



The Association of British Clinical Diabetologists (ABCD) nationwide exenatide audit

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Introduction

The current widespread availability of modern internet technology among health care professionals provides a novel possibility for monitoring safety and efficacy of new medications on a large scale that has not been possible in the past. With this in mind, the Association of British Clinical Diabetologists (ABCD) launched a project in December 2008 to accelerate understanding of exenatide 18 months after its launch in the UK, through a nationwide audit of its use in real life clinical practice. In particular, the aims were to examine the extent of clinical usage of exenatide in the UK and ascertain whether the experience matched data from phase III trials. It was hoped that safety and efficacy of the agent in clinical practice could be assessed, including observation of the degree and outcomes of any off-licence usage. In this way it was hoped that this nationwide collaborative effort could inform future practice and guidelines.

Methods

From December 2008 to December 2009, the ABCD invited diabetes physicians across the UK to submit data on their patients recently commenced on or starting exenatide therapy. All data submitted to the ABCD were either through an online web-hosted, password-protected questionnaire or an e-mailed spreadsheet. To protect confidentiality, all data were anonymised

ABSTRACT

In December 2008, to accelerate understanding of a new agent, the Association of British Clinical Diabetologists (ABCD) launched a nationwide audit on the use of exenatide in clinical practice.

A password-protected online questionnaire for collection of anonymised patient data was established and diabetes specialists in the UK were given persistent encouragement to submit data on their exenatide-treated patients. Baseline and latest HbA_{1c}, weight, body mass index (BMI), waist circumference, blood pressure and lipids were compared and adverse events related to exenatide were quantified.

A total of 315 contributors from 126 centres submitted data on 6717 patients (54.9% male) – mean baseline age was 54.9 years, HbA_{1c} 9.47% (80mmol/mol), weight 113.8kg, BMI 39.8kg/m². Of these, 4551 and 4385 had dated baseline and latest HbA_{1c} and weight respectively. Mean (±SE) HbA_{1c} fell by 0.73±0.03% (p<0.001) and weight by 5.9±0.1kg (p<0.001) at a median (range) of 26.1(6.6–164.1) and 26.0(6.6–159.0) weeks respectively. The following parameters also showed significant falls (p<0.001): BMI 2.2±0.1kg/m², waist circumference 5.1±0.3cm, systolic blood pressure 3.6±0.6mmHg, total cholesterol 0.16±0.03mmol/L and HDL cholesterol 0.03±0.01mmol/L. Triglycerides decreased by 0.14±0.06mmol/L (p=0.009). The change in diastolic blood pressure was not statistically significant. In all, 23.7% of patients reported gastrointestinal side effects with 7.2% having to stop exenatide permanently. Hypoglycaemia rates were 3.3% before and 5.6% after exenatide use (p<0.001). After scrutiny, one case of pancreatitis and four cases of renal failure occurring in patients on exenatide had no obvious alternate cause. All other reported side effects had <1% incidence. The rate of exenatide discontinuation was 19.9% throughout the span of the audit, most commonly due to gastrointestinal side effects (36.1%) and lack of glycaemic or weight benefit (33.8%).

This large scale audit confirmed the effectiveness of exenatide in clinical use and highlighted rare associated adverse events. Importantly, we have successfully demonstrated a novel approach by a national specialist society to independently monitor the efficacy and safety of a new treatment. Copyright © 2010 John Wiley & Sons.

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KEY WORDS

exenatide; GLP-1 agonist; type 2 diabetes; audit

with participating centres retaining patient-identifiable information locally. Diabetes physicians were periodically encouraged to submit data through the length of the audit, although participation was entirely voluntary. Parameters sought included patients'

age, diabetes duration, gender, ethnic background, baseline and follow-up HbA_{1c}, weight, body mass index (BMI), waist circumference, blood pressure, lipids, details of baseline and latest diabetes treatment, changes to diabetes treatment at exenatide initiation,

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Table 1. Baseline characteristics of patients in the nationwide exenatide audit

	Mean (SD) or %	n
Male	54.9%	6375
Caucasian	84.4%	5099
Age (mean, years)	54.9 (10.6)	6234
Duration of diabetes (median [interquartile range], years)	8 (5–13)	5025
HbA _{1c} (mean, %)	9.47 (1.69)	6597
Weight (mean, kg)	113.8 (23.4)	6509
BMI (mean, kg/m ²)	39.8 (8.0)	3554
Systolic BP (mean, mmHg)	139.5 (18.8)	3112
Diastolic BP (mean, mmHg)	78.5 (11.3)	3112
Cholesterol (mean, mmol/L)	4.35 (1.12)	3002
HDL cholesterol (mean, mmol/L)	1.11 (0.30)	2498
Triglycerides (mean, mmol/L)	2.57 (2.00)	2115

n = number from the 6717 patients with this data item submitted.

