Structured patient education for people with type 2 diabetes: the X-PERT Programme in Ireland

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The prevalence of type 2 diabetes has risen globally in recent years, with most recent estimates of 129,052 people in the Republic of Ireland (4.3%).[1] Along with the risk of long term complications, people with diabetes have a 2-5 fold risk of developing CVD, a concern to health services in terms of service provision, morbidity and cost implications. Diabetes is a life long condition in which the person with the diabetes is central to looking after their own care[2] and self-management education, is central to any good diabetes service.[2] People with diabetes see a health professional for a mere three hours each year and have to self manage their condition for the other 8,762 hours.

It is recognised that self-management is critical in optimising the health of people with diabetes.[3,4,5] To promote self management a structured patient education programme is recommended. Such programmes must be based on patient centred models of care rather than the traditional medical model; which historically meant health professionals imparting knowledge to patients and expecting compliance and adherence to their instruction.

Structured patient education aims to empower people to increase control over their condition by providing them with knowledge, skills and confidence to self-manage. The National Institute for Clinical Excellence (NICE) in the UK has developed key criteria[6] which diabetes structured patient education programmes should meet. The philosophy behind these criteria is that the programme should be evidence based, flexible to the needs of the individual, involve the users in the development and share its aims with patients, carers and family. Under the NICE key criteria, structured patient education programmes for people with diabetes should have:

- An underlying philosophy
- A structured written curriculum
- Appropriately trained trainers
- A quality assurance programme
- An audit programme

One example of a structured patient education programme which meets these criteria and which has been extremely successful is the Diabetes EXpert Patient Education versus Routine Treatment (X-PERT) Programme in the UK. This is a structured group education programme for people with type 2 diabetes, facilitated through six weekly 2.5 hour sessions, where participants are educated on diabetes self-management. This allows group support and participation and also maximises the efficiency of the service provided from both dietetic time and cost point of view.

X-PERT UK was evaluated via randomised controlled trial and was shown to positively impact on clinical, lifestyle and psychosocial outcomes.[7] Through this programme, 15 hours contact time with a health professional via group work was

Table 1.

Outcome	Baseline Mean (SD)	3 Months Mean (SD)	6 Months Mean (SD)	p value
Body Weight (kg)	85.7 (13.9) n=46	84.0 (13.4) n=44	83.2 (12.5) n=42	0.000 (n=39)
HbA1c (%)	7.5 (1.8) n=45	6.9 (1.0) n=44	6.7 (1.0) n=41	0.021 (n=38)
Diabetes Knowledge Test (% Correct)	36%	59%	59%	0.000 (n=37)
Diabetes Empowerment Score (max score = 5)	3.74 ± 0.78	4.22 ± 0.45	4.19 ± 0.46	0.001 (n=22)

compared to 1 hour total contact time with a GP, practice nurse and a dietitian, combined.

In 2005 the Community Nutrition and Dietetic Service, HSE South, began liaison with the X-PERT UK to adapt the programme for Ireland, as at that time there were no such programmes in Ireland. A six month pilot of the adapted X-PERT Ireland programme showed similar positive results with regard to impact on clinical, lifestyle and psychosocial outcomes, a sample of which are shown in Table 1.

The X-PERT Programme is a specially designed patient education programme via group work, which aims to provide people with the confidence, knowledge and skills necessary to self-manage their diabetes. It is not a set of strict instructions that dictate behaviour change and then measure success based on levels of compliance, but a new tried and tested approach to patient education, that focuses on patient-centred care and patient activation. The flexible curriculum addresses the needs of the group at hand while aiming to cover a number of topics over the course of the six weeks. While the curriculum is health professional directed, a collaborative approach is used throughout.

Participants are encouraged to actively participate at all times. This is facilitated by the use of client centred facilitation skills by the health professional. The aim is to involve each person in adapting the information they receive to their personal diet and lifestyle rather than trying to adapt the participants to one standard treatment. A crucial part of the programme is providing all participants with their personal Diabetes Health Profile – a form that lists all relevant clinical parameters in diabetes care (weight, BMI, glycated haemoglobin, cholesterol, ACR, etc). Significant time is spent explaining this form at week 1 and it is revisited later in the programme to ensure that all participants understand the importance of each clinical outcome and how they may be able to improve any parameters that are not within the recommended ranges. The Practice Nurse is an invaluable support in aiding the provision of these forms, as all participants are encouraged to attend the GP surgery for a diabetes check up and blood test prior to attendance at the programme. During the evaluation of the X-PERT Ireland pilot 100% of participants felt the explanation and use of this personal Diabetes Health Profile helpful and important in managing their diabetes.

The aim is to involve each person in adapting the information they receive to their personal diet and lifestyle rather than trying to adapt the participants to one standard treatment.

