# DELIVERY OF TZIELD® ▼ (TEPLIZUMAB) INFUSIONS AT UNIVERSITY HOSPITALS BIRMINGHAM, & BIRMINGHAM WOMEN'S AND CHILDREN'S NHS FOUNDATION TRUST

**INDICATION:** TZIELD® (TEPLIZUMAB) IS INDICATED TO DELAY THE ONSET OF STAGE 3 TYPE 1 DIABETES IN ADULT AND PAEDIATRIC PATIENTS 8 YEARS OF AGE AND OLDER WITH STAGE 2 TYPE 1 DIABETES (T1D)[1]

Tzield® ▼ (teplizumab)

TZIELD Prescribing Information can be accessed by clicking **here**, or by scanning the QR code below.This promotional material has been developed and funded by Sanofi and is intended for healthcare professionals and other relevant decision makers in the United Kingdom (UK).

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UKdrugsafety@sanofi.com

In developing this case study, Sanofi would like to acknowledge the assistance of:

- **Professor Parth Narendran**, Professor of Diabetes Medicine and Consultant at University Birmingham Hospitals NHS FT,
- **Dr Renuka Dias**, Consultant Paediatric Endocrinologist, University of Birmingham and Birmingham Women's and Children's NHS FT,
- **Tayebah Abbasi**, Principal Pharmacist, Birmingham Women's and Children's NHS FT

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Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

# EXECUTIVE SUMMARY

## Establishing a TZIELD® infusion service for patients with Stage 2 T1D: Learning from Birmingham.

TZIELD® (teplizumab) is the first disease-modifying therapy licensed in the UK to delay progression to Stage 3 T1D in patients with Stage 2 disease. Delivery requires 14 consecutive days of intravenous (IV) infusions, creating new service and operational considerations for NHS Trusts.[1]

### Why TZIELD was introduced

- Clinicians had a strong research and clinical interest in presymptomatic T1D and immunomodulatory therapies
- Prior to TZIELD, there were no proactive identification routes or treatment options for patients with Stage 2 T1D beyond monitoring
- Significant unmet needs were recognised in early detection, consistent management and patient support

### How delivery was achieved

- Existing infrastructure was used wherever possible, including infusion suites and Clinical Research Facilities, supported by flexible staffing models
- Pharmacy teams played a critical role in medication supply, electronic prescribing, dose titration and staff training
- Close coordination across clinical, pharmacy, laboratory and nursing teams enabled uninterrupted delivery

### Impact

- Clinicians were able to move from monitoring alone to offering an active intervention for presymptomatic T1D
- The delivery of TZIELD led to increased awareness of presymptomatic T1D amongst healthcare professionals, particularly in primary care
- Local experience is contributing to the development of emerging national guidance and resources

### Key learnings for other Trusts

- Early engagement with pharmacy, nursing and governance teams is essential
- Services can be established using existing facilities with appropriate planning
- Sustainable delivery will require clear pathways for patient identification, funding and workforce capacity
- Specialist centres are likely to lead early adoption

This case study demonstrates that **delivery of TZIELD within the NHS is feasible** and provides practical, transferable insights to support other Trusts considering service development.

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

PI

## Sanofi would like to thank

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without whom this case study could not have been developed.

