Case Study & Final Report: Sanofi & University Hospital Southampton Chronic Graft versus Host Disease Pathway Mapping Project (cGvHD)

1.0 Background

The Wessex Blood and Marrow Transplant service is based at Southampton General Hospital, University Hospital Southampton NHS Foundation Trust. The service covers a wide geographical area including Hampshire, the Isle of Wight, South Wiltshire, Dorset, Western Sussex, and the Channel Islands. In 2022, the WBMT and Cellular Therapy programme was recognised as the highest performing European centre for allogeneic transplants and third for autologous transplants, with approximately 60 allografts performed in 2024.

As part of its ongoing commitment to high quality care, the service recently launched a complex cGvHD treatment clinic, staffed by three consultants on a rotational basis, a Clinical Nurse Specialist, and a transplant Clinical Fellow. Following this development, clinical leads identified a potential gap in women's health post-transplant, specifically around the identification of gynaecological cGvHD and its differentiation from symptoms of hormonal deficiency. A new referral pathway for women over the age of forty has since been developed to begin addressing this gap.

This case study documents a collaborative working agreement between Sanofi and University Hospital Southampton NHSFT to map and review the cGvHD pathway, with an extended focus on the gynaecological cGvHD element. The mapping exercise was designed to inform a service evaluation report that the Bone Marrow and Transplant team can use to consider any changes needed to improve the service.

1.1 Project Aim

A collaborative working agreement between Sanofi and UHS to undertake Pathway mapping and service evaluation of the post-transplant service including a detailed look in relation to women with genital cGvHD. This will help identify any gaps in service provision and variations in care which will inform recommendations and an action plan on areas for potential improvement (to be developed and agreed by the NHS steering group members).

The aim of the project is:

- To map and review the cGvHD pathway to optimise service capacity and efficiency, improve patient care, deliver a positive patient experience and patient outcomes when undergoing post-transplant treatment within the UHS service.

2.0 Project Objectives

The project will aim to deliver the following objectives:

- Map and evaluate the cGvHD pathway post-transplant, to identify any service gaps and variation in patient care
- Identify potential areas for improvement
- Map capacity and demand of cGvHD clinic and appropriate elements of the service
- Produce an action plan with support from steering group based on pathway mapping exercise to inform decisions around potential improvements to the service
- Produce a case study of the outputs and outcomes of the project to share learning with other NHS organisations.

3.0 Project Outcomes and Benefits

The expected outcomes and benefits of the project were:

Benefits to patients:

- Improvement in co-ordination of care and patient experience
- Earlier patient identification and improved access to treatment with a cohesive treatment approach
- Streamlined care ensuring more effective transit through the BMT service.

Benefits to the NHS:

- Clarity of existing pathway and where the gaps and issues exist
- Optimise the service offerings to patients provided through the current GVHD pathway
- Earlier identification of patients requiring intervention
- Greater understanding of the pressure points within the system and what improvements may need to be made.

Benefits to Sanofi:

- Gain insight on the pressure points and priorities within the BMT service at UHS
- Greater clarity of the challenges surrounding the services ability to deliver and tailor services to patient need and provide learning to improve Sanofi's ability to support other BMT services within the UK

- Improved corporate reputation within UHS by supporting them improve the quality of their care for patients
- As Sanofi produce a medicine for cGvHD, if overall patient care is optimised there may be an increase in the usage of this product in line with national and local guidelines.

4.0 Project Implementation

The Project Steering Group consisted of the following representatives from University Hospital Southampton NHS Trust:

- Consultant Haematologist Transplant Cellular Therapy Director
- Consultant Haematologist and cGvHD Lead
- Senior BMT & CT Clinical Nurse Specialist
- BMT Data Manager
- BMT Data Manager

Sanofi

- Project Manager
- Supporting Project Manager

4.1 Implementation Timeline

Project Initiation (July – August 2025)

- Established Project Steering Group comprising UHS clinical leads, specialist data managers, and Sanofi NHS Engagement Managers to oversee project delivery
- Developed and agreed full project plan and Terms of Reference with the Steering Group
- Set up Microsoft Teams page to facilitate project communications and information sharing
- Agreed meeting cadence with biweekly Steering Group meetings scheduled through to project close
- Completed CXQ project set-up to enable formal project tracking and evaluation

Implementation Phase (August – October 2025)

- Conducted group and individual key stakeholder interviews to inform pathway mapping
- Completed comprehensive cGvHD pathway mapping exercise