The X-PERT visual aids and resources used throughout the programme are central to enhancing participants' understanding of diabetes and health. A five step empowerment model for goal setting is used to help clients make the changes they feel are personally meaningful. Questions are welcomed at any point and discussions of participants' own experiences of living with diabetes are central to the programme. The sharing of personal experiences has been reported as one of the most helpful parts of the programme. At the end of the programme clients are asked to complete an evaluation and are asked to share any comments or suggestions they may have. Following on from the six-week programme, participants are offered regular refresher sessions; at least one within the following six months; an annual update session and annual sessions thereafter. This continuing care is in line with strong evidence for the value of patient follow up in chronic disease management.[8]

What is the X-PERT Programme all about? (Table 2 overleaf)

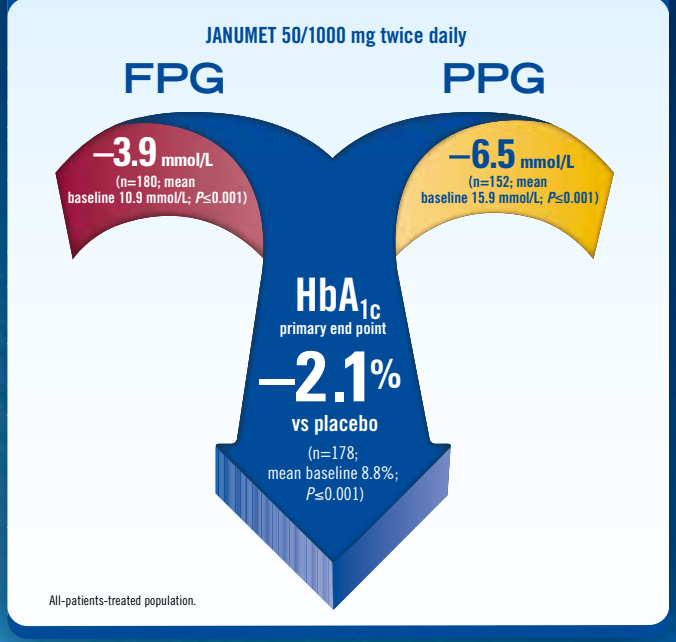
Following the success of the pilot of X-PERT Ireland, funding was allocated to allow further development of the programme here. Partnership with X-PERT UK allowed a Train the Educators programme to be developed for X-PERT Ireland so that Community Dietitians could be trained in its delivery. Since Autumn 2007, 93 Community Dietitians from the four HSE regions of Ireland have been trained as X-PERT Ireland Educators. X-PERT Educators collect data on every programme delivered and this is entered into the X-PERT online database. A recent review of the X-PERT Ireland section of the database showed that 227 programmes have been delivered across the Republic of Ireland since 2006, educating 2712 people with type 2 diabetes. Attendance has been excellent with 85.3% attending four or more of the six sessions with the mean number of sessions attended standing at five out of six. The mean evaluation score of the programme by participants was

For patients not adequately controlled on metformin alone,

Powerful glucose reductions to help get patients to goal[1,a]

Janumet® (sitagliptin/metformin)

Glucose reductions at 24 weeks



All-patients-treated population.

Additional HbA_{1c} results at 24 weeks[1,a]

- 1.3% placebo-adjusted HbA_{1c} reduction with metformin 1000 mg twice daily (n=177; mean baseline 8.7%; $P \leq 0.001$)
- 1.6% placebo-adjusted HbA_{1c} reduction with JANUMET™ (sitagliptin/metformin, MSD) 50/500 mg twice daily (n=183; mean baseline 8.8%; $P \leq 0.001$)
- 1.0% placebo-adjusted HbA_{1c} reduction with metformin 500 mg twice daily (n=178; mean baseline 8.9%; $P \leq 0.001$)
- 0.8% placebo-adjusted HbA_{1c} reduction with sitagliptin 100 mg once daily (n=175; mean baseline 8.9%; $P \leq 0.001$)

JANUMET:

Powerful efficacy to help get patients to goal[1]

As an adjunct to diet and exercise,

- ✔ For patients uncontrolled on metformin alone[2]
- ✔ In combination with a glitazone or sulfonylurea[2]
- ✔ In combination with insulin[2]