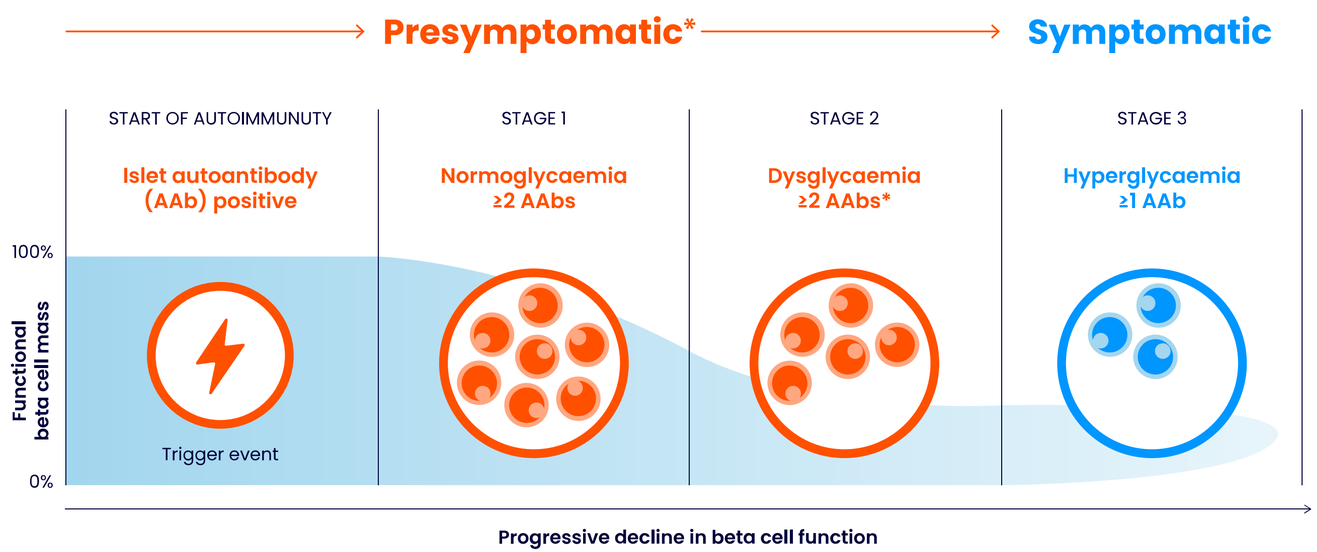
Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

PI

# INTRODUCTION TO THIS CASE STUDY

This case study describes the experiences of two NHS Trusts in Birmingham who have delivered TZIELD infusions to paediatric and adult patients. It is based on interviews with two clinicians and a principal pharmacist. It aims to provide practical advice for Trusts considering establishing a local service, drawing on the Birmingham teams' experience.

**Figure 1.** Stages of type 1 diabetes




## Background

T1D, characterised by autoimmune destruction of insulin-producing beta cells in the pancreas[2], starts before symptoms arise.[3] It is now recognised that T1D progresses in stages (**Figure 1**).[4,5]

TZIELD is the first and only approved disease-modifying therapy to delay progression of Stage 2 autoimmune T1D.[1,6-8] It is a single-course treatment administered by intravenous infusion over 14 consecutive days.[1]

Delivering 14 days of infusions involves logistical planning for Trusts. This case study explores how these challenges were addressed in Birmingham and shares practical insights to inform service development elsewhere.

Adapted from: Sims EK, *et al. Diabetes*. 2022;**71**(4):610-623 and Phillip M, *et al. Diabetes Care*. 2024;**47**(8):1276-1298.
Early stage T1D = presymptomatic Stage 1 and Stage 2.
*Some people with confirmed persistent prior multiple autoantibody positivity may revert to single autoantibody status or negative status.

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

PI

# INTRODUCTION TO THE TRUSTS

## Birmingham Children's Hospital

is one of Britain's leading specialist paediatric centres, seeing **>90,000 children and young people every year.**[9]

- Patients are seen from the local population and nationally for specialist services[9]
- The diabetes service provides care and support for patients aged up to 19 years old

## University Hospitals Birmingham NHS Foundation Trust (UHB)

serves the West Midlands region, treating over **~2.2 million patients annually.**[10]

- The Trust sees patients from across the West Midlands region and nationally[10]
- The Trust adult diabetes service sees patients with T1D aged 16 years+

Both Trusts see newly diagnosed patients on a regular basis.

