

NHSBT Board**Update on the development of a new cellular therapies strategy**

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Status: Official

Exec Sponsor: Paresh Vyas

Previously reported at and any associated decisions

Previously presented at July ET, Clinical Services SMT and October ET

Equality, Diversity and Inclusion Impact

Any stem cell and cellular therapeutics strategy needs to address the fact that people needing a transplant have a 75% chance of not having a first choice, sibling donor. Subsequently if you are from a white background you have a greater than 80% chance of finding an unrelated donor, if you are from a BAME background you have a significantly lower chance - less than a 60% chance of finding a suitable (unrelated or haplo) donor.

Executive Summary

In July this year, we presented some initial thoughts on future ways of working for our Stem Cells and Therapeutics teams to the ET and a Board seminar on the area as a whole. We presented an initial version of this paper to ET. The paper provides an update on progress to date and seeks views from the Board, noting significant changes to the NHS driven by COVID-19.

- Have we missed anything material in our early analysis of the external environment and internal scrutiny that we should be addressing in our broad strategic themes and work-plan?
- Are there any aspects that require us to commission further, more in-depth market research and analysis to support e.g. how CMT fits in the emerging cell therapies market?
- Are there any areas of activity missing from our draft work-plan that you would have expected to see?
- Does our emerging work-plan go far enough in terms of our ambition e.g. does it align with our stated strategic shifts to be systems leaders / proactive and clinically responsive / modern & agile / a top choice for talent?

1.0 Background

As part of the Clinical Services directorate reorganisation, a new team was created; Stem Cells and Therapeutics (SCT) that includes Stem Cell Donation and Transplantation (BBMR and the NHS Cord Blood Bank) and the laboratory network of Cellular and Molecular Therapies (including the Clinical Biotechnology Centre). The intention is that TAS will be part of this in the future as well.

Further work has been undertaken to understand the current state in the field, develop insights and identify key themes and initiatives that NHSBT should pursue to develop its cellular therapy aspirations. We have undertaken a more detailed formalised approach to strategy

development, aligned to the organisational design principles and retrospectively ensured the initial stages were within scope of the new organisational strategy development process. The Board is asked to consider the approach, its output to date and our proposed way forward to develop a new ambitious cellular therapies strategy.

2.0 Framing the strategy

There are over 4000 stem cell transplants performed per year across the NHS. NHSBT's cellular therapies team currently support around 42% of patients undergoing stem cell transplantation within England, provide donors and donor products for patients around the world and have taken an increasing role in the development and delivery of Advanced Therapy Medicinal Products (ATMPs), the next generation of cellular therapies.

Despite historical efforts and progress, some hard facts remain about the risks and outcomes for stem cell patients. Not every patient can access a suitable donor and only 25% have a first-choice sibling donor. If you are from a white background you have a greater than 80% chance of finding an unrelated donor while if you are from a BAME background you have less than a 60% chance of finding a suitable (unrelated or haplo) donor. Stem cell transplant is considered one of the riskiest procedures performed by the NHS with the chance of dying from complications of transplant as high as 25-30% and for some diseases relapse rates of over 50%. During and after transplant a patient's quality of life can be severely affected, in particular by side effects such as chronic GvHD. This strategy will consider what steps we can take to improve both the outcome and quality of life for patients requiring these kinds of treatment.

Both within the stem cell transplant field and beyond the development and delivery of ATMPs is progressing at speed. ATMPs hold the potential in stem cell transplant to improve outcomes and reduce side effects. NHSBT holds a key role over the next 5 years in the UK ATMP landscape, as these emerging therapies are developed and applied to an ever-broadening range of indications. The UK market for cell and gene therapies is growing rapidly and previous predictions have estimated the value between £0.4Bn to £0.6Bn per year by 2025 and £0.9Bn to £1.3Bn by 2030¹. The market segments into approximately 44% gene therapy, 33% T-cell immunotherapy and 22% non-oncology cell therapy.

Recent market research points to a current UK industry turnover already reaching £0.3Bn with 100% growth in employment, 200% in industry value and 60% in manufacturing space between 2018 and 2020 alone². In December 2018 the UK Government published an update on its Life Sciences Industrial Strategy reinforcing its commitment to making the UK a global hub for advanced therapies³. Growth of NHSBT's ATMP market share will be a key focus of our new strategy but we need to carefully consider our aspirations within market segments.