JANUVIA® Sitagliptin **JANUMET®** Sitagliptin/metformin hydrochloride
ABRIDGED PRESCRIBING INFORMATION Refer to Summary of Product Characteristics (SmPC) before prescribing **PRESENTATION** **Januvia®** 100 mg film-coated tablet containing 100 mg of sitagliptin. **Janumet®** 50 mg/850 mg and 50 mg/1000 mg tablets each containing 50 mg sitagliptin and 850 mg or 1000 mg metformin hydrochloride. **USES** For patients with type 2 diabetes mellitus **Januvia** is indicated to improve glycaemic control: as **monotherapy** • in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance as **dual oral therapy** in combination with • metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control • a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contra-indications or intolerance • a PPARγ agonist (i.e. a thiazolidinedione) when use of a PPARγ agonist is appropriate and when diet and exercise plus the PPARγ agonist alone do not provide adequate glycaemic control as **triple oral therapy** in combination with • a sulphonylurea and metformin when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control. • a PPARγ agonist and metformin when use of a PPARγ agonist is appropriate and when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control. **Januvia** is also indicated as add-on to insulin (with or without metformin) when diet and exercise plus stable dosage of insulin do not provide adequate glycaemic control. **Janumet:** as an adjunct to diet and exercise to improve glycaemic control in patients inadequately controlled on their maximal tolerated dose of metformin alone or those already being treated with the combination of sitagliptin and metformin. • in combination with a sulphonylurea (i.e., triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea. • as triple combination therapy with a PPARγ agonist (i.e., a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a PPARγ agonist. • as add-on to insulin (i.e., triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in patients when stable dosage of insulin and metformin alone do not provide adequate glycaemic control. **DOSAGE AND ADMINISTRATION Januvia** - One 100 mg tablet once daily, with or without food. **Janumet** - The dose of antihyperglycaemic therapy with Janumet should be individualised on the basis of the patient's current regimen, effectiveness, and tolerability while not exceeding the maximum recommended daily dose of 100 mg sitagliptin. For patients not adequately controlled on metformin alone, the usual starting dose of Janumet should provide sitagliptin dosed as 50 mg twice daily (100 mg total daily dose) plus the dose of metformin already being taken. For patients switching from co-administration of sitagliptin and metformin, Janumet should be initiated at the dose of sitagliptin and metformin already being taken. For patients inadequately controlled on dual combination therapy with the maximal tolerated dose of metformin and a sulphonylurea **or** with maximal tolerated dose of metformin and a PPARγ agonist **or** with maximal tolerated dose of metformin and insulin, the dose of Janumet should provide sitagliptin dosed as 50 mg twice daily (100 mg total daily dose) and a dose of metformin similar to the dose already being taken. All patients should continue their diet with an adequate distribution of carbohydrate intake during the day. Overweight patients should continue their energy-restricted diet. **Januvia and Janumet** - In combination with a sulphonylurea or with insulin, consider a lower dose of sulphonylurea or insulin, to reduce risk of hypoglycaemia. **Renal impairment:** See Precautions. **Hepatic impairment:** For ***Januvia*** only - no dosage adjustment necessary for patients with mild to moderate hepatic impairment. Januvia has not been studied in patients with severe hepatic impairment. For ***Janumet*** only – do not use. Elderly < 75 years: For ***Januvia*** only - no dosage adjustment necessary. For ***Janumet*** only - use with caution as age increases. Monitoring of renal function is necessary to aid prevention of metformin-associated lactic acidosis. **Elderly ≥ 75 years:** Exercise care as there are limited safety data in this population. **Children:** not recommended below 18 years of age. **CONTRA-INDICATIONS For Januvia** - Hypersensitivity to active substance or excipients. For Janumet - Hypersensitivity. Diabetic ketoacidosis and diabetic pre-coma. Moderate and severe renal impairment (creatinine clearance < 60 ml/min). Acute conditions with the potential to alter renal function such as dehydration, severe infection, shock. Intravascular administration of iodinated contrast agents. Acute or chronic disease which may cause tissue hypoxia such as cardiac or respiratory failure, recent myocardial infarction, shock. Hepatic impairment. Acute alcohol intoxication, alcoholism. Lactation. **PRECAUTIONS** ***For Januvia and Janumet*** *- General:* do not use in patients with type 1 diabetes or for diabetic ketoacidosis. *Pancreatitis:* Post-marketing experience - spontaneously reported adverse reactions of acute pancreatitis. Inform patients of the symptom of acute pancreatitis: persistent, severe abdominal pain. Resolution of pancreatitis has been observed after discontinuation of sitagliptin, but very rare cases of necrotizing or haemorrhagic pancreatitis and/or death have been reported. If pancreatitis is suspected, Januvia or Janumet and other potentially suspect medicinal products should be discontinued. *Hypoglycaemia when used with other anti-hyperglycaemic agents:* Rates of hypoglycaemia reported with sitagliptin were generally similar to rates in patients taking placebo. When sitagliptin was added to a sulphonylurea or to insulin, the incidence of hypoglycaemia was increased over that of placebo; therefore consider a lower dose of sulphonylurea or insulin to reduce the risk of hypoglycaemia when administering Janumet or Januvia. *Hypersensitivity reactions:* Serious hypersensitivity reactions have been reported, including anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. Onset occurred within the first 3 months after initiation of treatment with some reports occurring after the first dose. If suspected, discontinue Januvia or Janumet. ***For Januvia only*** - As experience is limited, patients with moderate or severe renal impairment should not be treated with Januvia. ***For Janumet only*** *- Lactic acidosis and renal function:* a very rare, but serious, metabolic