+ See Box 1

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

PI

# HOW THE DELIVERY OF TZIELD CAME ABOUT

## Clinician interest

There was established research activity in emerging T1D therapies across both Trusts, through which research programmes* identified a cohort of patients eligible for TZIELD. At the time of writing, the paediatric service hosts one of only two early T1D clinics in the UK, accepting national referrals. UHB also runs an early T1D service taking referrals for adults nationally.

## First treatment for patients already identified

Prior to the advent of TZIELD, there was no proactive treatment available to manage disease progression. Standard of care was to monitor patients until they developed Stage 3 symptomatic disease and initiated on insulin. The paediatric early T1D service was established ahead of the Managed Access Pogramme for TZIELD being opened, and was led out of the need to manage patients identified through ELSA as well as patient/family interest.

## Managed Access Programme

TZIELD received marketing authorisation (MA) in the UK in August 2025 and at the time of this case study was undergoing appraisal by the National Institute for Health and Care Excellence (NICE). Prior to MA, Sanofi made the treatment available through a Managed Access Programme (MAP), enabling Trusts to access the drug free of charge for eligible named patients.

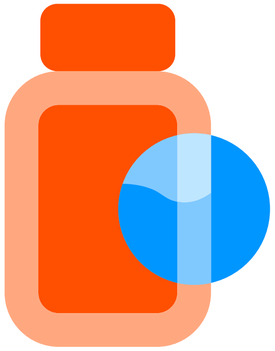
## Unmet needs

Unmet needs within the detection and management of people at risk of T1D were recognised. Clinicians in both Trusts identified the need for the product and sought agreement on its use in eligible named patients.

## Additional factors

The early T1D clinic in paediatrics was established at the point that the MAP had opened. Proactive enquiries and interest amongst patients and their carers was also a factor.

+ See Box 2



*ELSA (EarLy Surveillance for Autoimmune diabetes) and T1DRA (Type 1 Diabetes Risk in Adults) are UK based research studies to identify people at risk of developing T1D. The goals of ELSA and T1DRA are to find patients with presymptomatic T1D and monitor their progression, not necessarily to provide treatment.

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

PI

# DRIVERS FOR CHANGE: HOW AGREEMENT WAS GAINED TO DELIVER TZIELD

There was strong clinical support for treating eligible patients, including engagement from allied teams including haematology and anaesthetics, and senior Trust colleagues. Following the first infusion, the required infrastructure and processes became clearer, reducing barriers for subsequent patients.

Delivery of TZIELD differed between the paediatric and adult Trusts.