Table 3. Paired baseline and latest data available in the nationwide audit

	n	Weeks after exenatide start, median (range)
HbA _{1c}	4551	26.1 (6.6–164.1)
Weight	4385	26.0 (6.6–159.0)
Body mass index	2360	26.0 (6.6–150.6)
Waist circumference	511	25.0 (6.0–146.0)
Systolic and diastolic BP	1246	26.1 (6.0–112.1)
Cholesterol	1470	26.3 (6.0–115.6)
HDL cholesterol	1220	26.3 (6.0–115.6)
Triglycerides	998	26.4 (6.0–107.7)

adverse events, exenatide discontinuation, patient satisfaction, and the use of a professional driving licence. Follow-up data were grouped into three-monthly intervals in the first year (taken as ± 45 days) and six-monthly intervals after the first year (± 90 days). A final report prior to the end of the audit was sought with details of the

latest parameters recorded. All gastrointestinal side effects including nausea and vomiting were reported collectively as a group. All variables used for analyses were on-treatment data rather than intention-to-treat.

For this report, we compared baseline and latest HbA_{1c}, weight, BMI, waist circumference, blood

Table 2. Diabetes treatment of patients at exenatide initiation in the nationwide audit

Metformin	84.0%
Sulphonylurea	49.5%
Thiazolidinedione	27.1%
DPP4 inhibitors	2.2%
Meglitinides	2.0%
Acarbose	0.9%
Anti-obesity medication	2.0%
Insulin	33.9%

DPP4 inhibitors: dipeptidyl peptidase-4 inhibitors.

pressure and lipids, using paired t-tests to assess for statistical significance. Differences in incidence of hypoglycaemia before and after exenatide use were compared using Chi-square tests. Gastrointestinal side effects, other notable adverse events, frequency and reasons for exenatide discontinuation were quantified.

Results

Participation in the audit

A total of 315 contributors from 126 centres throughout the UK submitted data on 6717 patients in the audit. Contributors to the audit are listed in Appendix 1 (available online at www.practicaldiabetesinternational.com). Overall, 39.6% of patient data were submitted online and 60.4% via an e-mailed spreadsheet. In total, there were 570 945 data items submitted for analysis.

Baseline characteristics of patients

Details of baseline characteristics and diabetes treatment are outlined in Tables 1 and 2.

Baseline and latest results

The percentages of patients with dated baseline and latest data are outlined in Table 3. Results on HbA_{1c}, weight, BMI, waist circumference, blood pressure and lipids are represented in Figures 1 to 4. Baseline data for these patients were comparable with the baseline data among the whole cohort. There were 4551 patients with dated baseline and latest HbA_{1c} and 4385 patients with dated baseline and latest weight. Mean (\pm SE) HbA_{1c} fell by $0.73 \pm 0.03\%$ from mean (SD) 9.48(1.69)% to 8.75(1.84)%



($p < 0.001$), and mean weight fell by 5.9 ± 0.1 kg from $113.9 (23.0)$ kg to $107.9 (22.6)$ kg ($p < 0.001$). This was at a median (range) of $26.1 (6.6-164.1)$ and $26.0 (6.6-159.0)$ weeks respectively after exenatide start (Figure 1). Similarly, BMI fell by 2.2 ± 0.1 kg/m² ($p < 0.001$), waist circumference by 5.1 ± 0.3 cm ($p < 0.001$), systolic blood pressure by 3.6 ± 0.6 mmHg ($p < 0.001$), total cholesterol by 0.16 ± 0.03 mmol/L ($p < 0.001$), and triglycerides by 0.14 ± 0.06 mmol/L ($p = 0.009$). HDL cholesterol fell by 0.03 ± 0.01 mmol/L ($p < 0.001$). The change in diastolic blood pressure (gain of 0.3 ± 0.4 mmHg) was not statistically significant. (Figures 2 to 4.)