complication can occur due to metformin accumulation. Cases in patients on metformin have occurred primarily in diabetic patients with significant renal failure. Reduce incidence by assessing other associated risk factors. If suspected, discontinue treatment and hospitalise patient immediately. If changes in clinical status of patients with previously controlled type 2 diabetes occurs, evaluate promptly for evidence of ketoacidosis or lactic acidosis in any patient with type 2 diabetes previously well controlled on Janumet who develops laboratory abnormalities or clinical illness (especially vague and poorly defined illness). If acidosis of either form occurs, stop Janumet immediately and initiate corrective measures.Determine serum creatinine concentrations regularly, i.e. at least once a year in patients with normal renal function and at least two to four times a year in patients with serum creatinine levels at or above the upper limit of normal and in elderly patients. Decreased renal function in elderly patients is frequent and asymptomatic. Exercise special caution where renal function may become impaired, e.g. when initiating antihypertensive or diuretic therapy or when starting treatment with a non-steroidal anti-inflammatory drug (NSAID). Surgery: due to metformin hydrochloride content of Janumet, discontinue treatment 48 hours before elective surgery with general, spinal or epidural anaesthesia. Do not resume earlier than 48 hours afterwards and only after renal function is normal. **DRUG INTERACTIONS** ***For Janumet only*** *- Alcohol:* avoid alcohol and medicinal products containing alcohol due to risk of lactic acidosis. *Cationic agents that are eliminated by renal tubular secretion (e.g., cimetidine):* these may interact with metformin by competing for common renal tubular transport systems. Consider close monitoring of glycaemic control, dose adjustment within the recommended posology and changes in diabetic treatment when these agents are co-administered. Iodinated contrast agents in radiological studies: intravascular administration of these agents may lead to renal failure, resulting in metformin accumulation and a risk of lactic acidosis. Discontinue Janumet prior to, or at the time of the test and do not reinstitute until 48 hours afterwards, and only after renal function is found to be normal. Combination requiring precautions for use: glucocorticoids (given by systemic and local routes) beta-2-agonists, and diuretics have intrinsic hyperglycaemic activity. Inform the patient and perform more frequent blood glucose monitoring, especially at the beginning of treatment. If necessary, adjust dose of the anti-hyperglycaemic medicine during therapy with, or on discontinuation of the other medicine. ACE-inhibitors: as these may decrease the blood glucose levels, if necessary, adjust dose of the antihyperglycaemic during therapy with, or on discontinuation of the other medicine. ***For Januvia and Janumet*** - Low risk of clinically meaningful interactions with metformin and ciclosporin. Meaningful interactions would not be expected with other p-glycoprotein inhibitors. The primary enzyme responsible for the limited metabolism of sitagliptin is CYP3A4, with contribution from CYP2C8. *Digoxin:* sitagliptin had a small effect on plasma digoxin concentrations, and may be a mild inhibitor of p-glycoprotein in vivo. No dosage adjustment of digoxin is recommended, but monitor patients at risk of digoxin toxicity if the two are used together.*Pregnancy and lactation:* Do not use during pregnancy or breastfeeding. **SIDE EFFECTS Refer to SmPC for complete information on side effects** There have been no therapeutic clinical trials conducted with Janumet tablets however Janumet is bioequivalent to co-administered sitagliptin and metformin. *Sitagliptin only:* In studies of sitagliptin 100 mg alone compared to placebo, adverse reactions considered as drug-related reported in patients treated with sitagliptin in excess (> 0.2 % and difference > 1 patient) of that in patients receiving placebo are headache, hypoglycaemia, constipation, and dizziness. Also, adverse experiences reported regardless of causal relationship to medication and more commonly in patients treated with sitagliptin included upper respiratory tract infection, nasopharyngitis, osteoarthritis and pain in extremity. *Metformin only:* Clinical Trial Data and Post-marketing data: *Very common (≥ 1/10):* gastro-intestinal disorders; *Common (≥ 1/100 to < 1/10):* metallic taste; *Very rare (< 1/10,000):* urticaria, erythema; pruritis; lactic acidosis; vitamin B12 deficiency; liver function disorders, hepatitis. *Sitagliptin with metformin: Common:* nausea; *Uncommon:* somnolence; upper abdominal pain, diarrhoea, blood glucose decreased, anorexia, weight decreased. *Sitagliptin with a sulphonylurea: Common:* hypoglycaemia. *Sitagliptin with metformin and a sulphonylurea: Very common:* hypoglycaemia; *Common:* constipation. *Sitagliptin with a PPARγ agent (pioglitazone): Common:* hypoglycaemia, flatulence, peripheral oedema. *Sitagliptin with a PPARγ agent (rosiglitazone) and metformin: Common:* headache, diarrhoea, vomiting, hypoglycaemia, peripheral oedema. *Sitagliptin with insulin with/ without metformin: Common:* headache, hypoglycaemia, influenza; *Uncommon:* dry mouth, constipation. *Sitagliptin with metformin and insulin: very common:* hypoglycaemia; *uncommon:* headache and dry mouth. *Post-marketing experience* additional side effects have been reported (frequency not known): hypersensitivity reactions, including anaphylaxis, angioedema, rash, urticaria, cutaneous vasculitis and exfoliative skin conditions including Stevens-Johnson syndrome (see precautions); acute pancreatitis, including fatal and non-fatal haemorrhagic and necrotizing pancreatitis (see precautions); impaired renal function, including acute renal failure (sometimes requiring dialysis); vomiting. **PACKAGE QUANTITIES Januvia** 100 mg film-coated tablets 28 tablets **Janumet** 50mg/850mg and 50mg/1000mg film-coated tablets 56 tablets **Marketing Authorisation Number Januvia** 100 mg: EU/1/07/383/014 **Janumet** 50 mg/850 mg: EU/1/08/455/003 **Janumet** 50 mg/1000 mg: EU/1/08/455/010 **Marketing Authorisation Holder** Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK **POM Date of review of prescribing information:** June 2011 © Merck Sharp & Dohme Limited,2011. All rights reserved. API.COMBINED JANUMET/JANUVIA.JUN11.IRL