By progressing initiatives across our 5 themes we aim to address these opportunities and challenges through access to donors, new cellular therapy products and R&D in key areas of patient need, driving change that would be transformative for patients.

¹ Advanced Therapies Manufacturing Taskforce Report, ABPI, 2016

² Cell and Gene Therapy Catapult, Annual Review, 2020

³ Life Sciences Sector Deal 2, Office of Life Sciences, 2018

3.0 Process and progress to date

We have sought to capture and understand a very clear current state of the cellular therapy community and NHSBT's cellular therapies by undertaking different forms of analysis including PESTLE, SWOT and stakeholder engagement. This information has then allowed us to form insights and develop broad themes with associated initiatives. We have sought to engage with the cellular therapy community, for their vision of the future and feedback both on what NHSBT does currently and where they believe our priorities should lie. These have taken the form of various 30-60min interviews and some examples of collated feedback are shown below.

Summary of collated feedback from external stakeholder engagement

- There are huge opportunities for NHSBT's cellular therapy programmes and we form a key part of UK infrastructure, with highly respected expertise in manufacturing, Quality and Qualified Persons activities.
- Key areas for NHSBT focus should be cellular therapy physical infrastructure and workforce development
- There is a desire to work more with NHSBT, with mutual desire to explore further partnerships
- The interviewees were keen to see NHSBT's programmes expand and offer its range of services to a wider audience
- Our services, capabilities and long-term aspirations are unclear, particularly to those who have not historically engaged with the organisation
- When partnering with NHSBT, the services provided are very high quality, dependable and valued
- NHSBT can be a difficult to engage with organisation, likely due to its size, and is hindered by a lack of agility, especially during the initial phases of collaborative working

4.0 Key external factors

4.1 UK Stem Cell Strategic Forum

The UK Stem Cell Strategic Forum (UK-SCSF) published well received reports in 2010 and 2014 and has been re-established under NHSBT sponsorship to publish new recommendations in autumn 2021 with a refreshed remit encompassing the entire UK cell therapy landscape including the pharmaceutical industry. It aims to develop a 10-year strategy for improving stem cell transplantation and advanced therapies, identifying shorter-term activities to be tackled immediately and providing recommendations to inform government (especially DHSC), commissioners, regulators and the wider transplant community. The Forum consists of representatives from transplant clinicians, the professional body British Society for Bone Marrow Transplantation and Cellular Therapies (BSBMTCT), NHSE Clinical Reference Group for BMT, registries, pharma, charities, patient representatives and NHSBT as both Sponsor and active participant.

The Forum has three workstreams and a cross cutting theme of data and outcomes. The workstreams are:

- 1: Stem cell supply; Considering the resilience of the cell supply infrastructure, ensuring it is sustainable and able to meet the needs of future patients and any requirements for advanced therapies.

2: Delivering for patients; Defining the need of patients, looking at pre-transplant unmet need and the current equity of access gap. Articulating patient experience of the transplant pathway, considering issues such as access to clinical trials, advanced therapies and what needs are not being met for those undergoing transplant.

3: Fit for purpose infrastructure; Focusing on physical infrastructure and delivery models, including research, with an emphasis on driving optimal service provision and identifying potential efficiencies.

Whilst NHSBT will have ambitions beyond this Forum it is critical that we fundamentally align our strategic intent. The work of the forum has played a key part in our shaping of the strategic themes presented below. NHSBT's cellular therapies teams will deliver the UK-SCSF outcomes and plans from 2021 onwards.

4.2 Threats and opportunities from COVID-19

Resilience of the UK cellular therapy supply chains has become a focus of initiatives from a local to national level. During the first wave of the pandemic we saw a significant impact on global stem cell transplant supply chains. As international stem cell supply chains have been disrupted, frozen cord blood has been viewed as a valuable product both nationally and internationally. The NHS Cord Blood Bank saw strong demand during this period including increased demand from UK centres and requests for urgent provision where adult donors succumbed to COVID-19 infection. As noted above, the stem cell community via the UK Stem Cell Strategic Forum has also highlighted UK-UK donor to patient provision as a key area for significant investment.