Magnitude of changes from baseline

The reductions of the various parameters as a percentage of their baseline value in descending order of magnitude were HbA_{1c} 7.7%, BMI 5.5%, triglycerides 5.5%, weight 5.2%, waist circumference 4.2%, total cholesterol 3.7%, HDL cholesterol 2.7% and systolic blood pressure 2.6%.

Adverse events with exenatide

Gastrointestinal side effects

A total of 1593 patients (23.7%) reported gastrointestinal side effects throughout the audit (see Table 4 for a summary of adverse events). In 1047 patients (15.6%) this was transient, and in 62 patients (0.9%) this required exenatide to be stopped temporarily. The remainder (484 patients [7.2%]) had to discontinue exenatide permanently due to unacceptable gastrointestinal side effects.

Hypoglycaemia

There were 223 patients (3.3%) reporting episodes of hypoglycaemia before exenatide was started and 377 patients (5.6%) after exenatide was started (difference: $p < 0.001$). Two cases of severe hypoglycaemia were reported, both among patients concurrently on insulin treatment.

Pancreatitis

There were four cases of pancreatitis reported in the audit. After scrutiny, three cases had alternate causes of pancreatitis such as gallstones, significant alcohol consumption or significant hypertriglyceridaemia and the

Figure 1. Baseline vs latest HbA_{1c} and weight following exenatide

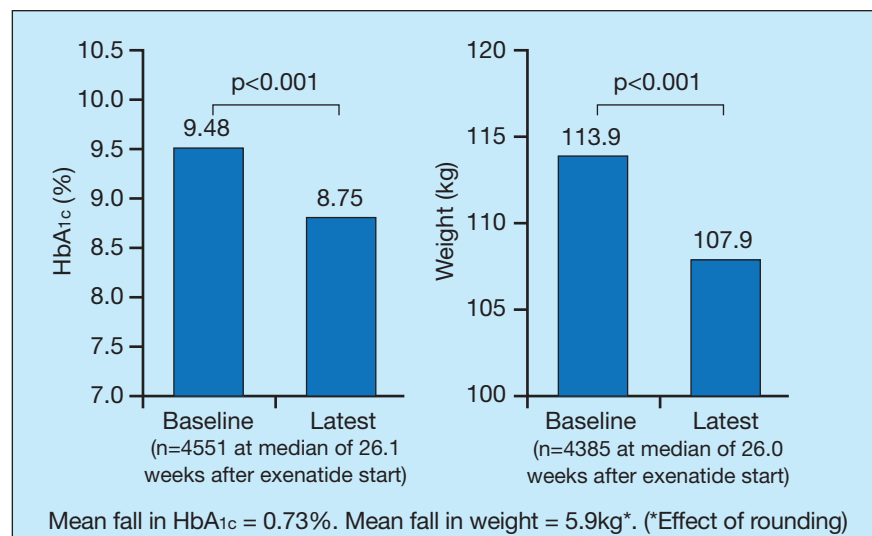


Figure 2. Baseline vs latest BMI and waist circumference following exenatide

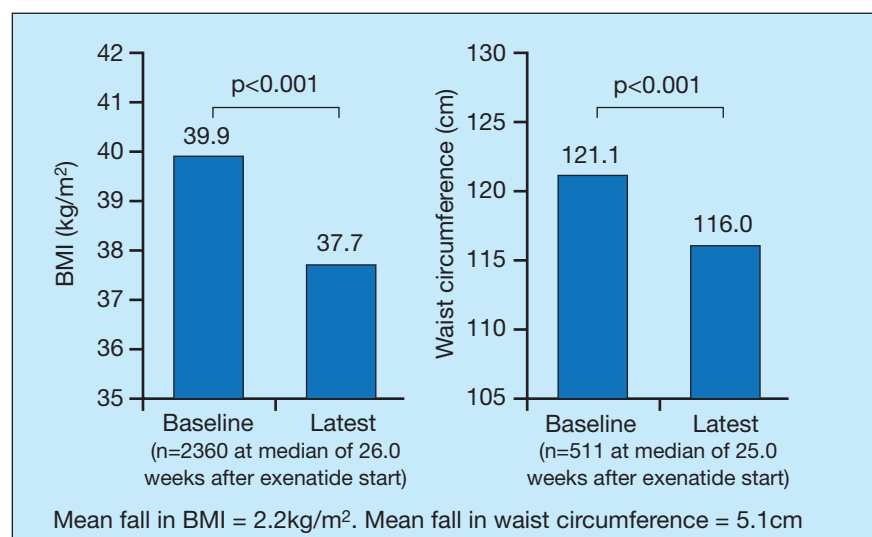
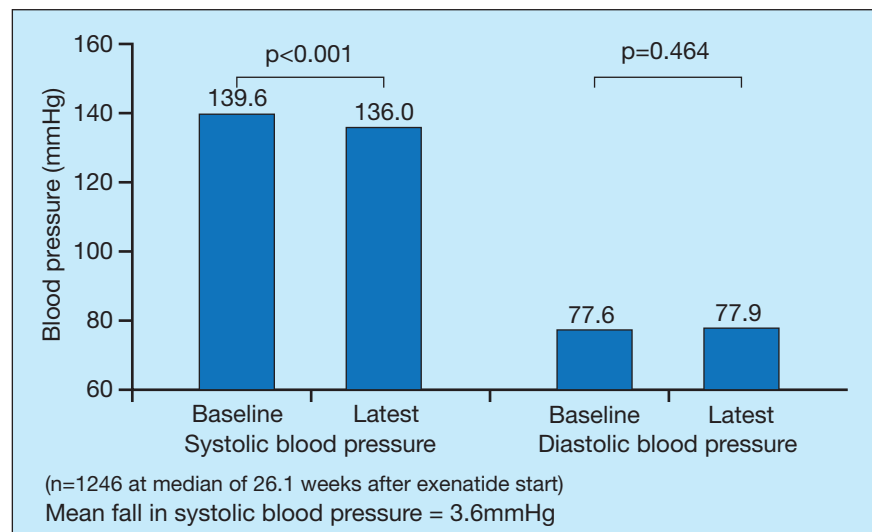


Figure 3. Baseline vs latest blood pressure following exenatide in 1246 patients