References: 1. Goldstein BJ, Feinglos MN, Lunceford JK, et al; for the sitagliptin 036 study group. Effect of initial combination therapy with sitagliptin, a dipeptidyl peptidase-4 inhibitor, and metformin on glycemic control in patients with type 2 diabetes. Diabetes Care. 2007;30(8):1979–1987. 2. Janumet SPC available at www.medicines.ie.

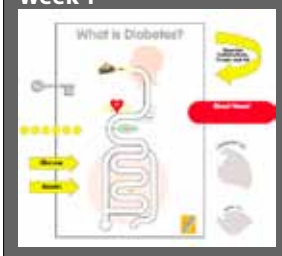
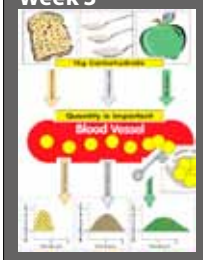
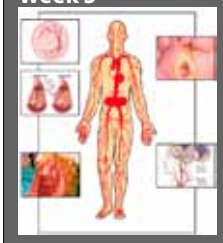
a A randomized, double-blind, placebo-controlled, parallel-group study evaluating the combination of sitagliptin + metformin administered as separate 50/850-mg or 50/1000-mg tablets compared with either agent alone in 1091 patients with type 2 diabetes inadequately controlled on diet and exercise (HbA1c ≥7.5% to ≤11%).1 FPG=fasting plasma glucose; PPG=postprandial glucose.

Further information is available on request from from MSD, Pelham House, South County Business Park, Leopardstown, Dublin 18 or from www.medicines.ie.