In manufacturing and storage, COVID-19 has driven a need to develop ever more rigorous business continuity plans focussing particularly on service failure through loss of staffing. NHSBT has already been contacted through numerous channels including direct from NHS Trusts and NHSE/I to support London stem cell transplantation units. Through this work NHSBT has begun exploring opportunities to refresh post-COVID-19 commissioning models and support the development of emerging Integrated Care Systems (ICS). Activity continues to rise, driven by increased work required to ensure allogeneic transplant pathways are safe during the pandemic, further increasing the workload of understaffed units. It is likely plans developed now, will become the building blocks of new operating models driving reconfiguration of stem cell transplant programmes. At a national level DHSC has identified stem cell supply chain resilience as a key component of the 5-year comprehensive spending review. A potential no deal exit from the EU will amplify pressure on cellular therapy initiatives to access UK based cellular therapy infrastructure. Our additional planned infrastructure will alleviate this to a certain degree but we must also look at optimising our existing estates, included extended hours and shift patterns.

4.3 UK clinical trial infrastructure

As noted above, the UK cell therapy supply chain has been under pressure during COVID-19 but demand for these services continues to grow driven by ongoing ambitions of academic, NHS and commercial partners to develop novel cellular therapies. A critical feature of the UK infrastructure is NHS penetration and the ability for new therapies to be tested under clinical trials. TAP and IMPACT are NHSBT (and other partner) sponsored clinical trial networks that have delivered significant benefits to haemato-oncology patients via novel agent and stem cell transplantation clinical trials, respectively. The networks have reduced clinical trial

development and delivery times as well as providing increased geographical equity of access for patients. Based on philanthropy, their operating models are now under severe threat and a solution to protect this UK capability is in late stages of development.

The Social Enterprise Clinical Research Organisation (SECRO) aims to build on the previous success of the IMPACT clinical trial network and represents a unique opportunity for the UK. SECRO is specifically aimed at supporting advanced therapies for the treatment of patients with haematological malignancies for whom access to novel treatments has been both challenging and geographically biased. The SECRO initiative has gained support from a wide range of key opinion leaders across the clinical, academic and industrial landscape with public support provided including Sir John Bell and a wide range of other high-profile individuals. The opportunities for us with SECRO (including becoming preferred supplier for cellular therapy services) will be presented in a separate ET paper.

Taking these factors together, we see that there may be opportunities for us to increase our 'share in the market' in terms of collection, manufacture, storage and the clinical trial field and we envisage a small number of no regrets decisions that we might want to take. Our broad themes and derived initiatives are presented below.

5.0 Strategic Vision, Themes and Initiatives

An emerging vision for our cellular therapies is "To save and improve even more lives by driving evolution of the cellular therapy system through innovation and collaboration to deliver growth, increased resilience and accelerated equitable access for all patients".

Below we present a summary of our key themes and selected initiatives under each theme. A summary of the analysis completed so far that is driving our initial, unconstrained work-plan is also included as an Appendix. Further detailed supporting analysis and information is also available on request.

Theme 1: Safe, secure supply; Strengthen the UK cellular therapy supply chain in manufacturing and clinical trial delivery

This theme, coupled with our second theme on donors, aims to address gaps and exploit opportunities across the UK cellular therapy supply chain. From both internal analysis and external stakeholder feedback NHSBT's role in the current and future of UK cell therapies is key to a futureproof resilient supply chain and with additional initiatives such as SECRO would provide the UK with a globally unique offering. We focus here on strengthening our existing infrastructure, completing construction and commissioning of our new key estates at Filton (new Clinical Biotechnology Centre) and Barnsley and expanding capabilities to develop and deliver novel cell and gene therapies including the use of viral vectors. We will continue to take a leadership role in the UK-SCSF and position ourselves ready to respond to its findings with both upgraded and new physical infrastructure. Key supply chain pinch points identified are viral vector manufacturing capacity, product/process development, storage and clinical trial capacity. Our skills and experience, both within GMP manufacturing and Quality Assurance are key enablers and recognised as such by the wider community. By driving infrastructure expansion supporting the various stages of ATMP development and delivery we will accelerate access for patients to more refined targeted therapies, improving outcomes and decreasing side effects versus existing treatments.

