FROM FIASP TO TRURAPI: CONVERSION IN INSULIN ASPART PRESCRIBING IN THE UNITED KINGDOM AND THE IMPACT OF DELIVERY-DEVICE PREFERENCES

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ABSTRACT

Introduction: In England, NovoRapid® dominated the rapid-acting insulin aspart market until 2017, when Fiasp® (next-generation fast-acting aspart) was launched, followed by Trurapi® (similar to NovoRapid®) after UK approval in 2021 (European marketing authorization 2020). **Methods:** Prescribing information from NHS primary care data was aggregated and adjusted to defined daily doses (DDD, 40 IU) between 2008 and 2024. Segmented regression models with two intervention points (Fiasp® Q1 2017, Trurapi® Q4 2021) were estimated, with separate analyses by device (pre-filled pens, cartridges, vials). **Results:** NovoRapid® continued to increase until 2017, when the growth slowed after the introduction of Fiasp. Fiasp® grew rapidly after launch and was approximately 1.25 million DDDs (95% CI 0.42 to 2.08 million) above the counterfactual two years after Trurapi® was introduced ($p < 0.001$). The uptake of Trurapi® was typical of biosimilar products, with approximately 5.4% of the market share by Q4 2024 (95% CI 4.8% to 7.2%). Adoption was greater in pens and cartridges than in vials, reflecting prescribers' and patients' familiarity with the originator products' pen platforms. **Conclusions:** In 17 years, the England insulin aspart market was transformed with successive product launches. In addition to clinical comparability, familiarity with the device and the timing in the market lifecycle were key factors in adoption. Monitoring utilization at both brand and device level may help policymakers and prescribers with biosimilar integration and ensure patient confidence.

Keywords: Biosimilar, Diabetes, Insulin aspart, Interrupted time series analysis, Utilization trends

INTRODUCTION

Biosimilars are similar but not identical copies of patent-expired biological medicines (Owens et al., 2012). Their introduction has expanded treatment options in diabetes care as they offer patients clinically similar, but more cost-effective alternatives to originator biological therapies (White et al., 2022). In England, where the National Health Service (NHS) operates within fixed budgets, biosimilars have been associated with cost savings, particularly in insulin therapy (Aladul et al., 2017).

Insulin glargine is the first insulin biosimilar to be authorised in England. Its introduction raised expectations that biosimilars could alter market share and reduce NHS expenditure (Chapman et al., 2017). Nevertheless, it was found that the uptake of glargine biosimilars was not solely driven by regulatory approval; other factors such as price differences, therapeutic equivalence and prescribers' and patients' preferences also had an impact on prescribing (Chapman et al., 2017; Agirrezabal et al., 2020; Aladul et al., 2018; Joshi et al., 2023).

Insulin aspart, a rapid-acting insulin analogue, is a key treatment for type 1 and type 2 diabetes. The insulin aspart market has historically been led by NovoRapid®, marketed by Novo Nordisk (Haahr & Heise, 2020). In 2017, Novo Nordisk launched Fiasp®, a reformulated insulin aspart with a faster onset of action, designed to more closely mimic physiological insulin secretion (Danne et al., 2019; Heise et al., 2015).

In 2020, the first biosimilar insulin aspart (Trurapi®, Sanofi) was granted marketing authorisation in Europe, and in 2021 in England (Morris, 2022). Clinically proven to be as effective and safe as NovoRapid® (Garg et al., 2020). The uptake in England, however, has been affected by a number of practical considerations such as product presentation: Trurapi® is presented in SoloStar® pens, while the originator products are presented in FlexTouch®, FlexPen®, Penfill® and vial formats. These variations in delivery devices, along with time of market entry, have affected real-world adoption.

The NHS commissioning guidance clearly states that Trurapi® is not interchangeable with Fiasp® and that all insulin prescriptions must contain the brand name, strength and device used to administer the insulin to ensure continuity of supply (NHS Cheshire and Merseyside Area Prescribing Group, 2024; Norfolk and Waveney Therapeutics Advisory Group, 2025). The regulatory and operational separation of the biosimilar and the reformulated originator further emphasizes the need for device-specific prescribing patterns in understanding market dynamics.

Patients' and prescribers' preferences for certain injection devices, based on familiarity, ease of use, dosing accuracy, or training, can have a significant impact on prescribing, particularly because diabetes is a chronic condition and patients require daily injections for their lifetime. This may also pose logistical and financial difficulties if switching between platforms is not supported (de Lusignan et al., 2022; Seidu et al., 2025; McEwan & Evans, 2025).

