Exploratory outcomes of the use of insulin degludec in the real world: data from the Association of British Clinical Diabetologists nationwide degludec audit

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Abstract

Insulin degludec is a long-acting basal insulin analog that is used as a single daily injection in people living with type 2 diabetes (T2DM) or in combination with rapid-acting analogs in basal-bolus regimens in people living with T2DM or type 1 diabetes (T1DM). Registration studies showed benefits of reduction of hypoglycaemia rate and severity compared to previously available long-acting insulins.

The Association of British Clinical Diabetologists nationwide clinical audit of insulin degludec is a real-world data program which includes a secondary care prospective data collection and a primary care retrospective data collection. Data were used to investigate the effects of degludec initiation in people living with T1DM or T2DM on hypoglycaemia rate and severity, change in haemoglobin A1c (HbA_{1c}) and weight change.

From the secondary care prospective and the primary care retrospective data 432 (of whom T1DM=273) and 3,513 (of whom T1DM=2,040) patients, respectively, were included in the analysis. HbA_{1c} change was non-significant in people with T1DM and T2DM who were switched to insulin degludec due to hypoglycaemia in the secondary care cohort. A significant reduction of 3 and 10 mmol/mol was observed in people with T1DM and T2DM, respectively, when the switch to degludec was prompted by reasons other than hypoglycaemia, and in people with T1DM this was also associated with a 2.5 kg weight gain. There was a clinically significant reduction in minor, severe and nocturnal hypoglycaemia in 62%, 45% and 54% of T1DM and in minor hypoglycaemia in 44% of T2DM in the prospective cohort.

Insulin degludec reduced HbA_{1c} in people with diabetes who were started for non-hypoglycaemia reasons and in people in the retrospective cohort. The extent of reduction in HbA_{1c} was similar in both cohorts, even after stratification for T1DM and T2DM. Overall, insulin degludec resulted in lower HbA_{1c} and modest weight gain in people starting for non-hypoglycaemia reasons and lower hypoglycaemia without any change in HbA_{1c} or weight in people switching due to hypoglycaemia.

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Key words: basal insulin, insulin degludec, glucose control, real world data, hypoglycaemia

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Introduction

There has been significant progress in the development of insulin analogs with various pharmacodynamic and pharmacokinetic features aiming to replicate physiological secretion patterns. This has enabled flexible administration and reduced risk of hypoglycaemia, with the ultimate aim of improving glycaemia and quality of life of people with diabetes mellitus.

Insulin degludec is a modified human analog insulin conjugated with a fatty acid side chain. These post-transcriptional modifications, alongside the slow dissolution pattern due to the formation of zinc-bind polymers, enhance its stability and prolong its duration of action.[1]

Developmental trials for degludec showed a duration of action of up to 42 hours and a half-life of approximately 25 hours, which is considerably longer than insulin detemir and insulin glargine.[2] Once the steady state is achieved, potential clinical benefits for insulin degludec treatment derive mainly from its longer duration of action and stable serum concentrations pattern.[3] These allow a single daily injection regimen (as opposed to twice daily detemir and NPH) and a

more predictable response within-patient, possibly leading to lower rates of severe hypoglycaemia.[4] Also, lower risk of hypoglycaemia may encourage caregivers and patients to self-titrate insulin, potentially making blood glucose targets easier to achieve. Weight gain is a common side effect of successful insulin therapy, although observational data from a single-centre study showed a reduction in insulin dose when switching to insulin degludec from another basal insulin.[5]

For almost 15 years Association of British Clinical Diabetologists (ABCD) has been conducting nationwide clinical audit on newly approved glucose-lowering drugs to provide real-world data on their safety and efficacy. Since 2014 degludec has been marketed and prescribed in the UK, and its use has been approved by the National Institute for Health and Care Excellence (NICE). A nationwide audit of degludec use in people with diabetes started the same year, with the aim of understanding the real-world effect of the use of insulin degludec in clinical practice in the NHS.

In the present paper, we analysed datasets originated from two different sources: a secondary care prospective data collection and a primary care retrospective data collection. The latter was anonymised data provided by Eclipse using Clinical Commissioning Groups (CCGs) registered with the audit program. Eclipse is a piece of electronic prescription auditing software that is used in clinical practice in some areas of the UK.

The analysis explores the treatment effect of degludec on glucose control and the rate and severity of hypoglycaemia.