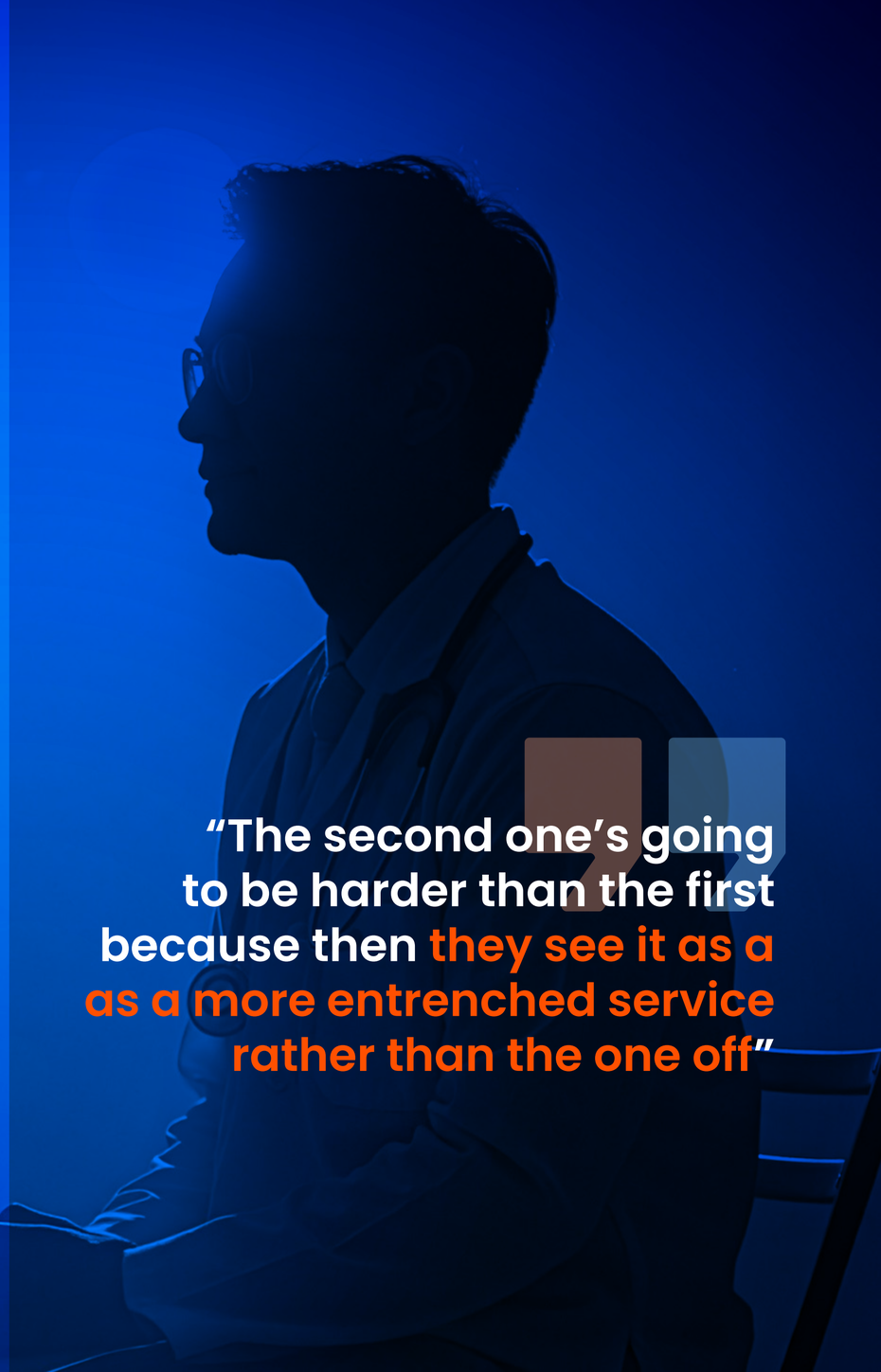
**Paediatric Trust**

- Implementation was initially challenging due to constraints around bed/infusion chair capacity, nursing availability, and associated funding
- Approval was sought by clinicians via the Trust Executive Committee, and the drug was progressed through the Drug and Therapeutics Committee
- The MAP opened in June/July and the first patient was infused in November. To date (March 2026) 3 patients have received TZIELD infusions in this Trust

**Adult Trust**

In contrast, delivery within the adult Trust was initially undertaken on a one-off basis, without formal approval for an ongoing service.

- One patient was infused using the existing infusion service, and the drug was progressed through the local medicines advisory group
- Approval was sought by clinicians via the Trust Executive Committee, and the drug was progressed through the Drug and Therapeutics Committee
- The time from patient identification to infusion was approximately 4-6 weeks



> “The second one’s going to be harder than the first because then they see it as a as a more entrenched service rather than the one off”

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

# PRACTICALITIES OF DELIVERING TZIELD INFUSIONS

**A different approach was taken regarding the logistics of delivering infusions in the two Trusts.**

## Paediatric setting

The lack of non-acute beds/infusion chairs available over the weekend led to an agreement to utilise the onsite Clinical Research Facility (CRF) as the setting for all 14 days of TZIELD infusions.

The existing workforce was utilised, with CRF nurses undertaking bank shifts to deliver the infusions. This proved valuable, as the team already had infusion experience and quickly became confident with administering TZIELD and required equipment.