This study therefore examines how successive insulin aspart products influenced prescribing in England. In particular, it explores whether delivery-device formats and the launch of an ultra-fast-acting branded formulation influenced biosimilar uptake. Using national primary-care prescribing data from 2008 to 2024, the study applied an interrupted time-series design with two intervention points to provide evidence for clinicians, payers, and policymakers regarding the integration of biosimilars and reformulated brands into routine diabetes care.

This study had two primary aims: (1) to quantify the impact of Fiasp® (2017) and Trurapi® (2021) on the prescribing trajectory of insulin aspart in England using interrupted time-series analysis; and (2) to determine whether delivery-device format (pre-filled pens, cartridges, vials) moderated the uptake of these products. These aims directly inform the integration of biosimilars and reformulated brands into routine diabetes care.

METHODS

Data source

The aggregated monthly prescribing data of all insulin aspart products dispensed in England primary care from January 2008 to December 2024 were downloaded from the NHS Business Services Authority (NHS BSA) Open Data Portal (NHS Business Services Authority, 2025). These data report the number of packs dispensed for each product and device format at practice level. As the datasets are publicly available and fully aggregated, no ethics approval or patient consent was required. British National Formulary (BNF) codes, Actual Medicinal Product (AMP) codes, and Actual Medicinal Product Pack (AMPP) codes were used to link products to metadata.

Defined Daily Doses (DDD)

Prescription volumes were standardized using the Defined Daily Dose (DDD) method developed by the World Health Organization (WHO). The WHO ATC/DDD Index (ATC code A10AB05) (WHO Collaborating Centre for Drug Statistics Methodology, 2025) defines 1 DDD of insulin aspart as 40 international units (IU). The number of DDDs was calculated as:

DDDs = Total amount prescribed (IU) / 40

This standardization allows comparison of prescribing volumes across products and presentations.

Outcome construction

The number of DDDs per month was determined for each product and delivery device by multiplying the number of dispensed packs by the number of insulin units per pack and dividing by 40 IU. Monthly values were aggregated to quarterly values to reduce short-term variation, but sensitivity analyses with monthly

values showed similar results. Products were grouped into three trade names, NovoRapid®, Fiasp®, and Trurapi®, and further classified into pre-filled pens, pen-fill cartridges, and vials.

Interrupted time-series design

Quarterly DDDs were modelled using segmented linear regression (Wagner et al., 2002). The time index (Time) was coded from 1 (Q1 2008) to 68 (Q4 2024). Two intervention indicators captured the launch of Fiasp® (coded 1 from Q1 2017 onward) and the entry of Trurapi® (coded 1 from Q4 2021 onward). Post-intervention slopes were coded as the number of quarters since each event. The general model was:

$$Y_t = \beta_0 + \beta_1(\text{Time}_t) + \beta_2(\text{Intervention1}_t) + \beta_3(\text{Time after Intervention1}_t) + \beta_4(\text{Intervention2}_t) + \beta_5(\text{Time after Intervention2}_t) + \varepsilon_t$$

where Y_t is the quarterly DDDs, β_0 is the baseline level, β_1 the underlying growth before Fiasp®, β_2 the immediate level change at Fiasp's launch, β_3 the change in slope thereafter, β_4 the level change at Trurapi's entry, and β_5 the change in slope after Trurapi's entry.

Sample size justification

The segmented regression model estimates six parameters (baseline level, pre-intervention slope, two level changes, and two slope changes). With 36 quarters (9 years) of pre-Fiasp® data and 32 quarters (8 years) of post-Fiasp® data, the ratio of observations to parameters exceeds 10:1, which is well above the minimum of 8–10 pre-intervention observations recommended for reliable interrupted time-series analysis (Wagner et al., 2002; Bernal et al., 2017). The Trurapi® intervention is supported by 55 pre-entry quarters, which is adequate for estimating post-intervention slope changes.

Statistical considerations

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Time-series residuals were checked for autocorrelation using the Durbin–Watson statistic and the Ljung–Box Q test; autocorrelation and partial autocorrelation functions (ACF/PACF) were also inspected visually. Where serial correlation was detected, Newey–West heteroskedasticity- and autocorrelation-consistent (HAC) standard errors were applied with a maximum lag of 4 quarters, capturing potential autocorrelation across four consecutive quarterly periods (approximately one year). Coefficients and effect sizes were similar to the primary analysis when models were re-estimated using monthly (unaggregated) data and autoregressive terms. Seasonal dummy variables were also tested, but no meaningful seasonal effects were observed. Model fit was evaluated by the adjusted R^2 and residual plots (see Figure S1A and S1B).

