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

SANTO COLOSIMO,1* YUE RUAN,1* ALISTAIR LUMB,1,2 RUSTAM REA,1,2 PAULA MCDONALD,6 STEPHEN C BAIN,4 RALPH ABRAHAM,5 IAN GALLEN,7 ROBERT EJ RYDER3 ON BEHALF OF THE ABCD NATIONWIDE DEGLUDEC AUDIT CONTRIBUTORS†

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 (HbA1c) 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. HbA1c 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 HbA1c in people with diabetes who were started for non-hypoglycaemia reasons and in people in the retrospective cohort. The extent of reduction in HbA1c was similar in both cohorts, even after stratification for T1DM and T2DM. Overall, insulin degludec resulted in lower HbA1c and modest weight gain in people starting due to non-hypoglycaemia reasons and lower hypoglycaemia without any change in HbA1c or weight in people switching due to hypoglycaemia.


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

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. 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 (HbA1c) prior to the switch to insulin degludec was compared with the latest HbA1c 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 HbA1c targets.

Data from each dataset were analysed independently and are illustrated in two different paragraphs of the results sections. With regards to weight and HbA1c 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 retrospective 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 HbA1c 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 HbA1c 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

<table>
<thead>
<tr>
<th>Reason for drug change: hypoglycaemia</th>
<th>T1DM (n=129)</th>
<th>T2DM (n=46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>45 (16)</td>
<td>64 (14)</td>
</tr>
<tr>
<td>Sex (male,n, %)</td>
<td>56, 43%</td>
<td>30, 65%</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>26.3 (5.0)</td>
<td>30.1 (7.6)</td>
</tr>
<tr>
<td>HbA1c (mmol/mol)</td>
<td>68.1 (18.8)</td>
<td>70.0 (20.6)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>74.7 (16.2)</td>
<td>74.3 (15.0)</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>126 (20)</td>
<td>130 (18)</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>76 (11)</td>
<td>75 (11)</td>
</tr>
<tr>
<td>HDL (mg/dL)</td>
<td>164 (0.46)</td>
<td>1.70 (0.54)</td>
</tr>
<tr>
<td>Cholesterol (mmol/L)</td>
<td>4.4 (1.0)</td>
<td>4.3 (0.9)</td>
</tr>
<tr>
<td>ALT (U/L)</td>
<td>18.0 (13.5, 27.0)</td>
<td>18.0 (13.0, 25.0)</td>
</tr>
<tr>
<td>Creatinine (umol/L)</td>
<td>77 (31)</td>
<td>78 (37)</td>
</tr>
</tbody>
</table>

Table 2. Baseline characteristics of the retrospective cohort

<table>
<thead>
<tr>
<th>Reason for drug change: hypoglycaemia</th>
<th>Whole (n=3,513)</th>
<th>T1DM (n=2,040)</th>
<th>T2DM (n=1,473)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>49.1 ± 8.9</td>
<td>40.5 ± 6.8</td>
<td>50.9 ± 14.8</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>28.8 ± 6.8</td>
<td>26.8 ± 5.8</td>
<td>31.5 ± 7.2</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>83.3 ± 21.2</td>
<td>78.7 ± 18.8</td>
<td>89.5 ± 22.7</td>
</tr>
<tr>
<td>Underweight/normal/overweight/obesity I/obesity II/obesity III (%)</td>
<td>31/29/130/212/9/6.9</td>
<td>37/35/120/212/9/6.9</td>
<td>31/29/130/212/9/6.9</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Reason for drug change: hypoglycaemia</th>
<th>TIDM</th>
<th>T2DM</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (mmol/mol)</td>
<td>68.1 (18.8)</td>
<td>70.0 (20.6)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>74.7 (16.2)</td>
<td>74.3 (15.0)</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>126 (20)</td>
<td>130 (18)</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>76 (11)</td>
<td>75 (11)</td>
</tr>
<tr>
<td>HDL (mg/dL)</td>
<td>164 (0.46)</td>
<td>1.70 (0.54)</td>
</tr>
<tr>
<td>Cholesterol (mmol/L)</td>
<td>4.4 (1.0)</td>
<td>4.3 (0.9)</td>
</tr>
<tr>
<td>ALT (U/L)</td>
<td>18.0 (13.5, 27.0)</td>
<td>18.0 (13.0, 25.0)</td>
</tr>
<tr>
<td>Creatinine (umol/L)</td>
<td>77 (31)</td>
<td>78 (37)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reason for drug change: other</th>
<th>TIDM</th>
<th>T2DM</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (mmol/mol)</td>
<td>810 (23.9)</td>
<td>780 (22.5)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>70.6 (23.1)</td>
<td>73.1 (23.4)</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>122 (18)</td>
<td>124 (16)</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>74 (11)</td>
<td>74 (10)</td>
</tr>
<tr>
<td>HDL (mg/dL)</td>
<td>1.48 (0.43)</td>
<td>1.45 (0.40)</td>
</tr>
<tr>
<td>Cholesterol (mmol/L)</td>
<td>4.39 (1.07)</td>
<td>4.32 (0.95)</td>
</tr>
<tr>
<td>ALT (U/L)</td>
<td>16.0 (12.0,24.0)</td>
<td>15.0 (10.0,24.0)</td>
</tr>
<tr>
<td>Creatinine (umol/L)</td>
<td>68 (24)</td>
<td>71 (24)</td>
</tr>
</tbody>
</table>

For people with T1DM switched to insulin degludec for reasons other than hypoglycaemia, there was a statistically significant reduction in HbA1c (-3.0 mmol/mol), which is also
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 HbA1c or weight (Table 3).