Methods

Data generation

Secondary care prospective data

Data from secondary care centre across the UK were prospectively entered into an online tool by ABCD members who participated in the audit program. After completion of data collection, data were extracted from the ABCD national degludec audit online tool. Patients were grouped according to whether they had type 1 diabetes (T1DM) or type 2 diabetes (T2DM), and whether the switch to insulin degludec had been made in order to reduce hypoglycaemia or for other reasons (Table 1). Alternative reasons included the requirement for once-daily administration, a history of missing insulin injections, consideration of pump therapy, the need for third-party administration and the use of more than 80 units of basal insulin. For all people with a follow-up visit, haemoglobin A1c (HbA_{1c}) prior to the switch to insulin degludec was compared with the latest HbA_{1c} measurement while on insulin degludec therapy, and weight prior to the switch was compared with the latest weight measurement while on insulin degludec therapy. This prospective data collection includes relevant clinical information such as reason for switching to degludec, rate and severity of hypoglycaemia reported through a blood glucose diary, and other metabolic parameters.

The inclusion criteria were at least three months following treatment. The range of follow-up was between 3 and 12 months. The data from the first visit after three months of treatment were counted in the audit.

Primary care retrospective data

As part of the ABCD nationwide audit, our research group coordinated a retrospective data collection from general practice (GP) records looking at people already on insulin treatment who switched to insulin degludec. These data were extracted through the use of a standalone medical record system (Eclipse) that is used for benchmarking and audit within GP practices in England. This retrospective cohort was assembled in a non-biased manner, i.e. including consecutive inclusion from a pre-specified date range.

Patients with T1DM or T2DM who switched to insulin degludec from another basal insulin (either human or analog) were included in the database. Data extracted included metabolic parameters, and anthropometric measurements as described in Table 2. Whenever available, 3-month, 6-month, 9-month, 12-month and most recent follow-up data were included.

Study design

For both datasets, patients with a coexistent repeat prescription for steroids were excluded from the analysis due to the impact of steroid treatment on glucose metabolism and hence glycaemia. People aged <18 years were also excluded due to age-related changes in weight, height and HbA_{1c} targets.

Data from each dataset were analysed independently and are illustrated in two different paragraphs of the results sections. With regards to weight and HbA_{1c} change, we used the secondary care data as a prospective validation cohort for the wider retrospective cohort of the primary care database.

Statistical analyses

Secondary care prospective data

For normally distributed clinical variables, paired t-test was used to compare the most recent clinical measurements with the data measured prior to starting treatment with insulin degludec. For non-normally distributed variables, the Wilcoxon signed-rank test was used. P values less than 0.05 were considered statistically significant. Mean ± standard deviation or median [interquartile range] were reported according to the normality of the dataset.

For those patients in whom degludec was started with the primary aim of reducing hypoglycaemia, frequency of minor (self-managed), severe (required third-party intervention) and nocturnal hypoglycaemia was assessed at follow-up visits and classified as to whether episodes had increased, decreased or stayed the same since the last visit based on patients' self-report. Descriptive analyses and comparative tests were performed with .jamovi (The jamovi project (2022). jamovi (Version 1.6), Sydney, Australia) and graphs were generated with Prism GraphPad 9 (GraphPad Prism version 9 for Mac, 2022, GraphPad Software, San Diego, California, US).

Primary care restrospective data

Comparative tests were used to assess statistical significance of changes in each variable (paired t-test, Anova for repeated measures, and mixed model tests as appropriate).

Comparison between cohorts

Mann-Whitney U test was performed to compare changes in HbA_{1c} and in weight between the retrospective cohort and the prospective validatory cohort. Comparison was made between the differences of each parameter from baseline to 12 months for the retrospective and from baseline to the first available follow-up for the prospective cohorts.

Results

Secondary care prospective data

Baseline

The secondary care prospective dataset included 624 people who switched to insulin degludec from another basal insulin at the time of the analysis, of whom 432 (69%) had data for more than one visit regarding the parameters being studied (Table 1).

Hypoglycaemia was cited as the reason for switching treatment in 129 people with T1DM and 46 people with T2DM. Treatment was switched for other reasons in 144 people with T1DM and 113 people with T2DM. The baseline characteristics for these people are reported in Table 1.