The potential for Type I error inflation from multiple comparisons should be recognized, as three trade names and three device formats (nine models) were estimated, each with up to six coefficients. No formal adjustment (e.g., Bonferroni) was made as the analyses are primarily descriptive and exploratory, designed to describe prescribing trends rather than test a single pre-specified hypothesis. This should be taken into account when interpreting the coefficients and p-values.

Effect size calculations

The regression coefficients and p-values were calculated, along with absolute and relative changes in DDDs at 12 and 24 months after each intervention, using forecasts from the observed model and a counterfactual scenario with no intervention. Effect sizes were estimated as the difference between these forecasts, which were clinically interpretable.

COVID-19 sensitivity analysis

To determine if the COVID-19 pandemic confounded the estimates of the Trurapi® intervention, a sensitivity analysis was performed by adding a binary indicator of the COVID-19 pandemic (coded 1 for Q1 2020 through Q4 2021 and 0 otherwise) to the segmented regression models.

Market share

The utilization was also evaluated in relative terms. Market share was calculated as the dispensed quantity of insulin aspart for a particular brand compared to the dispensed quantity of all brands in the same quarter, and then presented as a percentage. This is a complementary outcome that separates the absolute change in prescription volume from relative changes in market positioning.

Software

The analyses were conducted using Python 3.12 (statsmodels 0.14.1) with the statsmodels OLS.fit function with HAC standard errors (maximum lag = 4 quarters) to estimate the standard errors as HAC. The maximum lag of 4 quarters was chosen to account for possible autocorrelation in the quarterly data over a period of about one year. Python (Matplotlib 3.8) was used to generate figures. The segmented regression models were specified as ordinary least squares regression models with intervention indicators and post-intervention time trends. All analysis scripts, the dataset, and exact syntax used to estimate the models are available from Zenodo (https://doi.org/10.5281/zenodo.21325520) and from the corresponding author on reasonable request.

RESULTS

Analysis by trade name

Table 1 presents the estimated coefficients, 95% confidence intervals (CIs), and p-values from the segmented regression models for NovoRapid®, Fiasp®, and Trurapi®. Prior to the launch of Fiasp®, NovoRapid® prescriptions grew by approximately 227,735 DDDs per quarter (95% CI 215,143 to 240,328; $p < 0.0001$). Fiasp's introduction in Q1 2017 was associated with an immediate level decrease in NovoRapid® of 682,850 DDDs (95% CI −1,029,886 to −335,814; $p = 0.0003$), and the growth rate slowed markedly by 47,542 DDDs per quarter (95% CI −91,338 to −3,745; $p = 0.033$). Twelve months after Fiasp's entry, NovoRapid® use was approximately 508,000 DDDs lower than the counterfactual projection; after 24 months, the shortfall reached approximately 913,000 DDDs.

Fiasp® itself exhibited the opposite pattern: an initial level decrease of 528,511 DDDs (95% CI −889,352 to −167,670; $p = 0.004$) followed by a sustained quarterly increase of 182,194 DDDs (95% CI 141,169 to 223,218; $p < 0.0001$). The entry of Trurapi® in Q4 2021 was associated with a further drop in Fiasp® (β_4 = −325,413 DDDs; 95% CI −863,647 to 212,821; $p = 0.236$), but the post-Trurapi® slope accelerated by 111,637 DDDs per quarter (95% CI 65,582 to 157,692; $p < 0.0001$). At 24 months post-launch, Fiasp® prescribing exceeded the counterfactual by roughly 929,037 DDDs (95% CI 441,261 to 1,416,813).

Trurapi®, which entered the market in Q4 2021, began from zero prescriptions. The model estimated an initial level of −529,537 DDDs (95% CI −891,790 to −167,283; $p = 0.004$), reflecting statistical extrapolation prior to availability, and a subsequent quarterly increase of 174,790 DDDs (95% CI 128,163 to 221,416; $p < 0.0001$). By 24 months after entry, Trurapi® accounted for approximately 868,781 additional DDDs (95% CI 348,805 to 1,388,758) relative to the counterfactual.