Having continuity of nurses helped establish a 'clinical memory' within the nursing team, supporting familiarity with the infusion process, required equipment and management of any issues. Nurses within the CRF were also able to reconstitute the drug on site.

An anesthetist agreed to cannulate patients (primarily using peripheral cannulas) across the 14 days. This proved particularly helpful for one patient who required frequent cannulations due to poor venous access.

The Trust pathology lab prioritised processing of pre-infusion blood tests to ensure patients received their infusions promptly and discharged as quickly as possible.

Clinical support and advice were available from paediatric colleagues (US and UK) if required.

## Adult setting

Treatment was delivered in their established infusion suite Monday to Friday. Weekend use of the CRF addressed the lack of weekend infusion services.

The infusion suite nurses were already experienced in infusing complex drug regimes, administering pre-medication and aseptic reconstitution.

The team intends to expand weekend infusion-suite use, subject to securing adequate staffing.

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

PI

## Medication

Doses of TZIELD, including those needed for weekends, were dispensed in advance by the Trust pharmacies. They were collected and stored in fridges in the CRF or infusion suite.

Once the clinicians had assessed blood test results, nurses were informed to administer pre-medication and to start infusions.

## Monitoring

Monitoring and test results were received on time, with no delays to infusions. The Head of the biochemistry team was informed in advance of the required blood tests and the infusion schedule for each patient, allowing timely processing of results.