T1DM

For people with T1DM switched to insulin degludec due to hypoglycaemia, there was no significant change in HbA_{1c} or weight (Table 3). However, there was a clinically significant reduction in minor, severe and nocturnal hypoglycaemia in 62%, 45% and 54% of the studied people (Table 4).

Table 1. Baseline characteristics of the prospective cohort on the first visit

	Reason for drug change: hypoglycaemia		Reason for drug change: other	
	T1DM (n=129)	T2DM (n=46)	T1DM (n=144)	T2DM (n=113)
Age (years)	45 (16)	64 (14)	31 (19)	60 (12)
Sex (male,n, %)	56, 43%	30, 65%	73, 51%	61, 54%
Body mass index (kg/m²)	26.3 (5.0)	30.1 (7.6)	25.8 (7.1)	36.4 (8.7)

Table 2. Baseline characteristics of the retrospective cohort

	Whole (n=3,513)	T1DM (n=2,040)	T2DM (n=1,473)
Male (%)	1906 (54)	1131 (55)	775 (53)
Age (years)	49.1 ± 18.9	40.5 ± 16.8	60.9 ± 14.8
BMI (kg/m²)	28.8 ± 6.8	26.8 ± 5.8	31.5 ± 7.2
Weight	83.3 ± 21.2	78.7 ± 18.8	89.5 ± 22.7
Underweight/normal/ overweight/obesity I/ obesity II/obesity III (%)	3.1/29.1/30.2/ 21.2/9.6/6.9		
HbA_{1c} (%)	9.4 ± 2.0	9.2 ± 2.0	9.7 ± 2.0

For people with T1DM switched to insulin degludec for reasons other than hypoglycaemia, there was a statistically significant reduction in HbA_{1c} (-3.0 mmol/mol), which is also

Table 3. Change in clinical characteristics/outcomes after switching to insulin degludec from another basal insulin

	Reason for drug change: hypoglycaemia					
	T1DM			T12M		
	Before degludec	After degludec	P value	Before degludec	After degludec	P value
HbA_{1c} (mmol/mol)	68.1 (18.8)	70.0 (20.6)	0.08	64.6 (17.3)	61.7 (17.7)	0.10
Weight (kg)	74.7 (16.2)	74.3 (15.0)	0.90	84.7 (18.9)	84.6 (14.8)	0.58
SBP (mmHg)	126 (20)	130 (18)	0.33	133 (20)	135 (19)	0.96
DBP (mmHg)	76 (11)	75 (11)	0.46	75 (9)	74 (10)	0.71
HDL (mg/dL)	1.64 (0.46)	1.70 (0.54)	0.90	1.40 (0.61)	1.41 (0.53)	0.45
Cholesterol (mmol/L)	4.4 (1.0)	4.3 (0.9)	0.31	4.02 (1.26)	3.89 (1.09)	0.50
ALT (U/L)	18.0 (13.5, 27.0)	18.0 (13.0, 25.0)	0.63	21.0 (16.0, 25.0)	19.0 (16.0, 29.0)	0.87
Creatinine (umol/L)	77 (31)	78 (37)	0.81	119 (86)	120 (94)	0.71
	Reason for drug change: other					
	T1DM			T12M		
	Before degludec	After degludec	P value	Before degludec	After degludec	P value
HbA_{1c} (mmol/mol)	81.0 (23.9)	78.0 (22.5)	**<0.05**	87.1 (23.8)	76.8 (22.5)	**<0.01**
Weight (kg)	70.6 (23.1)	73.1 (23.4)	**<0.01**	103.5 (26.3)	103.0 (28.5)	0.19
SBP (mmHg)	122 (18)	124 (16)	**<0.05**	136 (19)	132 (22)	0.08
DBP (mmHg)	74 (11)	74 (10)	0.36	76 (13)	75 (12)	0.25
HDL (mg/dL)	1.48 (0.43)	1.45 (0.40)	0.18	1.15 (0.33)	1.14 (0.37)	0.85
Cholesterol (mmol/L)	4.39 (1.07)	4.32 (0.95)	0.30	4.36 (1.18)	4.35 (1.33)	0.31
ALT (U/L)	16.0 (12.0,24.0]	15.0 (11.0,24.0]	0.75	26.0 (19.8,34.0]	22.0 (16.0,32.0]	**<0.01**
Creatinine (umol/L)	68 (24)	71 (24)	0.31	99 (81)	96 (45)	0.78