Table 1: Segmented regression analysis of insulin aspart formulations

Parameter	NovoRapid® coefficient (95% CI)	p-value	Fiasp® coefficient (95% CI)	p-value	Trurapi® coefficient (95% CI)	p-value
Baseline level (β_0)	16,170,335(15,896,117 to 16,444,553)	<0.0001	0(0 to 0)	1.000	0(0 to 0)	—
Pre-Fiasp® slope (β_1)	+227,735 per quarter(215,143 to 240,328)	<0.0001	0(0 to 0)	1.000	—	—
Fiasp® level change (β_2)	−682,850(−1,029,886 to −335,814)	0.0003	−528,511(−889,352 to −167,670)	0.004	—	—
Slope change after Fiasp® (β_3)	−47,542 per quarter(−91,338 to −3,745)	0.033	+182,194 per quarter(141,169 to 223,218)	<0.0001	—	—
Trurapi® level change (β_4)	+653,430(43,648 to 1,263,211)	0.036	−325,413(−863,647 to 212,821)	0.236	−529,537(−891,790 to −167,283)	0.004
Slope change after Trurapi® (β_5)	+42,668 per quarter(−24,824 to 110,161)	0.215	+111,637 per quarter(65,582 to 157,692)	<0.0001	+174,790 per quarter(128,163 to 221,416)	<0.0001
Model fit	R^2 = 0.977Adj R^2 = 0.975DW = 2.156LBQ(4) = 10.27, p = 0.036		R^2 = 0.982Adj R^2 = 0.981DW = 1.094LBQ(4) = 33.67, p < 0.0001		R^2 = 0.945Adj R^2 = 0.942DW = 0.477LBQ(4) = 41.03, p < 0.0001	

(95% CIs and p-values are reported; negative baseline estimates for Fiasp® and Trurapi® reflect extrapolation prior to first prescriptions.)

Note. DW = Durbin–Watson statistic; LBQ = Ljung–Box Q statistic; — = not applicable (coefficient constrained to zero in the restricted model). Standard errors were estimated using the Newey–West heteroskedasticity- and autocorrelation-consistent (HAC) estimator with a maximum lag of four quarters. All coefficients are expressed as defined daily doses (DDDs) per quarter.

Device-level patterns

Analyses stratified by delivery device showed that substitution patterns varied across device types (Table 2).

NovoRapid®: Pens grew by 169,760 DDDs per quarter before 2017 but dropped immediately after Fiasp's launch (β_2 = −387,721 DDDs; 95% CI −576,180 to −199,262; p < 0.0001) and slowed thereafter (−37,490 DDDs per quarter; 95% CI −55,469 to −19,512; p < 0.0001). Vials declined by 212,001 DDDs at Fiasp's entry (95% CI −351,266 to −72,736; p = 0.003) but rebounded following Trurapi's launch, with a post-Trurapi® slope of +231,553 DDDs per quarter (95% CI 168,306 to 294,800; p < 0.0001). Cartridges showed a modest pre-Fiasp decline of −20,193 DDDs per quarter (95% CI −38,923 to −1,464; p = 0.035) and a post-Trurapi® slope of −31,410 DDDs per quarter (95% CI −52,178 to −10,642; p = 0.003).

Fiasp®: Pens did not exhibit a significant immediate jump at launch (β_2 = −101,704 DDDs; 95% CI −243,502 to 40,094; p = 0.160) but grew steadily (+41,942 DDDs per quarter; 95% CI 18,332 to 65,553; p = 0.0005). Although cartridges and vials initially declined (β_2 = −132,807 and −294,000 DDDs, respectively; p = 0.001 and p = 0.170), both later showed steep growth (slopes of +41,544 and +98,708 DDDs per quarter, respectively; p < 0.0001 and p = 0.003). These formats showed a temporary decline after Trurapi® entered the market but then increased again.

Trurapi®: Pens increased by 147,067 DDDs per quarter (95% CI 107,476 to 186,659; p < 0.0001). The increases in cartridge and vial use were more modest (18,881 and 8,842 DDDs per quarter, respectively; both p < 0.0001). At the two-year time point, Trurapi® cartridges exceeded the counterfactual by approximately 75,600 DDDs, and approximately 28,976 DDDs higher for vials.