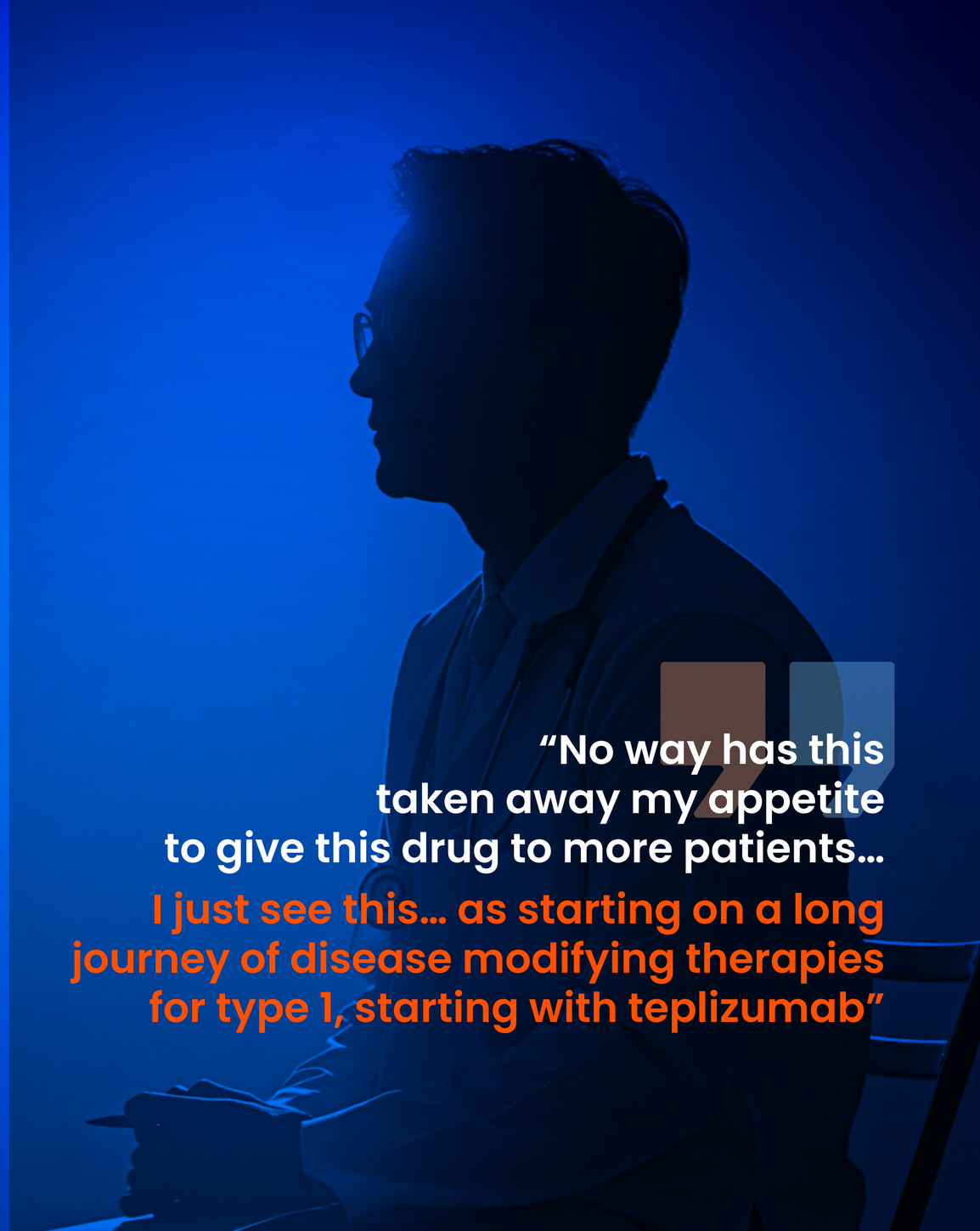
## Infusion delivery

In the **paediatric setting** there were no issues with infusion delivery, and at no point did therapy have to be paused.

- Once attendance had been agreed, co-ordination with the CRF manager ensured that all operational requirements were in place and delivery proceeded smoothly

In the **adult setting**, the patient experienced adverse events during the course of treatment.

- These were managed by the lead clinician in line with clinical judgement and existing protocols
- Importantly, these events did not deter either the clinician or the patient from continuing treatment, nor did they reduce clinician confidence in delivering TZIELD to future patients



**“No way has this taken away my appetite to give this drug to more patients...**

**I just see this... as starting on a long journey of disease modifying therapies for type 1, starting with teplizumab”**

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

PI

# PHARMACY PERSPECTIVE

How delivery was achieved and considerations for the future

## HOW THE PROCESS WORKED FOR PATIENTS INFUSED SO FAR

- The paediatric Trust does not have an aseptic unit on site. After review of the the Summary of Product Characteristics (SmPC), it was agreed that the drug could be stored and reconstituted appropriately in the CRF, enabling local preparation and administration
- Pharmacy ensured that the nurses administering the infusions had the necessary information for administration and that appropriate annotations were included on prescriptions

- To minimise the risk of wastage, wards did not hold more than one day's supply of medication
- As the pharmacy operated a seven-day service, vials were dispensed daily and collected by nursing staff, stored in refrigerated conditions as required
- No wastage occurred for the 3 patients who were infused

## FUTURE CONSIDERATIONS

- Once TZIELD has been approved through the Drug and Therapeutics Committee, pharmacy would need to:
  - Build and validate the drug within the Electronic Prescribing and Medicines Administration (EPMA) system
  - Develop a Trust-specific infusion monograph
  - Establish any required Blueteq or equivalent approval processes
- A Trust without a 7-day pharmacy service could feasibly issue the weekend vials on a Friday

A homecare option could be explored in future, with key considerations including:

- Asssurance of adequate refridgeration
- Availability of trained infusion nurses
- Clear allocation of responsibility for drug handling and wastage
- Given the risk of wastage, daily supply rather than delivery of the full 14-day course to a patients home may be preferable

These aspects would need to be clearly defined within service-level agreements.