Table 4. Change in frequency of hypoglycaemic episodes where reason for switching to insulin degludec was hypoglycaemia

	Type of hypoglycaemia	Reduced	Same	Increased
T1DM	Minor	42(62%)	23(34%)	3(4%)
	Severe	14(45%)	16(52%)	1(3%)
	Nocturnal	20(54%)	17(46%)	0(0%)
T2DM	Minor	11(44%)	11(44%)	3(12%)
	Severe	0(0%)	12(100%)	0(0%)
	Nocturnal	6(33%)	11(61%)	1(6%)

clinically significant. In this group there was also a statistically significant weight gain (+2.5 kg, Table 4).

T2DM

For people with T2DM switched to insulin degludec due to hypoglycaemia, there was a clinically significant reduction in minor hypoglycaemia in 44% of the studied people (Table 4). In this group there was no change in HbA_{1c} or weight (Table 3).

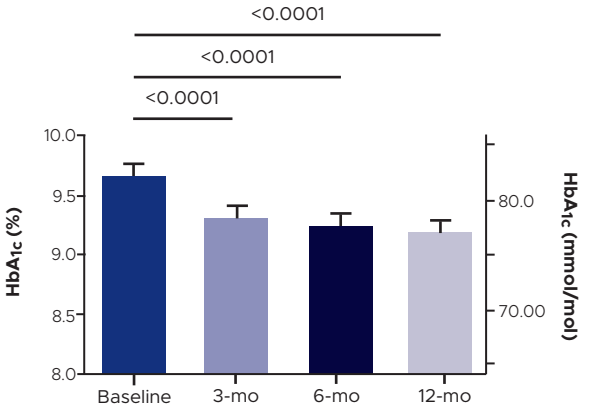
For people with T2DM switched to degludec for reasons other than hypoglycaemia, there was a significant reduction in HbA_{1c} (-10.3 mmol/mol) with no change in weight (Table 3).

Primary care retrospective data

Baseline

From the primary care retrospective dataset 3,513 subjects were extracted: 2,040 with T1DM and 1,473 with T2DM (Table 2). Mean age was 40.5 years for people with T1DM and 60.9 years for people with T2DM. Average BMI was in the overweight range for the whole cohort and the T1DM group (28.8 and 26.8 kg/m^2) and in the obesity range for the T2DM group (31.5 kg/m^2). Mean HbA_{1c} was above target range in the whole population (9.4%, 79 mmol/mol), slightly higher in the T2DM cohort (9.2 vs 9.7%, 77 vs 83 mmol/mol). Data regarding reasons for switching treatment are not available as this is not included in the standard form for drugs information entry in the record.

Figure 2. HbA_{1c} (% and mmol/mol) time-course measurements of T2 in the Eclipse cohort (n=1,462)



T1DM

HbA_{1c} 12 months after degludec initiation reduced by 0.1% (1 mmol/mol). This difference was statistically significant (p<0.001) (Figure 1) although unlikely to be clinically significant. Mean body weight increased by 1.2 kg (p<0.001) (Figure 3).

T2DM

Twelve months after the switch of treatment from a long-acting analog to degludec, subjects with T2DM experienced a HbA_{1c} reduction from 9.7 to 9.2% (82 to 76.8 mmol/mol, p<0.001)

Figure 1. HbA_{1c} (% and mmol/mol) time-course measurements of T1 in the Eclipse cohort (n=1,976)

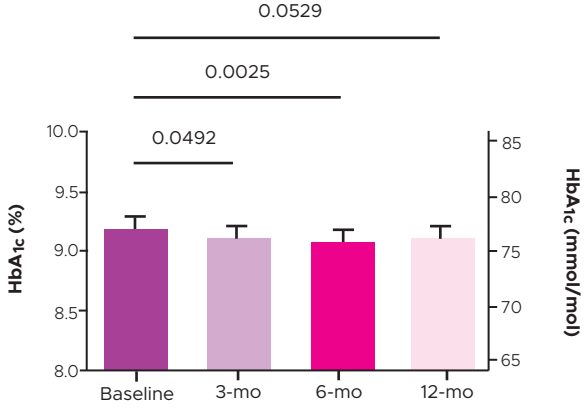


Figure 3. Weight (kg) time-course measurements of T1 in the Eclipse cohort (n=1,946)