Table 2: Device-level segmented regression coefficients

Product / Device	Baseline (β_0)	Pre-Fiasp slope (β_1)	Fiasp level change (β_2)	Fiasp slope change (β_3)	Trurapi level change (β_4)	Trurapi slope change (β_5)	Model fit
NOVORAPID®							
Pens	5,199,193(4,952,464 to 5,445,921)	+169,760(159,389 to 180,131)*p* < 0.0001	−387,721(−576,180 to −199,262)*p* < 0.0001	−37,490(−55,469 to −19,512)*p* = 0.0002	+611,030(286,161 to 935,899)*p* = 0.0002	−157,475(−182,599 to −132,350)*p* < 0.0001	R^2 = 0.990 DW = 1.736
Cartridges	10,504,333(10,013,280 to 10,995,386)	−20,193(−38,923 to −1,464) *p* = 0.035	−83,128(−346,460 to 180,203) *p* = 0.536	−13,041(−38,791 to 12,708) *p* = 0.098	+221,663(−40,562 to 483,887) *p* = 0.098	−31,410(−52,178 to −10,642) *p* = 0.003	R^2 = 0.740 DW = 1.583
Vials	466,809(347,633 to 585,985)	+78,169(72,899 to 83,438) *p* < 0.0001	−212,001(−351,266 to −72,736) *p* = 0.003	+2,990(−12,040 to 18,020) *p* = 0.335	−179,263(−543,685 to 185,159) *p* = 0.335	+231,553(168,306 to 294,800) *p* < 0.0001	R^2 = 0.991 DW

							= 1.095
FIASP®							
Pens (FlexTouch)	0	0	−101,704(−243,502 to 40,094) $p = 0.160$	+41,942(18,332 to 65,553) $p = 0.0005$	+964,845(173,347 to 1,756,344) $p = 0.017$	−70,906(−158,827 to 17,016) $p = 0.114$	$R^2 = 0.854$ DW = 0.679
Cartridges	0	0	−132,807(−209,947 to −55,668) $p = 0.001$	+41,544(34,592 to 48,496) $p < 0.0001$	−439,458(−912,688 to 33,773) $p = 0.069$	+199,450(120,878 to 278,021) $p < 0.0001$	$R^2 = 0.959$ DW = 0.560
Vials	0	0	−294,000(−713,670 to 125,670) $p = 0.170$	+98,708(34,551 to 162,865) $p = 0.003$	−850,801(−1,746,348 to 44,747) $p = 0.063$	−16,908(−81,787 to 47,972) $p = 0.610$	$R^2 = 0.738$ DW = 1.003
TRURAPI® (restricted model)							
Pens (SoloStar)	0	—	—	—	−444,608(−751,494 to −137,722) $p = 0.005$	+147,067(107,476 to 186,659) $p < 0.0001$	$R^2 = 0.944$ DW = 0.472
Cartridges	0	—	—	—	−55,184(−88,723 to −21,645) $p = 0.001$	+18,881(14,953 to 22,809) $p < 0.0001$	$R^2 = 0.962$ DW = 0.591
Vials	0	—	—	—	−29,745(−52,680 to −6,811) $p = 0.011$	+8,842(5,471 to 12,213) $p < 0.0001$	$R^2 = 0.877$ DW = 0.557

COVID-19 sensitivity analysis

A sensitivity analysis including a COVID-19 pandemic indicator (Q1 2020 to Q4 2021) showed that the COVID indicator was not statistically significant for NovoRapid® (coefficient = −118,557; p = 0.763) or Trurapi® (coefficient = +174,782; p = 0.089), although it was significant for Fiasp® (coefficient = +886,533; p = 0.014). The Trurapi® slope coefficient increased from 174,790 to 193,431 DDDs per quarter (+10.7%) when pandemic effects were controlled, and the Trurapi® level change became less negative (−529,537 to −403,014). These findings suggest that pandemic-era prescribing disruption did not substantially confound the observed biosimilar uptake patterns.

Visualization

Figure 1 presents the segmented regression model predictions for the three trade names. The black dashed vertical line indicates the launch of Fiasp® (Q1 2017), and the grey dotted vertical line indicates the entry of Trurapi® (Q4 2021). The piecewise slopes reflect the estimates reported above: NovoRapid® growth has slowed since 2017, whereas Fiasp® and later Trurapi® showed clear upward growth trends.