- Agreed data metrics and areas of interest for capacity and demand analysis, including the cGvHD clinic
- Identified service gaps, variations, and prioritised improvement opportunities within the pathway

Mid-Project Review & Data Collection (October – December 2025)

- Agreed patient service utilisation audit methodology as an adaptive approach to data collection, following challenges in obtaining direct service capacity data
- Conducted patient service utilisation audit, including a control group of five patients with comparable demographics
- Attempted to compile demographic data set covering transplant cohort, including lines of therapy and transplant type
- Reached out to external centres (Bristol, Manchester) to explore women's health and gynaecological protocols for benchmarking

Project Conclusion (January – March 2026)

- Completed data analysis of service utilisation audit, producing a presentation for Steering Group review
- Refined and updated pathway map incorporating staged clinical notes and specialist referral pathways
- Conducted consensus meeting (March) to align Steering Group on findings and recommendations
- Progressed close-out activities including final report preparation, case study write-up, and handover of materials to the Bone Marrow & Transplant Team
- Completed project evaluation via Customer Experience Survey

4.2 Progress against Project Objectives

A summary of the key outcomes in relation to the objectives of the project are shown in the table below:

Project Objective	Progress & Outcomes	Barriers & Challenges
Map and evaluate the cGvHD pathway post-transplant, to identify any service gaps and variation in patient care	• Full post-transplant pathway mapped across 5 key stages	Lack of engagement from gynaecology specialist limited gynae expert input into mapping of this referral pathway

	• Clinic structures, patient volumes and transition criteria documented • Specialist referral pathways mapped with named clinicians • Key gaps identified including inconsistent referrals, shared care breakdown post-COVID, and variation in processes • Visual pathway map produced and shared with steering group	
Identify potential areas for improvement	• Multiple improvement areas identified through pathway mapping and stakeholder engagement: • Some cGvHD assessment tools and scoring criteria implemented • Specialist referral processes mapped and improvement opportunities identified with respect to gynaecology • Digital patient education, personalised care plans and enhanced shared care protocols identified as opportunities for future implementation • Clear improvement roadmap established for ongoing service development	

Map capacity and demand of cGvHD clinic and appropriate elements of the service	• Service utilisation audit conducted across patients stratified by cGvHD severity • Capacity gap identified in Early Transplant Clinic • Day unit utilisation shown to be significantly higher in severe/extensive patients • Disease severity directly correlates with multi-specialty coordination needs, emergency admissions and bed days	• Multiple booking systems made data consolidation difficult • Original patient cohort insufficient, requiring expansion • Late Effects Clinic data insufficient as all patients developed cGvHD within 12 months • Led to project delays and overrunning on expected timelines
Produce an action plan with support from steering group based on pathway mapping exercise to inform decisions around potential improvements to the service	• Action plan developed in collaboration with steering group included in this report • Actions aligned to both immediate improvements and longer-term service development	• Hospital Fire impact required reallocation of clinical priorities • Disrupted steering group coordination and finalisation of the action plan
Produce a case study of the outputs and outcomes of the project to share learning with other NHS organisations	• Project outputs documented including pathway maps, service utilisation audit and improvement actions • Key learning identified for wider NHS transplant centres • Challenges encountered provide realistic learning for other organisations on timeframes and resource requirements • Case study to be finalised on project completion for dissemination	• Project timeline extended beyond original projections due to data collection issues • Incomplete Late Effects data limits case study comprehensiveness

5.0 Project Outputs

cGvHD Pathway Map

A comprehensive post-transplant cGvHD pathway was developed and agreed with the Steering Group, spanning five key clinical stages from transplant to long-term follow-up. The pathway map documents:

- Clinic structures, patient volumes, and transition criteria between care settings
- Decision trees for clinical management at each stage
- Specialist referral pathways, including gynaecological referral criteria and processes
- Identified service gaps and variation points, with particular focus on the gynaecological cGvHD element
- Potential options for improvement at each stage of the pathway

The pathway map was refined iteratively throughout the project, incorporating staged clinical notes developed by the CNS team, and was reviewed and agreed by the full Steering Group at the consensus meeting in March 2026.