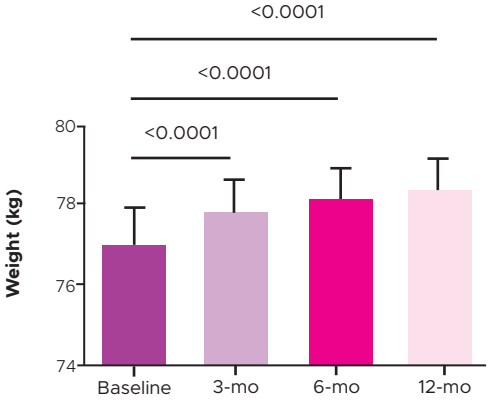


Figure 4. Weight (kg) time-course measurements of T2 in the Eclipse cohort (n=1,440)

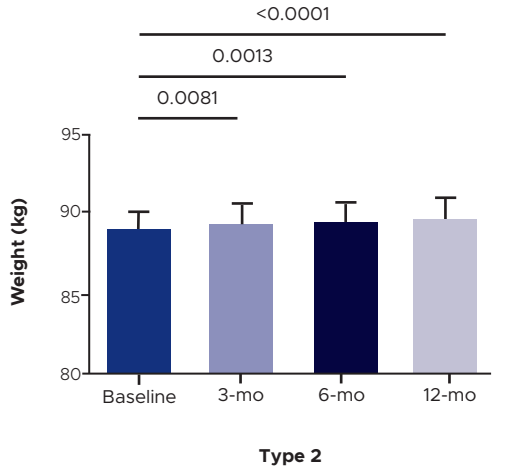


Figure 5. Comparison of change in HbA_{1c} for Prospective and Retrospective cohorts in T1 diabetes (p=0.3643, n=239 vs 183)

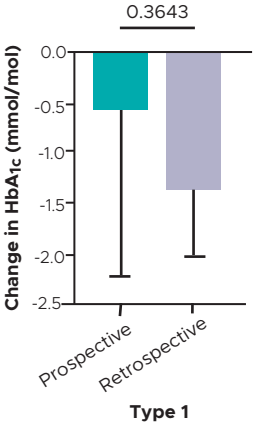


Figure 6. Comparison of change in HbA_{1c} for Prospective and Retrospective cohorts in T2 diabetes (p=0.9354, n=123 vs 1402)

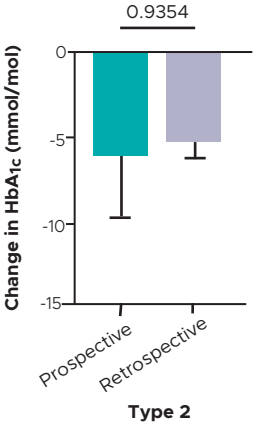


Figure 7. Comparison of Weight Change for Prospective and Retrospective cohorts in T1 diabetes (p=0.1807, n=226 vs 1701)

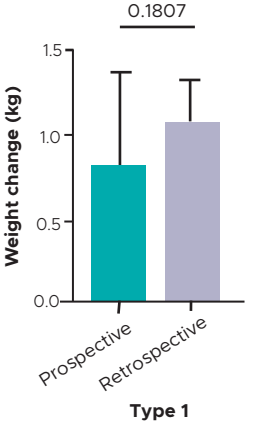
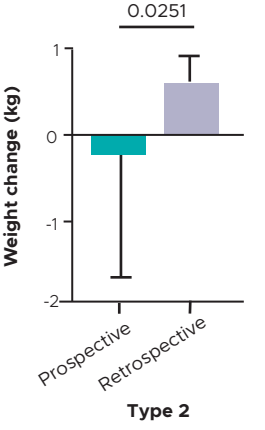


Figure 8. Comparison of Weight Change for Prospective and Retrospective cohorts in T2 diabetes (p=0.0251, n=118 vs 1348)



(Figure 2). A mean weight gain of 0.7kg (+0.9%, p<0.0001) was observed (Figure 4).

Comparison between cohorts

A Mann-Whitney U comparative test showed no significant difference in the change of HbA_{1c} for either T1DM or T2DM in the two cohorts (Figure 5 and 6). Change in body weight was not different among T1DM across the two cohorts (Figure 7), whilst the change in weight among T2DM was significantly different between the prospective and retrospective cohorts (Figure 8).