remaining case (a very mild case) had no obvious alternate cause besides the use of exenatide. (See Table 5 for a summary description of the cases.)

Acute renal failure

There were 14 cases of acute renal failure reported in the audit (see Table 6). Six cases were as a result of nausea, vomiting or diarrhoea resulting in

dehydration. Four of the remaining eight cases (Case numbers 7, 8, 13 and 14) did not have a reported alternative cause for renal failure.

Other side effects

Other reported side effects had a less than 1% incidence. This included headaches, fatigue, dizziness and injection site issues such as bleeding

and local skin reaction. Of note, there were 13 cases of reported allergy to exenatide including five cases of anaphylactic-like reactions.

Discontinuation of exenatide

A total of 1339 out of 6717 patients (19.9%) stopped exenatide at some stage of the audit, with 1122 patients having dates of discontinuation. The median (range) time to discontinuation was 16.6(0.1–160) weeks from exenatide start. Of these patients, 459/6717 (6.8%) stopped exenatide prior to three months after initiation. Thirty-two of 6717 (0.5%) restarted exenatide after stopping. Among the 1339 patients who stopped exenatide the most common reasons were: gastrointestinal side effects (36.1%), lack of treatment response (33.8%) and non-gastrointestinal side effects (15.7%). Of the 33.8% of patients who discontinued due to lack of treatment response, 23.1% were due to lack of glycaemic control only, 0.4% were due to lack of weight response only, 4.3% were due to both, and 6.1% had unspecified lack of treatment response.