Service Utilisation Audit

A patient service utilisation audit was conducted across a cohort of post-transplant patients, stratified by cGvHD severity. Key findings included:

- **Early Transplant Clinic**: No significant difference in clinic attendance frequency was identified between patients with differing cGvHD severity levels. This is likely reflective of the blurring between acute and chronic GVHD within the first two years post-transplant, during which the majority of patients — regardless of cGvHD status — remain under the Early Transplant Clinic rather than transitioning to the dedicated cGvHD or Late Effects clinics
- **Capacity gap**: The data suggests that demand may outstrip current capacity within the Early Transplant Clinic, based on an allograft volume of approximately 70 patients per year
- **Non-elective admissions**: Broad variation was observed across severity groups, with slightly greater consistency amongst moderate, severe, and extensive patients. This variation is likely attributable to the small sample size
- **Day unit utilisation**: Significantly higher in severe and extensive patients, reflecting the historical reliance on extracorporeal photopheresis (ECP) as a

primary treatment modality. As newer drug therapies replace ECP, a corresponding shift in workload from the day unit to clinic settings is anticipated

- **Late Effects data**: Insufficient data was available from the Late Effects Clinic for this cohort, as all patients in the audit developed cGvHD within 12 months of transplant and had not yet transitioned to late effects follow-up. This represents a recognised limitation of the audit methodology

Note on data limitations: The audit period included the COVID-19 pandemic, which significantly impacted service delivery and patient attendance patterns. This should be considered when interpreting findings, as the data may not be fully representative of current day-to-day service activity.

Benchmarking and External Engagement

As part of the project, the team engaged with external NHS transplant centres to explore best practice in women's health and gynaecological cGvHD management:

- **Bristol:** Contact established with the women's health lead. A written explanation of the Bristol women's health protocol has been shared with the UHS CNS team. A planned shadow visit is being arranged for the UHS CNS team to observe the Bristol service in practice. The Bristol service operates in a more ambulatory model, including home visits, which would require adaptation for the UHS setting
- **Manchester**: Outreach conducted as part of the benchmarking exercise

These external engagements have directly informed the improvement actions identified in this report.

6.0 Key Findings and Observations

The project identified the following key findings across the post-transplant cGvHD pathway:

Clinical Pathway and Service Delivery

- The post-transplant pathway is well-established and clinically robust, with clear structures for patient management across early transplant, cGvHD, and late effects settings
- **Acute-chronic GVHD overlap**: There is a recognised and clinically significant overlap between acute and chronic GVHD within the first two years post-transplant. This means the majority of cGvHD management occurs within the Early Transplant Clinic rather than the dedicated cGvHD clinic, making cGvHD workload less visible in service data and complicating capacity planning

- **Evolving treatment landscape**: The shift from extracorporeal photopheresis (ECP) to newer drug therapies is changing service utilisation patterns, transferring workload from day unit settings to clinic environments. This has direct implications for future clinic capacity requirements
- **Assessment standardisation opportunity**: cGvHD assessment, staging, and quality of life scoring is more consistently completed in the Late Effects Clinic than in the busier Early Transplant Clinic, representing an opportunity for standardisation across all settings

Gynaecological cGvHD Management

- A referral process for gynaecological cGvHD has been established in collaboration with the gynaecology CNS, but this is not yet formalised as a standardised protocol or SOP
- **Reactive rather than proactive approach**: The current approach largely responds to patient-reported symptoms rather than proactively screening for gynaecological cGvHD. Patient activation and awareness of gynaecological symptoms is variable; not all patients feel comfortable disclosing intimate symptoms
- **Improvement opportunity identified**: Structured, proactive symptom identification through regular questionnaires has been identified as a key improvement area. While discharge education is provided to all patients via CNS-led discharge talks, a more systematic ongoing patient activation approach is needed

Capacity, Workforce, and System Pressures

Growing demand from improving outcomes:

- Improving transplant outcomes are resulting in a growing cohort of patients with long-term chronic conditions, including cGvHD, placing increasing pressure on late effects and long-term follow-up services
- Current reporting frameworks (based on annual incidence and rolling cohorts) may under-represent the true cumulative workload of cGvHD, as they do not capture patients who developed the condition in prior years and continue to require active management

Workforce and service capacity challenges:

- The Late Effects service has experienced a reduction in senior medical resource, impacting specialist cover and contributing to complex patients remaining in the Early Transplant Clinic longer than may be clinically necessary

- Service utilisation audit identified a capacity gap in the Early Transplant Clinic, based on an allograft volume of approximately 70 patients per year

Shared care and repatriation barriers:

- Referring centres have been de-skilled in the management of post-transplant patients following centralisation during the COVID-19 pandemic, creating barriers to patient repatriation and increasing workload concentration at the transplant centre

Commissioning context:

- The BMT CRG is completing the BMT service specification with greater emphasis on long-term outcomes and chronic GVHD management beyond day 100
- Annual quality reviews increasingly focus on five-year outcomes, strengthening the case for investment in long-term follow-up and cGvHD management

7.0 Action Plan

The following action plan was developed and agreed with the Steering Group at the consensus in March 2026. Actions are prioritised and assigned to named leads, with agreed timelines.

