over, and for younger people with some serious medical conditions, including diabetes.

INDEPENDENT DIABETES TRUST SNIPPETS

Dispelling the myth about eating for two in pregnancy

New research shows that in women who have developed gestational diabetes during pregnancy, being obese before the pregnancy and putting on more weight afterwards, massively increases the risk of later developing Type 2 diabetes. (Diabetologia, 23.03.15) The Royal College of Midwives commented that this research underlines the need for women to start their pregnancy in optimal health at a healthy weight and to maintain this during and after their pregnancy… Behind all of this is a pressing need for more health education for the population as a whole.

Baby's gender may influence diabetes risk

A new study suggests that a baby's gender appears to affect a mother's risk for diabetes during pregnancy (gestational diabetes) and Type 2 diabetes after pregnancy. Researchers reviewed information from nearly 643,000 women in Canada who had their first child between 2000 and 2010.

Women who were carrying a son were more likely to develop gestational diabetes but women who developed gestational diabetes while pregnant with a daughter had a higher risk of developing Type 2 diabetes after pregnancy. While the study found a link between a baby's gender and a mother's risk of diabetes, it was not designed to prove cause-and-effect. (Journal of Clinical Endocrinology & Metabolism, May 20th 2015).

Health in an aging world

For the first time in history, during the next 5 years people aged 65 years and older in the world will outnumber children younger than 5 years. According to a commentary in The Lancet (Vol 385, February 7th 2015), the aging of populations is poised to become the next global health challenge.

Onions could lower blood glucose and cholesterol levels

Onion bulb extract could reduce high blood glucose and cholesterol levels, according to new research. The study, presented at the Endocrine Society's 97th annual meeting in San Diego, was conducted on diabetic rats. When the rats were given onion bulb extract - in combination with metformin, their blood glucose and cholesterol levels were significantly reduced. Will the results be the same in humans?

Drinking coffee results in less calcium build up in arteries

Research carried out in the US found that drinking three to five cups of coffee a day was associated with less calcium build-up in the arteries. The researchers said that the study did not show a direct cause-and-effect relationship between coffee and reduced calcium in the arteries, but the association was very strong. They suggest that coffee may reduce the risk for Type 2 diabetes, a risk factor for hardening of the arteries but they do not go as far as recommending people to drink coffee to prevent heart disease. They say that people should not be concerned about drinking coffee as it is not harmful to the heart.

Anyone for Tea?

A study recently published in the Journal of Endocrinological Investigation has concluded that drinking chamomile tea can have benefits for people with Type 2 diabetes. The study took 64 people with Type 2 diabetes, and asked half of them to drink a cup of chamomile tea three times a day, after each main meal [3 grams of tea in 150mls of water]. The other half were asked to drink water. After eight weeks the researchers found some very interesting results. Compared to the group that drank water, the group that drank chamomile tea had:

- Significantly improved glycaemic control [HbA1c].
- Significantly decreased insulin resistance.
- Significantly reduced levels of LDL [bad] cholesterol.

Chamomile tea is readily available in supermarkets.

Eating chocolate, what's it all about?

A British study that followed almost 21,000 adults for an average of 12 years found those who ate the most chocolate had lower heart attack, stroke and diabetes rates as well as lower BMI, blood pressure and inflammation, when compared with people who consumed the least chocolate. Researchers also analysed past studies and found chocolate eaters were less likely to have or die from a range of cardiovascular problems, compared with those who did not eat chocolate. (BMJ: Heart June 2015)

From your editor – Jenny Hirst

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