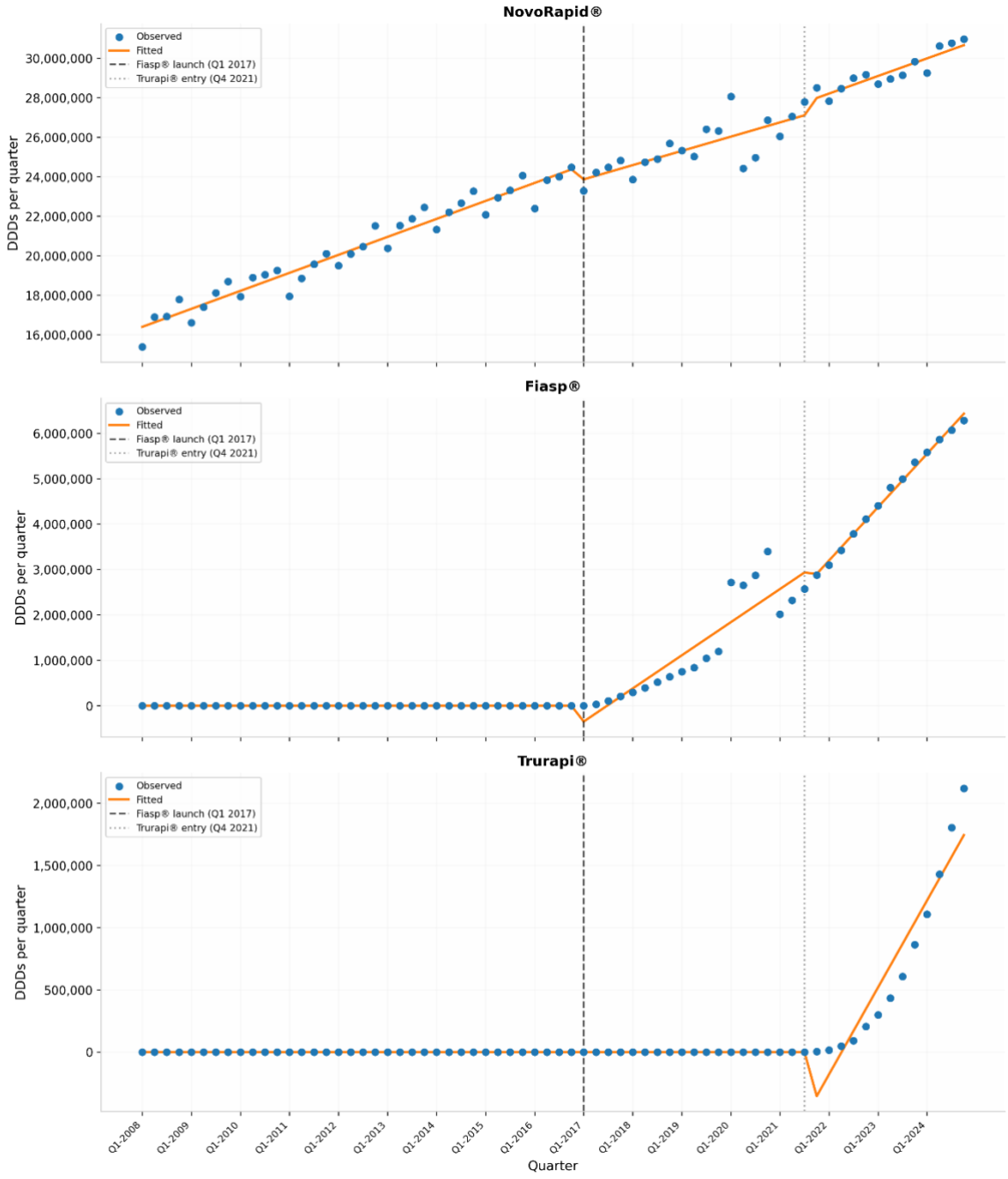

Figure 1: Insulin aspart products segmented regression predictions (2008–2024).

Blue dots represent the observed number of prescriptions in DDDs, while the fitted segmented regression lines are represented by solid orange lines. The black dashed vertical line represents the entry of Fiasp® (Q1 2017), and the grey dotted vertical line represents the entry of Trurapi® (Q4 2021).

Market share analysis

In addition to segmented regression models in DDDs, we analyzed the relative growth of each product over time in the overall insulin aspart market. Before the introduction of Fiasp®, NovoRapid® was the only product available. Fiasp® started at zero in 2017 but gradually grew, reaching approximately 14.9% of prescriptions by Q4 2023 and 16.0% by Q4 2024. The share of NovoRapid fell in tandem from 82.7% in Q4 2023 to 78.7% by Q4 2024. Trurapi® was launched in Q4 2021 and, as is typical, uptake was relatively low at first, increasing from 2.4% in Q4 2023 to approximately 5.4% in Q4 2024 (Figure 2). These relative trends support the DDD-based results, showing that NovoRapid® growth slowed while Fiasp® and Trurapi® gained market share, but not as a consequence of a change in overall insulin aspart prescribing.