MSD DIABETES

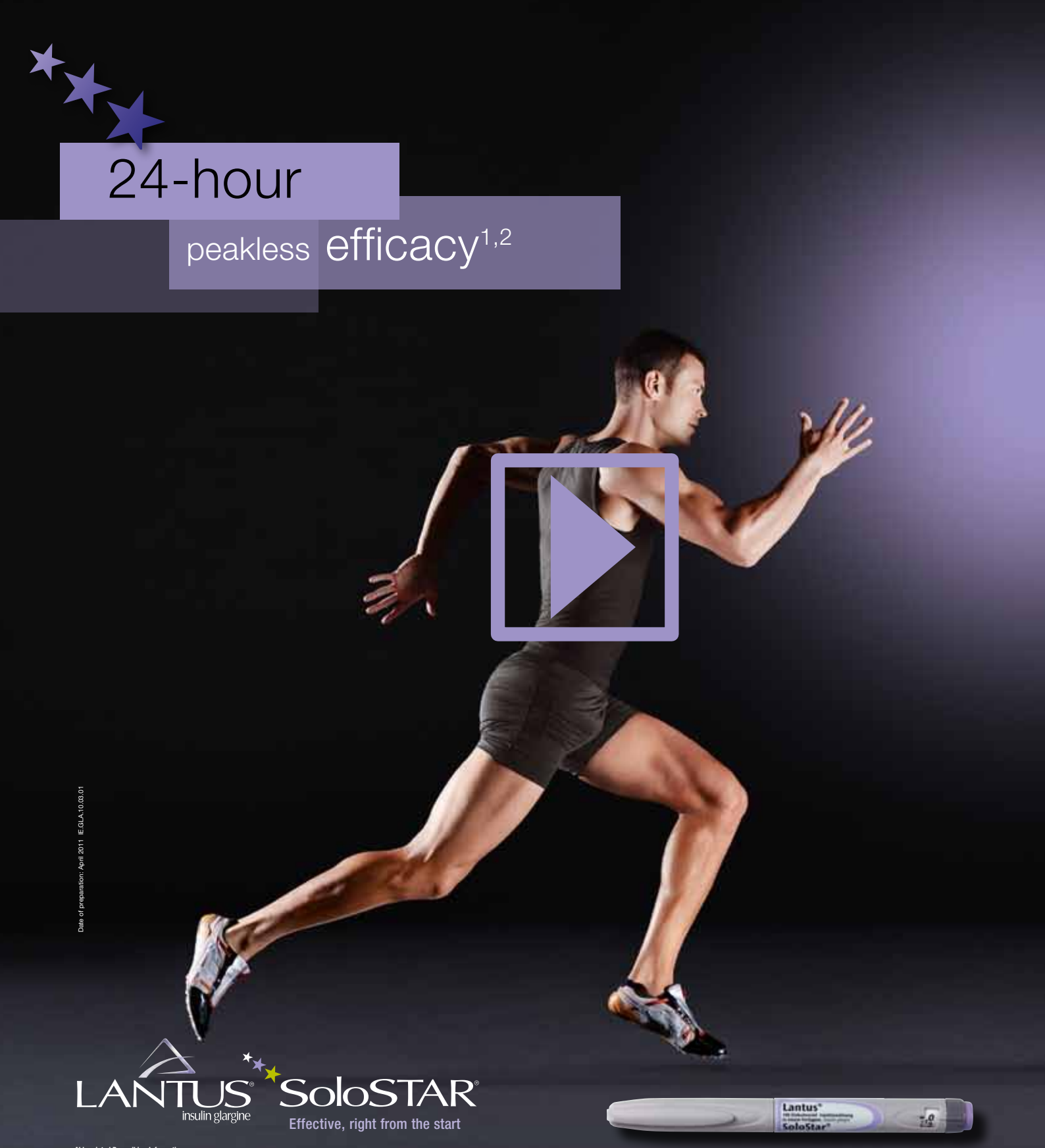
07-12-JMT-2011-IRL-4707-J

Table 2.

Week	Content
Week 1 	**What is diabetes?** Self monitoring of blood glucose. Understanding medication. Diabetes health results – what do they mean?
Week 2 	**Weight management; energy balance.** Healthy eating and portion control. Physical activity.
Week 3 	**Carbohydrate awareness.** What are carbohydrates? How starches and sugars affect blood glucose levels. Dispelling myths of the sugar-free diet.
Week 4 	**Reading food labels (supermarket tour).** A virtual supermarket is created giving clients an opportunity to ask questions, read labels and become more informed about the foods they eat.
Week 5 	**Possible complications of diabetes (short and long term).** Prevention of these. Living with diabetes.
Week 6 	**Are you an X-PERT?** Game designed to recap on main messages of the programme in a fun way while helping to increase skills, knowledge and confidence in making informed decisions regarding diabetes self-management. Questions and answers. Comments and feedback. Sharing of resources.
Refreshers and Annual Sessions	**Recap on aspects of 6 week programme as per patient requests.** Further goal setting.
20 minutes at end of each week – Goal setting with five step Empowerment Model.	

24-hour

peakless efficacy[1,2]