For people with T2DM switched to degludec for reasons other than hypoglycaemia, there was a significant reduction in HbA1c (-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/m²) and in the obesity range for the T2DM group (31.5 kg/m²). Mean HbA1c 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.

**T1DM**

HbA1c 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 HbA1c reduction from 9.7 to 9.2% (82 to 76.8 mmol/mol, p<0.001)
A mean weight gain of 0.7 kg (+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 HbA1c 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 HbA1c. 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 HbA1c 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 HbA1c benefit was not seen in those switched for hypoglycaemia.

The extent of the reduction in HbA1c 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.8

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
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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Conflict of interest
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References
Appendix - ABCD nationwide Degludec audit contributors

The following are those whom we know about.

ABCD nationwide Degludec audit – initial setup, maintenance and nationwide analysis: Ryder REJ, Cull ML, Rea R, Lumb, A. James Eyles

England - Adult
Barnsley Hospital NHS Foundation Trust, Barnsley Hospital NHS Foundation Trust: Enis Murdzic, E C Uchebegu
Bolton NHS Foundation Trust, Royal Bolton Hospital: Ambar Basu, Harri Bhatia
County Durham and Darlington NHS Foundation Trust, University Hospital of North Durham: Kamal Abouglia, Sinkankth Mada
Dorset County Hospital Foundation trust, Dorset County Hospital Foundation Trust: Adeeil Ghaffar, Andrew Maklkin, Mo-Lee Wong, Fiona Wotherspoon
East and North Hertfordshire NHS Trust, East and North Hertfordshire NHS Trust: Bef Summerhayes, Jaimi Joharatnam
East Sussex Healthcare NHS Trust, Conquest Hospital: Erwin Castro, Amanda Combes, Umesh Dashora, Valerie Edwards, Sathis Kumar
Gloucestershire Hospitals NHS Foundation Trust, Gloucestershire Hospitals NHS Foundation Trust: Alison Evans, Penny Lock-Pullan
Great Western Hospital NHS Foundation Trust, Great Western Hospital NHS Foundation Trust: Sahid Ahmed, Beas Bhattacharya, Paul Price, Vladimir Vaks
Hampshire Hospitals NHS Foundation Trust, Royal Hampshire County Hospital: Jimmy Li Voon Chong, Steve Gleisner, Hull and East Yorkshire NHS Trust, Hull and East Yorkshire NHS Trust: Ali Ahmed, Kamrudeen Mohammed, Thozhukhat Sahyapalan
King's College Hospital NHS Foundation Trust, Orpington Hospital: Yee Seun Cheah, Danielle Lewis, David Hopkins, Arun Gurumadala
King's College Hospital NHS Foundation Trust, Princess Royal University Hospital: Yee Seun Cheah, David Hopkins, Danielle Lewis
London Medical, London Medical: Ralph Abraham, Eva Palk
NHS Croydon Clinical Commissioning Group, Selston Park Medical Practice: Yee Seun Cheah, Arun Gurumadala, David Hopkins, Danielle Lewis
Oxford Centre for Diabetes, Endocrinology, and Metabolism (OCDEM), Churchill Hospital: Chitrabanu Bailav, Saeed Elmuitad, Ahmed Faheerahman, Steven Gough, Shaobai Khan, Alastair Lumb, Katharine Owen, Rustam Rea, Tamar Saeed, Katie Seal, Haval Surchi, Garry Tan
Penrith Acute Hospitals NHS Trust, Fairfield General Hospital: Salah Kouta, Susannah Rowles, Helen Smirhurst, Andrea Taylor, Janet Wild
Penrith Acute Hospitals NHS Trust, Penrith Acute Hospitals NHS Trust: Linda Adams, Sunil Bagewadi, Deepak Bhatnagar, Helena Broude, Kelly Chee, Cuong Dang, Deborah Freeman, Deborah Hall, Kathryn Holland, Dene Hunsdale, Krishnamurthy Jagadish, Jane Benni Jedda Joneson, Yogesh Kalia, Rachel Kirkham, Salah Kouta, Isha Malik, Lucy McAndrew, Biswa Mishra, James Moro, Anindya Mukherjee, Parameswara Prakash
Nicola Rothwell, Susannah Rowles, Helen Smirhurst, Rachel Stott, Stephanie Tarpey, Andrea Taylor, Jenna Tilbury, Adele West, Janet Wild, Paula Yates
Royal United Hospitals Bath NHS Foundation Trust, Royal United Hospital: Tony Robinson, Alexandra Ward
Sandwell & West Birmingham Hospital NHS Trust, Sandwell & West Birmingham Hospital NHS Trust: Ansu Basu, Parjat De, Chris Evans, Bob Ryder, Mahender Yadavari
South Tyneside and Sunderland NHS Foundation Trust, Sunderland Royal Hospital: Peter Carey, Nimantha De-Alwis, Ashwin Joshi, Rahul Nayar
South Tyneside and Sunderland NHS Foundation Trust, South Tyneside District Hospital: Anjula Dave
Taunton & Somerset NHS Foundation Trust, Taunton & Somerset NHS Foundation Trust: Joanne Watson
The Princess Alexandra Hospital NHS Trust, The Princess Alexandra Hospital: DK Sennik, A Shakoor, N Htwe
United Lincolnshire Hospitals NHS Trust, Pilgrim Hospital: Koshy Jacob, Azhar Hussain Rizvi
University College London Hospitals NHS Foundation Trust (UCLH), University College Hospital: Andrew Barron
West Hertfordshire Teaching Hospitals NHS Trust, Watford General: Chantal Kong, Ana Polejak
Whittington Health NHS Trust, Whittington Health: Marla Barnard, Nicole Braham, Anastasia Dimakopoulou, Ploutarchos Tsouli
Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust, Royal Albert Edward Infirmary: Mohit Kumar