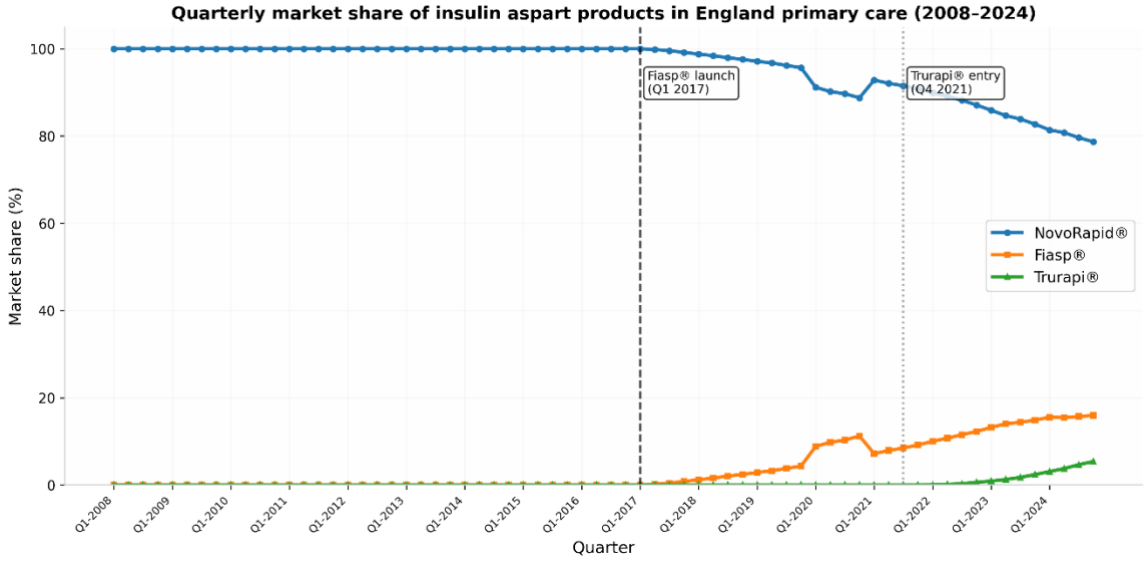

Figure 2: Quarterly market share of insulin aspart products in England primary care (2008–2024).

DISCUSSION

This study aimed to explore the insulin aspart market in England over 17 years, including the launch of Fiasp® in 2017 and the subsequent introduction of the biosimilar Trurapi® in Q4 2021. We analysed prescribing changes in relation to these events using an interrupted time-series design, with sensitivity analyses and autocorrelation checks. We assessed the impact of the device format on prescribing.

Substitution dynamics

The results suggest that the launch of Fiasp® slowed the growth of NovoRapid®, especially in the pen category. This pattern is consistent with previous research suggesting that prescribing shifts toward familiar device platforms occur at the population level when reformulated products maintain device continuity (Abitbol & Chu, 2025). Aggregate dispensing data cannot confirm individual patient switching; however, the observed population-level substitution toward Fiasp® pens—coupled with the simultaneous decline in NovoRapid® pen growth—supports the inference that device familiarity facilitated prescribing transitions. Fiasp® maintained the same FlexTouch®/FlexPen® platform as NovoRapid® and provided a faster onset of action that supported uptake without major changes in practice. Furthermore, England prescribing guidance states that cost differences between cartridge and pen devices are relatively small and that this may have helped with the uptake of Fiasp (Somerset Prescribing Formulary, 2025; Abitbol & Chu, 2025). This continued use of vials until 2021, and the subsequent rise in use since Trurapi® was introduced, further illustrates the impact of the delivery format on real-world prescribing. It is important to clarify that this post-2021 increase in vial prescribing reflects a rebound in NovoRapid® vial use (post-Trurapi® slope +231,553 DDDs per quarter; 95% CI 168,306 to 294,800; $p < 0.0001$) rather than uptake of Trurapi® vials, which remained minimal (approximately 1.7% of total vial volume in the study dataset). The limited Trurapi® vial uptake is consistent with the smaller price advantage of Trurapi® vials (~20% less than NovoRapid® vials) compared with pens and cartridges (~34–38% less). Furthermore, vials are predominantly used in secondary care for inpatient sliding-scale and insulin-infusion protocols, where switching to a biosimilar vial may be constrained by hospital formulary governance and the need for specialist oversight. Insulin vials are usually reserved for in-patient use (such as continuous subcutaneous insulin infusion and variable rate intravenous insulin infusion) and the market for vials is largely confined to hospital settings where familiarity with the device and protocol standardisation are more important than unit cost.