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts
PI

# PHARMACY PERSPECTIVE

## Electronic prescribing and dose management

### DOSE CALCULATION AND PRESCRIBING

- The Electronic Prescribing and Medicines Administration (EPMA) system calculated the patient's TZIELD dosage based on body surface area (BSA). This was then checked and signed off by pharmacy to ensure accuracy

- Due to the required dose titration over the 14-day course, TZIELD was prescribed on a daily basis. This approach avoided all doses appearing on the medication administration record (MAR) at once, which could increase the risk of administration errors
- The advanced prescribing feature was utilised on the EPMA to accommodate daily prescribing. This allowed pharmacy to have vials prepared for each day in advance and ensure adequate stock availability

+ See Box 3
+ See Box 4

### CONSIDERATIONS FOR OTHER TRUSTS

- For Trusts without access to electronic advance prescribing, consideration would be needed for how daily prescriptions would be authorised
- Consider how doses will be collected and where they will be stored if pharmacy is not available over weekends

- Paediatric Trusts routinely manipulate vials for dosing, whereas other Trusts may be less familiar when handling a new drug
- Nursing staff will need access to SmPC information via a Trust intravenous drugs monograph

- Communication between pharmacy and the speciality team is vital to ensure sufficient stock is in place to avoid delays in treatment, especially as patient numbers increase
- Pharmacy typically lead on training for the endocrine team and wider clinicians including how the drug works, vial sizes and dosing, adverse events and monitoring

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

PI

# IMPACT OF DELIVERING TZIELD

### Impact for clinicians
TZIELD has enabled a shift from purely monitoring disease progression to offering an active intervention for people with presymptomatic type 1 diabetes. This was perceived as a significant and positive change in clinical practice.

### Impact for patients
Access to TZIELD, especially in paediatrics, provided reassurance that every possible step had been taken to delay progression to symptomatic disease. Parents reported feeling more hopeful and engaged in the management of their child's condition.

### Impact for primary care
GP letters now include the SNOMED code for presymptomatic* T1D (1290118005) to flag patients to primary care teams. This helps to code patients within their clinical systems and to raise awareness of early-stage disease. Where patients were treated outside their local area, links were established with local diabetes teams to ensure continuity of care and shared understanding of the patient's disease status and treatment history.

### Resources
A national package of resources for healthcare professionals is currently in development. This includes guidance on monitoring presymptomatic T1D in paediatrics and joint adult and paediatric guidance on the delivery of TZIELD, to which the paediatric clinician has contributed.

### Awareness of T1D
Awareness of presymptomatic T1D appears to be rising in primary care, but this has yet to develop in general paediatrics or emergency departments; by contrast, awareness and enthusiasm are growing among clinicians seeing adults.

*Early stage T1D = presymptomatic Stage 1 and Stage 2.

"It's kind of the ultimate aim, isn't it, to offer something that can delay progression"

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

# CONSIDERATIONS AND ADVICE FOR SETTING UP A TZIELD DELIVERY SERVICE 1/2

## Finding patients, funding the service and infusion delivery setting

**Finding patients** suitable for TZIELD requires an established pathway for detecting presymptomatic T1D. Trusts may wish to consider how similar pathways could be embedded locally, whether through research participation, specialist clinics or alternative detection models.

**Funding the service** is likely to require a business case covering service provision and drug acquisition costs, as adult and paediatric diabetes services may currently be funded via block contracts.

**Infusion delivery settings** may incude existing infusion suites, CRFs (where available) or homecare provision. To deliver infusions, staff competencies and weekend provision should be considered.

- As clinicians become more confident with using TZIELD, a combined model of hospital-based care during dose titration followed by community-based infusions could be considered. Management of adverse events and access to lab results in a community setting would need to be agreed
- Services are likely to develop organically driven by clinician interest and need to ensure equitable access to treatment across regions
- Specialist centres are likely to lead on delivery, due to limited experience on the use of TZIELD ahead of NICE guidance

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

PI

# CONSIDERATIONS AND ADVICE FOR SETTING UP A TZIELD DELIVERY SERVICE 2/2

## Clinic settings, protocols and training

**Clinic setting:** In paediatrics, a dedicated presymptomatic T1D clinic may be appropriate to support diagnosis and follow-up monitoring, due to the specific needs of these patients and their families compared to later stage patients. However, as numbers of adult patients will be lower, they may be more efficiently managed within established diabetes clinics.