Figure 4. Baseline vs latest lipids following exenatide

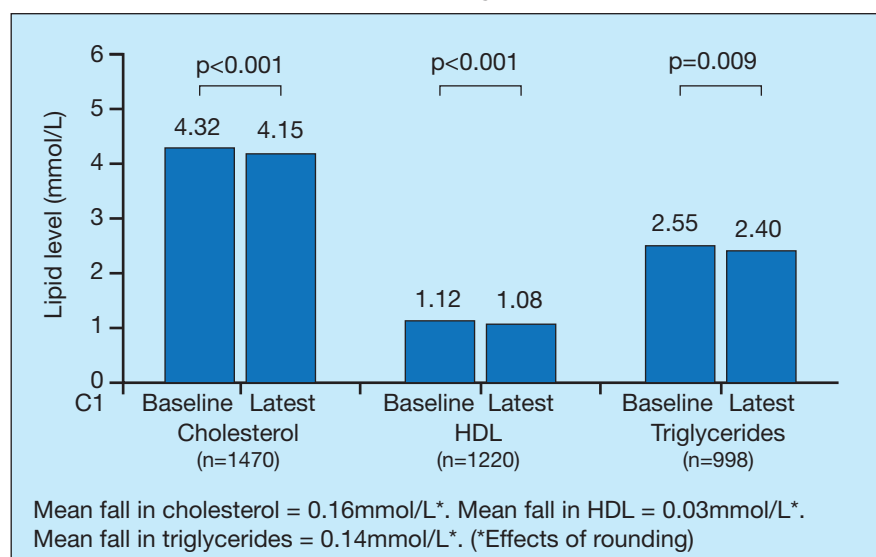


Table 4. Summary of adverse events in patients in the nationwide audit

Adverse event	Total number (n=6717)	Percentage of total
Total GI side effects	1593	23.7%
Transient GI side effects	1047	15.6%
Stopped temporarily*	62	0.9%
Stopped permanently*	484	7.2%
Post exenatide hypoglycaemia	377	5.6%
Pre exenatide hypoglycaemia	223	3.3%
Pancreatitis	See Table 5	
Acute renal failure	See Table 6	
Headache	51	0.76%
Fatigue	35	0.52%
Dizziness	15	0.22%
Injection site problems	8	0.12%
Allergic reaction	13 (5 anaphylaxis)	0.19%

* Due to gastrointestinal (GI) side effects.

Discussion

The ABCD nationwide exenatide audit was a large scale audit examining the effects of exenatide in real clinical practice in the UK. Duration of follow-up results was up to three years after exenatide initiation, with a median follow up of approximately six months. The audit confirmed the effectiveness of exenatide in clinical use, including benefits in HbA_{1c} and weight reduction in patients with type 2 diabetes.

This report is intended to give a broad description of the structure of the audit and the main findings. Different patient groups and treatment changes are likely to influence the outcomes of the various parameters reported, including HbA_{1c}, weight, blood pressure and lipid profiles. The findings on the proportion of patients who responded to treatment, HbA_{1c} and weight changes at different time intervals, as well as the effects of exenatide on concurrent insulin use, are intended for future reports.

The patients in the audit, and also the outcomes with exenatide treatment, are different from those



published in phase III clinical trials. It can be seen from the audit that, in real life clinical practice in the United Kingdom, mean baseline HbA_{1c} and BMI among participants were higher than those in published trials of exenatide involving patients with type 2 diabetes (9.47% vs 7.9–8.6% and

39.8kg/m² vs 30–36kg/m², respectively).^{1,2} Of interest, the average BMI in the audit was much more comparable with a retrospective analysis based on prescription records performed in the United States (BMI 38.5kg/m²), although glycaemic control remained poorer in the ABCD audit.³ A further

important difference is that, instead of being insulin naïve, slightly over a third of our patients were already on insulin during exenatide initiation. Hence, any comparisons of HbA_{1c} and weight outcomes are difficult. Mean HbA_{1c} reduction was 0.73% and weight reduction was 5.9kg in the ABCD audit as opposed to a weighted mean reduction of 0.97% and 1.4kg in a meta-analysis of the major trials on exenatide¹ and 0.5% and 3.0kg in the retrospective study quoted from the USA above.³

Our interpretation of the findings on blood pressure and lipid changes with exenatide use are guarded as changes to blood pressure and lipid lowering treatment were not analysed concurrently. The lowering of systolic but not diastolic blood pressure, however, does echo the findings of other reports^{4–6} but is in contrast to other studies finding both SBP and DBP being reduced^{3,7} or having effects on neither SBP nor DBP.⁸ Reports on the effects on lipid profile with exenatide have also been variable, with the meta-analysis by Amori *et al.* finding no significant changes,¹ while others have found lowering of total cholesterol and triglycerides,^{3,5,7}

Table 5. Reported four cases of pancreatitis in the ABCD nationwide exenatide audit

Pancreatitis?	Summary
Possible exenatide pancreatitis – mild case	Mild epigastric pain and tenderness 2.5 weeks after starting exenatide. Amylase 820U/L. Weight and glycaemic control had improved; she felt great and was disappointed to have to stop. Symptoms improved rapidly on stopping exenatide
Pancreatitis not due to exenatide	Gall stone pancreatitis with episodes prior to exenatide. Link to exenatide unlikely
Pancreatitis not due to exenatide	Significant alcohol consumption prior to admission. Extreme hypertriglyceridaemia (87.8mmol/L). 2 previous admissions with severe abdominal pain prior to exenatide
Comment by his diabetologist: 'Was it gall stones or was it exenatide? I will never know'	ITU with pancreatitis after one year on exenatide without problems. Multiple gall stones on CT. Patient died on ITU of myocardial infarction. 'Pancreatitis secondary to gall stones' on Part B of death certificate. ITU team did not know he was on exenatide