LANTUS® insulin glargine SoloSTAR®

Effective, right from the start

Date of preparation: April 2011 IE.GLA.10.03.01

Abbreviated Prescribing Information
Lantus® 100 Units/ml solution for injection (insulin glargine).
Presentation: 1 glass vial/pack containing 10ml solution (1,000 U insulin glargine, equivalent to 36.4mg) or 5 glass cartridges/pack each containing 3ml solution (300 U insulin glargine, equivalent to 10.92mg) or packs of 5 OptiSet® pens each containing 3ml solution (300 U insulin glargine, equivalent to 10.92mg) or packs of 5 Solostar® pens each containing 3ml solution (300 U insulin glargine, equivalent to 10.92mg). (Excipients: zinc chloride, m-cresol, glycerol, hydrochloric acid, sodium hydroxide and water for injection). **Indications:** Treatment of adults, adolescents and children of 6 years or above with diabetes mellitus, where treatment with insulin is required. **Dosage and Administration:** Lantus contains insulin glargine, an insulin analogue, and has a prolonged duration of action. Lantus should be administered subcutaneously once daily at the same time each day and the dose should be individually adjusted. *Elderly population (≥ 65 years old):* Progressive deterioration of renal function may lead to a steady decrease in insulin requirements. *Renal impairment:* Insulin requirements may be diminished due to reduced insulin metabolism. *Hepatic impairment:* Insulin requirements may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism. *Paediatric population:* Safety and efficacy of Lantus have been established in adolescents and children of 6 years and above. In children (aged 6 years or above), only evening administration has been studied. Due to limited experience on the efficacy and safety of Lantus in children below the age of 6 years, Lantus should only be used in this age group under careful medical supervision. Close metabolic monitoring is recommended during transition from other insulins to Lantus and in circumstances that increase susceptibility to hypo- or hyperglycaemia. Lantus must not be mixed with other insulins or diluted. Mixing or diluting can change its time/action profile and mixing can cause precipitation. **Contraindications:** Hypersensitivity to insulin glargine or to any of the excipients. **Precautions and Warnings:** Lantus is not the insulin of choice for treatment of diabetic ketoacidosis. In case of insufficient glucose control or a tendency to hypo/hyperglycaemic episodes, all relevant factors must be reviewed before dose adjustment is considered. Insulin administration may cause insulin antibodies to form. In rare cases, these insulin antibodies may necessitate adjustment of the insulin dose in order to correct a tendency to hyper- or hypoglycaemia. Particular caution should be exercised, and intensified blood monitoring is advisable, for patients in whom hypoglycaemic episodes might be of clinical relevance and in those with intercurrent illness, where dose adjustments may be required. Warning signs of hypoglycaemia may be changed, less pronounced or absent in certain risk groups, including patients in whom: glycaemic control is markedly improved; hypoglycaemia develops gradually; an autonomic neuropathy is present; or elderly patients. Prolonged effect of subcutaneous Lantus may delay recovery from hypoglycaemia. Adherence of the patient to the dosage and dietary regimen, correct insulin administration and awareness of hypoglycaemia symptoms are essential to reduce the risk of hypoglycaemia. Cardiac failure has been reported when pioglitazone was used in combination with insulin; especially in patients with risk factors for heart failure. Observe for signs and symptoms of heart failure (weight gain and oedema) if pioglitazone is used with Lantus. Discontinue pioglitazone if symptoms of cardiac deterioration occur. **Interactions:** Substances that may enhance the blood glucose-lowering effect and increase susceptibility to hypoglycaemia include oral antidiabetic medicinal products, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAO inhibitors, pentoxifylline, propoxyphene, salicylates and sulfonamide antibiotics. Substances that may reduce the blood glucose-lowering effect include corticosteroids, danazol, diazoxide, diuretics, glucagon, isoniazid, oestrogens and progestogens, phenothiazine derivatives, somatropin, sympathomimetic medicinal products (e.g. epinephrine [adrenaline], salbutamol, terbutaline), thyroid hormones, atypical antipsychotic medicinal products (e.g. clozapine and olanzapine) and protease inhibitors. Beta-blockers, clonidine, lithium salts or alcohol may potentiate or weaken the blood glucose-lowering effect of insulin. Under the influence of sympatholytic medicinal products, the signs of adrenergic counter-regulation may be reduced or absent. **Fertility, Pregnancy and Lactation:** *Pregnancy:* For insulin glargine no clinical data on exposed pregnancies from controlled clinical trials are available. A moderate amount of data on pregnant women exposed to marketed insulin glargine indicate no adverse effects of insulin glargine on pregnancy and no malformative nor feto/neonatal toxicity. Animal data do not indicate reproductive toxicity. The use of Lantus may be considered during pregnancy, if necessary. *Breastfeeding:* It is unknown whether insulin glargine is excreted in human milk. No metabolic effects of ingested insulin glargine on the breastfed newborn/infant are anticipated since insulin glargine as a peptide is digested into aminoacids in the human gastrointestinal tract. Breastfeeding women may require adjustments in insulin dose and diet. *Fertility:* Animal studies do not indicate direct harmful effects with respect to fertility. **Effects on ability to drive and use machines:** The patient's ability to concentrate and react may be impaired as a result of hypo/hyperglycaemia or, for example, as a result of visual impairment. Patients should be advised to take precautions to avoid hypoglycaemia whilst driving or operating machinery. **Adverse Reactions:** Hypoglycaemia, in general the most frequent adverse reaction of insulin therapy, may occur if the insulin dose is too high in relation to the insulin requirement. **Metabolism and nutrition disorders:** Very Common (≥ 1/10): Hypoglycaemia. **Skin and subcutaneous tissue disorders:** Common (≥ 1/100 to <1/10): Lipohypertrophy. **General disorders and administration site conditions:** Common: Injection site reactions such as: redness, itching, pain, itching hives, swelling or inflammation. Paediatric Population (≤18 years): relatively more frequent injection site reactions, injection site pain and skin reactions (rash, urticaria) were received from post marketing surveillance. Please refer to the Summary of Product Characteristics (SPC) for complete list of adverse reactions. **Overdose** may lead to severe and sometimes prolonged and life-threatening hypoglycaemia. Mild episodes can usually be treated with oral carbohydrates. More severe episodes may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. **Pharmaceutical Precautions:** Store unopened cartridges/vials/OptiSet/ Solostar pens at 2°C–8°C. Do not freeze. Once opened, do not store above 25°C and use within 4 weeks. Once in use, do not refrigerate OptiPen® Pro pen (containing cartridge), vial, OptiSet or Solostar pens. **Legal Category:** POM. **Marketing Authorisation Numbers:** Lantus 100 U/ml solution for injection in a cartridge (5 cartridges/pack): EU/1/00/134/006, Lantus 100 U/ml solution for injection in a 10ml vial (1 vial/pack) EU/1/00/134/012, Lantus 100 U/ml OptiSet solution for injection (5 pens) EU/1/00/134/010, Lantus 100 Units/ml solution for injection in a pre-filled pen (Solostar® 5 pens) EU/1/00/134/033. **Marketing Authorisation Holder:** sanofi-aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany. Please refer to SPC which can be found on IPHA @ http://www.medicines.ie/ before prescribing. For further information contact IEmedinfo@sanofi-aventis.com or Medical Information Department, sanofi-aventis Ireland Ltd., 18 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24. Ph.: 01 403 5600.
Information about adverse event reporting can be found at www.imb.ie
Adverse events should be reported to the sanofi-aventis Drug Safety Department
Date of Revision: March 2011