Action	Detail	Lead	Timeline
Develop and implement a patient activation questionnaire for gynaecological cGvHD symptoms	Develop a structured questionnaire to proactively identify gynaecological and menopausal symptoms in post-transplant women. To be administered at regular intervals, aligned to three-monthly time point bloods. Informed by Bristol women's health protocol. Focus initially on women, with potential to extend to all patients.	CNS	6 Months
Shadow visit to Bristol Women's Health Clinic	Two CNS to undertake a shadow visit to the Bristol women's health service to observe their protocol and approach in practice. Learnings to be adapted and	CNS	6 Months

	incorporated into the UHS service model.			
Standardise the gynaecological referral process and criteria	Develop a formal SOP/protocol for gynaecological referral, including standardised referral criteria, swab collection requirements (viral, bacterial, STI), and documentation standards. To be developed in collaboration with the gynaecology CNS team to ensure buy-in and sustainability.	CNS	6 Months	
Develop a business case for a senior specialist role in Late Effects	Develop a formal business case for the creation/recreation of a senior medical specialist role within the Late Effects service, to address the gap in continuity, expertise, and capacity for complex cGvHD patients. Project findings to be used as supporting evidence. Business case preparation delegated to BMT Consultant, with Transplant Director as accountable officer.	Transplant Director	12 Months	
Conduct a needs assessment with referring centres	Engage with referring centres to understand barriers to patient repatriation, including clinical knowledge gaps, capacity constraints, and confidence levels. Use findings to develop a targeted education and outreach programme and define criteria for patient repatriation.	Haematology Consultant	6 Months	**8.1**

8.0 Project Conclusion and learnings

This collaborative working project has successfully delivered a comprehensive mapping and evaluation of the post-transplant cGvHD pathway at University Hospital Southampton. The project has:

- Provided the Steering Group with a clear, documented view of the current pathway, including service gaps and variation
- Generated evidence-based insights into service utilisation patterns and capacity pressures
- Identified a focused and achievable set of improvement actions, agreed and owned by the clinical team
- Supported the development of a rationale for investment in late effects specialist resource
- Strengthened connections with external centres and facilitated benchmarking against best practice

The project has been conducted in a complex operational environment, including the impact of a hospital fire, NHS restructuring, and the ongoing legacy of the COVID-19 pandemic on service delivery and data availability. These factors have been acknowledged throughout and have informed a pragmatic and adaptive approach to project delivery.

8.1 Learning for Other NHS Organisations

The following learning points are offered for other NHS transplant centres considering similar pathway mapping exercises:

- **Early engagement with all stakeholders is critical**: Engagement with the gynaecology CNS team was limited during this project, which constrained the depth of mapping in this area. Early, sustained engagement with all relevant specialties — including those outside the core transplant team — is recommended
- **Data availability and methodology require early agreement**: The original data collection methodology required adaptation due to the complexity of booking systems and data gaps from the COVID period. Building flexibility into the methodology from the outset, and agreeing a clear data governance approach early, will reduce delays
- **Allow for extended timelines when planning pathway mapping projects** – We initially set an ambitious three-month timeframe, which extended to six months.

Data collection challenges, stakeholder availability, and operational disruptions can all significantly impact delivery schedules.

- **Blurring of acute and chronic GVHD has significant service implications**: The overlap between acute and chronic GVHD within the first two years post-transplant means that cGvHD workload is often invisible within early transplant clinic data. Pathway mapping exercises should explicitly account for this
- **Improving outcomes create new service pressures**: As transplant outcomes improve and more patients survive with long-term chronic conditions, the demand on late effects and long-term follow-up services will grow. Services should proactively plan for this accumulating workload
- **Repatriation of patients to referring centres requires sustained effort**: De-skilling of referring centres during the pandemic has created barriers to repatriation that require a structured, relationship-based approach to resolve. A needs assessment of referring centres is a practical first step
- **Collaborative working adds value beyond the immediate project**: The structured approach of a collaborative working project provides a framework for clinical teams to step back, reflect on their service, and identify priorities in a way that day-to-day clinical pressures often prevent

9.0 Project Resource Utilisation

The total Indirect cost of the project was £6471

This was split into NHS and Sanofi contribution as follows:

- NHS Indirect Contribution = £3606
- Sanofi Indirect Contribution = £2865

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