Table 6. Reported cases of acute renal failure in the ABCD nationwide exenatide audit

Case	Cause of acute renal failure (other possible causes documented if known)	Underlying renal impairment or nephropathy
1–6	Nausea, vomiting or diarrhoea leading to dehydration	2 of the 6 cases
7	Creatinine rose 3 weeks after exenatide start (72 to 115mmol/L, peak 150mmol/L); normalised with exenatide discontinuation	No
8	Creatinine rose from 122 to 477mmol/L 12 weeks after exenatide start; exenatide stopped	Yes
9	Creatinine rose from 107 to 250mmol/L 7 months after exenatide start, significant underlying vascular disease and hypertension, monoclonal gammopathy, US shows renal cortical thinning and vascular calcification	Yes
10	Diagnosed with immune complex glomerulonephritis and renal failure; exenatide stopped	Unsure
11	Diagnosed with interstitial nephritis, thought to be due to omeprazole use	No
12	Renal failure associated with sepsis, diarrhoea and vomiting, improved with treatment of sepsis	Unsure
13	Acute renal failure 3 months after exenatide start	Unsure
14	Unable to clarify with contributor	Unable to clarify with contributor

lowering of LDL^{3,9} and an increase in HDL.^{7,10} The lowering of HDL cholesterol in our study was an unexpected finding and is at odds with a general reduction of BMI in patients in the audit. However, it should be pointed out that the difference in HDL before (1.12mmol/L) and after (1.08mmol/L), whilst statistically significant, may not be biologically or clinically relevant (both are 1.1mmol/L if taken to one decimal place).

The low rates of hypoglycaemia and severe hypoglycaemia are consistent with other studies on exenatide.¹ Rates of gastrointestinal side effects were lower in our study (23.7%) compared with the meta-analysis (41.9% for nausea alone) but were similarly mostly transient. Rates of exenatide discontinuation due to gastrointestinal side effects appear to be higher in clinical use in the UK than in clinical trials (7.2% vs approximately 4%).¹ More importantly, the audit highlighted the high rate of discontinuation in clinical practice (19.9% at a median of 16 weeks) when lack of treatment response was more prominently accounted for than in published trials. Notable adverse events possibly related to exenatide included pancreatitis, acute renal failure and anaphylactic reactions which have been reported and discussed elsewhere.^{11–17}

A limitation of this audit is that patient data were not always complete. For example, while there were 6597 patients with baseline HbA_{1c}, paired follow-up HbA_{1c} was only available in 4551 patients. Several reasons contributed to the loss of numbers for HbA_{1c} and other parameters; firstly, follow-up data without dates or that were after exenatide discontinuation were excluded; secondly, not all clinical services in the UK measure frequently parameters such as waist circumference or lipid profiles; and, finally, the ease of participation in the audit was hampered as it involved voluntary personal time and commitment.

In conclusion, we have successfully demonstrated a novel approach by a national specialist society to monitor independently the efficacy and safety of a new treatment. This approach can be applied to other

Key points

- In the ABCD nationwide exenatide audit, modern internet technology allowed members of a national specialist society to coordinate the monitoring of the usage, safety and efficacy of a new therapy. This represents a novel approach which might be utilised for other new treatments and other national specialist societies
- 315 contributors from 126 centres submitted data on 6717 patients on exenatide use in clinical practice
- The effectiveness of exenatide treatment in real clinical practice was confirmed including a reduction of HbA_{1c} and weight
- The audit provides findings on more obese, more hyperglycaemic and, in some cases, insulin-treated, patients with type 2 diabetes as compared with phase III clinical trials
- Rare adverse events were monitored and highlighted with the audit. There were one case of pancreatitis and four cases of renal failure occurring in patients treated with exenatide which had no obvious alternative cause

newly available treatments. The ABCD is currently undertaking a prospective audit with another GLP-1 agonist, liraglutide, which will address limitations in the design of this exenatide audit. The approach could also be adopted by other specialist societies for new treatments. Rare adverse events can also potentially be highlighted among a large patient group by extending audits over a longer period of follow up than is possible in most clinical trials.

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Appendix 1. ABCD nationwide exenatide audit contributors

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