Wales - Adult
Cwm Taf Morgannwg University Health Board, Royal Glamorgan Hospital: Hussam Abusahmen
Hywel Dda University Health Board, Prince Philip Hospital: Sam Rice
Swansea Bay University Health Board, Neath Port Talbot Hospital: Charles Beavestock, Mahmoud Chokor, Rajesh Patel
Swansea Bay University Health Board, Singleton Hospital: Steve Bain,

Scotland - Adult
NHS Greater Glasgow and Clyde, Queen Elizabeth University Hospital, Glasgow: Brian Kennon
NHS Lothian, St Johns Hospital: N Htwe
Northern Ireland - Adult
Belfast Health and Social Care Trust, Belfast City Hospital: Ian Wallace
Northern Health and Social Care Trust, Causeway Hospital: Mona Abouzaid, Sumana Gidwani, Fred Williams
South Eastern Health and Social Care Trust, The Ulster Hospital: Ursula Brennan, Roy Harper, Paula McDonald

Southern Ireland - Adult
Health Service Executive North West Region, Letterkenny University Hospital: Ashfaqee Memon

England - Paediatric
Bedfordshire Hospitals NHS Foundation Trust, Bedford Hospital: Khalia Shah-Enderyb, Babita Khetriwal
Bedfordshire Hospitals NHS Foundation Trust, Luton and Dunstable University Hospital: Nisha Nathwani
Cambridge University Hospitals NHS Foundation Trust, Addenbrooke's Hospital, Rachael Williams
Chester Hospital Foundation University Trust, Chester Hospital Foundation University Trust: Nicola Cackett
East and North Hertfordshire NHS Trust, Lister Hospital: Jennifer Hollis, Cristina Marie
East Suffolk and North Essex NHS Foundation Trust, Ipswich Hospital: Jackie Buck, Sadie Cooper
James Paget University Hospitals NHS Foundation Trust, James Paget Hospital: Julie Wright
Mid and South Essex NHS Foundation Trust, Broomfield Hospital: Sharmila Nambiar
Mid and South Essex NHS Foundation Trust, Southend University Hospital: Claire Levine
Norfolk and Norwich University Hospitals NHS Foundation Trust, Norfolk and Norwich University Hospital: Vipan Datta
North West Anglia NHS Foundation Trust, Hinchingbrooke Hospital: Melanie Bywater, Madhu Easwaran, Rajiv Gooonetilleke, Kozhimuttam Ramesh, Victoria Surrell
Peterborough and Stamford Hospitals NHS Foundation Trust, Peterborough and Stamford Hospitals NHS Foundation Trust: Diana Young
The Princess Alexandra Hospital NHS Trust, Princess Alexandra Hospital: Amith Nuti
The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust, The Queen Elizabeth Hospital: Kings Lynn: Barbara Piel
West Hertfordshire Teaching Hospitals NHS Trust, Hemel Hempstead Hospital: Catriona Hurley, Fiona Mcleish, Heather Mitchell, Iola Harold-Sodipo
West Suffolk NHS Foundation Trust, West Suffolk Hospital: Paula Olsen

Eclipse Users
Berkshire West, Royal Berkshire NHS Foundation Trust: Ian Gallen
Gloucestershire, Gloucestershire Hospitals NHS Foundation Trust: Alison Evans, Suzanne Phillips
Ipswich and East Suffolk, East Suffolk and North Essex NHS Foundation Trust: Gerry Rayman
Leicester, University Hospitals of Leicester NHS Trust: Alison Gallagher
Leicester, University Hospitals of Leicester NHS Trust: Alison Gallagher
Luton, Luton & Dunstable Hospital NHS Trust: Shu-Ching Soo
Norfolk, The Norfolk and Norwich NHS Trust: Ketan Dharitaya
Sheffield, Sheffield Teaching Hospitals NHS Trust: Jackie Elliott
Somerset, Yeovil District Hospital NHS Trust: Alex Bickerton
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