**Protocols, guidelines and pathways:** National bodies and clinical networks will ultimately define standardised protocols, pathways and guidance for TZIELD. Adult resources are expected to build on paediatric materials, with some developed jointly across age groups.

- In the interim, clinicians and pharmacy teams with experience of delivering TZIELD may be willing to share their locally developed materials to support other Trusts
- ABCD/BPSED consensus guidelines on teplizumab are due to be published

**Education and training:** Nurses delivering infusions will require access to local drug monographs, validated dosing tools and aseptic preparation areas. They will need to be competent in vial manipulation for dosing and in managing adverse events. Pharmacy teams typically lead on education for the nurses and wider endocrine team around TZIELD.

ABCD, Association of British Clinical Diabetologists; BPSED, British Society for Paediatric Endocrinology and Diabetes.

“Talk to colleagues and [use] peer support… It’s lines of communication that make things work, really, more than anything else”

“To the pharmacy team, get involved early, rather than later… make sure you’ve got all of your processes in place”

# CLOSING THOUGHTS

**This case study demonstrates that delivery of TZIELD within the NHS is feasible and provides practical, transferable insights to support other Trusts considering service development.**

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts
PI

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Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts
PI

## BOX 1. NEW DIAGNOSES

**Within both Trusts the majority of patients with new diagnoses of T1D are admitted via A&E, with diabetic ketoacidosis (DKA) being a major cause of admission in children.**

Clinicians stated the following approximate figures in relation to their services:

- ~10-20% of paediatric referrals are via primary care
- ~5% of adults are referred by their GP having been misdiagnosed with type 2 diabetes initially
- ~40 children and young people and ~20 adults have a new diagnosis of T1D annually

Executuve summary
Introduction
Rationale
Gaining agreement
Practicalities
Impact
Consideration and advice
Closing thoughts

PI

## BOX 2. UNMET NEEDS IN PRESYMPTOMATIC T1D

Clinicians stated that:

- The **management of early stage T1D is inconsistent** across regions, e.g., follow-up and monitoring due in part to the lack of directive UK guidelines. Clinicians need more guidance on how to manage and support patients prior to progesssion of symptomatic disease
- **Additional funding** may be required to sustain infrastructure for managing presymptomatic patients long term, and separate clinics may be needed for presymptomatic paediatric patients due to their distinct needs
- **Knowledge and engagement** are growing, especially in paediatrics, but adult services are progressing more slowly, likely reflecting differing understandings of disease progression in adults versus paediatrics

## BOX 3. RECOMMENDED DOSING SCHEDULE FOR TZIELD BASED ON BODY SURFACE AREA (BSA)*[1]

| Day | 1 | 2 | 3 | 4 | 5-14 |
|---|---|---|---|---|---|
| **Dose micrograms/m²** | 65 | 125 | 250 | **500** | **1,030** |

* The dosing schedule in TN-10 was different to the recommended dosing schedule in the SmPC.[1]

## BOX 4. ADVANCED PRESCRIBING IN AN EPMA SYSTEM

### Prescribers enter a dose schedule covering the full course

Advanced prescribing allows a clinician to set up multiple doses over time in a single structured order – instead of creating separate prescriptions each day, the prescriber defines a planned sequence.

The sequence is then stored with defined:

- Start date/time
- Duration
- Dose for each time interval
- Any conditional rules, e.g., lab result-based dosage adjustments

### Prescribers do not have to authorise each day's dose

Once the schedule is entered and the overall order is authorised, daily doses are automatically released according to the plan.

Nursing teams record administration normally, and the EPMA system brings forward the correct day's dose for each administration time.

### Prescribers only need to intervene if:

- The dose schedule needs changing, e.g., to accommodate missed doses
- The patient's clinical condition changes
- A pharmacist queries or rejects the order
- Protocol-driven adjustments are required but not automated