1. Porcellati F et al, Diabetes Care Vol 30; No 10; 2447 - 2452 October 2007. 2. Lantus SPC.

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Table 3. X-PERT Ireland Audit Results 2006-2011

	Baseline	6 Months	1 Year	2 Years
HbA1c %	7.3 (n=1150)	6.8 (n=298)	6.9 (n=182)	7.0 (n=36)
Weight kg	89.4 (n=1209)	85.1 (n=297)	85.1 (n=167)	84.4 (n=35)
BMI kg/m2	31.9 (n=1178)	30.6 (n=283)	30.2 (n=166)	29.6 (n=35)
Total Cholesterol mmol/l	4.3 (n=1230)	4.1 (n=304)	4.0 (n=188)	3.8 (n=38)
LDL Cholesterol mmol/l	2.4 (n=1119)	2.3 (n=269)	2.2 (n=177)	1.9 (n=33)
HDL Cholesterol mmo/l	1.2 (n=1123)	1.2 (n=269)	1.2 (n=178)	1.1 (n=34)
Triglycerides mmol/l	1.7 (n=1170)	1.6 (n=290)	1.5 (n=180)	NA
Systolic Blood Pressure mmHg	134.9 (n=964)	135.8 (n=248)	134.8 (n=160)	133.5 (n=21)
Diastolic Blood Pressure mmHg	77.8 (n=962)	76.7 (n=248)	76.1 (n=160)	73.9 (n=21)
Empowerment Score	3.8 Max score = 5	4.3 Max score = 5	4.3 Max score = 5	NA

(Figures taken from data entered by August 20th 2010)

96.7%. Clinical and empowerment data, as displayed in Table 3, shows positive improvements, similar to those seen the UK and Irish trials and in line with Audit Standards set out by X-PERT UK.

It is well recognised that structured education should be an integral part of diabetes care.[2-6] Group work programmes offer an economic and useful way of facilitating such education and X-PERT is one such programme that has been extremely successful in Ireland and the UK. X-PERT Ireland was the first such structured education programme to be evaluated in Ireland and proved to be cost and resource effective. The findings provide an insight into possible solutions for treating what is a serious, expensive and increasing national problem. Any method of equipping people with the skills and confidence to self-manage their condition offers immense benefits, both to the individual and to the health system. There is potential to use this model of care in the management of many chronic conditions.

Comments from participants

'For the first time in my life I feel like I am the one in control of my diabetes'

'I am learning new skills every week to help me manage my diabetes and also to manage my foods'

'It really helped me and my family take a better look at our food and portion sizes'

'These sessions have been really good and helpful. I hope to live a healthier lifestyle, thank you'

'Without this programme I would remain ignorant to my diabetes. The instructor is very good and explains it in the greatest of detail'.

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