The same substitution patterns were also evident from the market share trends. The proportion of NovoRapid® declined over time, whereas the proportion of Fiasp® was approximately 16% by the end of 2024, and Trurapi® was approximately 5.4% by the end of 2024. The correlation between absolute DDD and relative market share suggests that these changes are not just the result of fluctuations in the overall demand for insulin aspart, but rather reflect real changes in insulin aspart prescribing.

Biosimilar adoption curve

Trurapi® had a typical biosimilar uptake trajectory, with slow uptake in the early years, and steady growth as more prescribers became familiar with its inclusion in the formularies. The biggest increase was in pen formats, further emphasizing the need for familiarity with the devices. The reduction in Fiasp® prescriptions in the first few months after the launch of Trurapi® was followed by a rise in the number of prescriptions, suggesting that the biosimilar did not immediately replace the reformulated originator product.

This is comparable to the situation in England with insulin glargine and growth hormone biosimilars, which were initially underutilized, despite their clinical equivalence (Aladul et al., 2017; Agirrezabal et al., 2020; Aladul et al., 2018). Trust seems to be established over time, especially among patients who are stable on current treatment. Our findings are consistent with those of Abitbol and Chu (2025), who emphasized the need for device compatibility and prescriber guidance in order to achieve successful biosimilar uptake.

Policy implications

The results underscore the need to consider more than just unit costs when encouraging the use of biosimilars among payers and policymakers. Introducing biosimilars using familiar delivery devices and providing clear guidance and harmonized inclusion in formularies can help to speed up adoption. Monitoring trends at both the brand and device levels, can help ensure more accurate forecasting and budgeting. The analysis also demonstrates the value of open prescribing data to assess the impact of products and policy changes in the real world, in near-real time.

Limitations

This study relied on aggregated prescribing data and does not examine individual-level switching, adherence, or clinical outcomes. DDDs are a standardized measure, but do not account for dose titration or treatment duration. The models included adjustment for autocorrelation and were tested in various specifications. However, the influence of unmeasured factors, such as changes in list price, procurement policy, or disruption related to COVID-19, may have influenced prescribing. A formal COVID-19 sensitivity analysis showed that the pandemic indicator was not statistically significant for NovoRapid® ($p = 0.763$) or Trurapi® ($p = 0.089$), and the Trurapi® coefficients were robust to pandemic adjustment, suggesting that the observed device-specific patterns are not artifacts of pandemic disruption alone. Patient-level data and qualitative studies of prescriber and patient preferences could give further insight into biosimilar uptake.

CONCLUSION

This study demonstrates how the introduction of a reformulated originator (Fiasp®) and a biosimilar (Trurapi®) influenced the England insulin aspart market. The interrupted time-series design with diagnostic checks revealed that Fiasp® reduced the long-term growth of NovoRapid®, especially in pen formats, and Trurapi® followed the typical biosimilar pattern of slow uptake initially followed by gradual growth. Continuity in delivery systems facilitated adoption, while device format consistently influenced prescribing. These results emphasize that, besides clinical equivalence and cost, delivery devices and practice familiarity remain important considerations for policymakers and prescribers when integrating biosimilars into routine practice. Prescribing surveillance at brand and device level can help to ensure that the benefits of biosimilars—improved access and cost savings—are achieved without compromising patient care. The central message of this study is that the delivery device may matter more than price in determining whether a new insulin product succeeds. Fiasp® was adopted rapidly because it kept the familiar FlexTouch®/FlexPen® platform, whereas Trurapi® gained share slowly despite the cost advantages expected of a biosimilar. Policies that promote biosimilars should therefore address device familiarity and support for switching, rather than focusing on price alone.

Conflicts of Interest

The authors declare no conflicts of interest.

Ethics Approval

This study used aggregated, publicly available National Health Service prescribing data and did not involve any patient-level records, identifiable information, or direct contact with patients. Because of this, formal research ethics committee approval and individual consent were not required under local guidance for studies based on anonymized public datasets.

Data Availability

The aggregated prescribing data used in this study are publicly available from the NHS Business Services Authority (NHS BSA) Open Data Portal (https://opendata.nhsbsa.net/). These data are open-access and available to all researchers without restriction. Researchers requiring further details about the source dataset may also contact the NHS BSA Data Services team at DataServicesSupport@nhsbsa.nhs.uk. All analysis scripts, the dataset and exact syntax used to estimate the models are available from Zenodo (https://doi.org/10.5281/zenodo.21325520) and from the corresponding author on reasonable request.

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