Discussion

Analysis of prospectively collected data from the ABCD nationwide audit provides a privileged opportunity for validating data and outcomes from the larger retrospective primary care cohort. It also provides further insights on the clinical context that led to the switch to insulin degludec. In fact, degludec seemed to provide clinically relevant benefits in reducing hypoglycaemia episodes in both T1DM and T2DM in the retrospective audit, and this was achieved without a significant increase in HbA_{1c}. For the subgroup of people with T2DM that switched to degludec due to hypoglycaemia, numbers were small, which may have masked an effect on severe/nocturnal hypoglycaemia.

In the prospective cohort, there was a clinically and statistically significant reduction in HbA_{1c} for those with T1DM and T2DM who were switched to degludec for reasons other than hypoglycaemia. This was only seen in the retrospective cohort for those with T2DM. One potential explanation for this difference between the two cohorts is that the retrospective cohort included those switched to degludec for all reasons, and the HbA_{1c} benefit was not seen in those switched for hypoglcycaemia.

The extent of the reduction in HbA_{1c} in the subgroup of subjects who started degludec for reasons other than hypoglycaemia is similar to the reduction observed in the retrospective cohort even after stratification for T1DM and T2DM. Therefore, despite being less flexible compared to twice-daily basal insulin, degludec entails a lower risk of severe hypoglycaemia when the switch to degludec is due to concern for hypoglycaemia. This real-world evidence confirms the results of a recently published crossover trial aimed at testing the potential benefits on hypoglycaemia risk of degludec vs glargine.[6]

Weight change was consistent in T1DM but not in T2DM when the prospective and retrospective cohorts were compared.

With regard to the retrospective cohort, the nature of data

Key messages

- Insulin degludec reduced HbA_{1c} in people with diabetes who were started for non-hypoglycaemia reasons
- Insulin degludec resulted in lower hypoglycaemia without significant change in HbA_{1c} or weight in people switching due to hypoglycaemia
- Benefits from degludec observed in clinical trials are confirmed in real world primary and secondary care settings

collection may produce some bias. First, we used records that were not designed for the study and this may have affected the quality of data. This also comes with a significant loss of follow-up data, which carries the risk of selection bias. Moreover, details of confounder variables such as intercurrent acute conditions, changes in other medications, especially initiation of novel anti-diabetic drugs (e.g. incretins and SGLT2i) in the T2DM subgroup, and consistency of taking medication, are not available. Similarly, other important variables such as the clinical reason for long-acting analog replacement, rate and severity of hypoglycaemia, and change and total daily insulin doses were also not available.

Secondly, heterogeneity of titration protocols across primary and secondary care centres and the absence of any data on adherence and motivation are limits to the interpretation of the long-term efficacy of the switch. Since the treatment change was required for clinical reasons, management was unlikely to be optimal prior to the switch, meaning that any change might be associated with improvement.

Conclusions

The results from the present study suggest that the use of degludec, tested in two different real-world settings, was beneficial in terms of glycaemia and the rate and severity of self-reported hypoglycaemia in specific sub-cohorts of people with diabetes compared to their previous treatment. Weight gain was seen in both the T1DM and T2DM population for people switching to insulin degludec due to non-hypoglycaemia reasons.

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REJR has received speaker fees, and/or consultancy fees and/or educational sponsorships from BioQuest, GI Dynamics and Novo Nordisk.
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Acknowledgement ABCD nationwide Degludec audit contributors - see Appendix online at www.bjd-abcd.com.

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Sandwell & West Birmingham Hospital NHS Trust, Sandwell & West Birmingham Hospital NHS Trust: Ansu Basu, Parijat De, Chris Evans, Bob Ryder, Mahender Yadagiri
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West Hertfordshire Teaching Hospitals NHS Trust, Watford General: Chantal Kong, Ana Pokrajac
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Wales - Adult

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Hywel Dda University Health Board, Prince Philip Hospital: Sam Rice
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Northern Ireland - Adult

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England - Paediatric

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Sheffield, Sheffield Teching Hospitals NHS Trust: Jackie Elliott
Somerset, Yeovil District Hospital NHS Trust: Alex Bickerton
West Essex, The Princess Alexandra Hospital NHS Trust: Devesh Sennik
West Essex, West Essex CCG: Anurita Rohilla
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