Theme 2: Diverse donor base; Strengthen the UK cellular therapy supply chain for donors and donor products

Increasing UK deployment of the cellular therapies, in both existing and broadening clinical indications, means increased demand for both routine stem cell transplantation products and starting materials for ATMPs. In addition, key aspirations of both the UK-SCSF and DHSC are to increase equity of access for our population and deliver better outcomes through access to well matched products. Supply chain pressures during COVID-19 have also highlighted the value of UK-UK stem cell provision and a well-stocked NHS cord blood bank. We focus here on driving growth of our BBMR FIT panel, continuing to focus on recruitment of BAME mothers for cord blood and becoming the ATMP starting material supplier of choice. Through these initiatives we will increase equity of access, provide greater access to high quality adult donors and support the next generation of cell therapy products providing patients with both the current and future cell therapy products they need. Key supply chain pinch points identified are clinical (apheresis and non-apheresis) and non-clinical procurement, including adult donor and cord derived products.

Theme 3: Modernised service model; Develop optimal cellular therapy operating, commissioning and financial models

The existing operating model for stem cell transplantation within the UK is long standing and based on assumptions challenged during COVID-19. We focus here on exploring and developing new ways of working, from more strategic partnerships with individual Trusts up to Integrated Care System wide relationships. We reflect on our internal operating models to ensure we are resilient and enhance our capabilities to work in the new cellular therapy system by refreshing customer facing initiatives such as our Pathfinder service, striving to be ever more agile and easy to partner with. Expansion of our autologous cell processing offering to London hospitals would grow NHSBT activity while increasing non-NHSBT ATMP capacity by freeing up existing close to patient facilities. This would increase patient access to new therapies under clinical trial and thereby improve chances of survival and quality of life.

Theme 4: Optimise resources; Drive innovation to deliver better outcomes for patients through optimised use of data and aligned R&D

Perhaps the single greatest opportunity within cellular therapies today is the integration, collation and analysis of data to drive patient outcomes. Transformative improvement in clinical cellular therapies within the NHS will require evidence driven patient pathways. Data covering the patient pathway from diagnosis to outcome are siloed within several different institutions and often incomplete. There is currently no holistic approach across the patient pathway to bring together this valuable data into a single point. Data on the unmet need are also difficult to obtain. We therefore propose exploring a centralised NHS Cellular Therapies data centre hosted by NHSBT in partnership with the BSBMTCT, Anthony Nolan and later collaborating with research bodies such as the NIHR. We believe this data initiative could deliver development of the clinical evidence base supported by centralisation, analysis and dissemination of national data sets, research, clinical audit and operational efficiency programmes. Further access by commercial partners could form the development of a self-sustaining business model. This initiative will accelerate key areas such as clinical benchmarking as well as industry led novel therapy development.

In addition, we have the unique opportunity to refocus our own R&D programme to align with UK-SCSF, DHSC and our own operational priorities to deliver not only cutting-edge research but increased numbers of products and services for our patients. We will deliver this through

an R&D programme closely linked with operational teams and a new Therapeutics BTRU, tasked with answering the key questions in the current clinical field. The new BTRU challenge focuses on key patient need areas covering better transplant matching, leveraging GvL, reducing GvHD and managing infection.

Our cellular therapy programme also requires ongoing expert input and horizon scanning capabilities so we will commission a world-class Scientific Advisory Board of international experts across the cell and gene therapies.

Theme 5: Great place to work; Drive the development of the future cellular therapy workforce

All our past achievements and future aspirations in cellular therapies are reliant on one thing; our staff. Through our staff development and training programmes we will enable both our own strategies but also that of the wider cellular therapy community. NHSBT has long been perceived as a training organisation and building on this we will focus on developing an end to end career pathway in the cellular therapies, exploring Royal Colleges membership at a senior level and developing apprenticeship programmes to support not only NHSBT's workforce needs but also the Governments levelling up agenda in the North of England. We also aim to develop an HEE funded (application submitted) clinical academy working with the Chief Scientists office and support wider cellular therapy initiatives through training such as the Cell and Gene Therapy Catapults Advanced Therapy Treatment Centres (ATTC). Positioning ourselves close to clinical practice will be delivered through joint medical consultant posts within selected strategic partnership Trusts. We will also encourage agility through specific programmes in curiosity and growth mindset while enshrining NHSBT's corporate goals on diversity and inclusion and health and wellbeing in our workforce planning.

6.0 Key next steps

We propose the below next steps in strategy development:

- Understand what Board members would like to see as a next step – e.g. Invite Board members to attend a cellular therapies strategy development workshop, including key external stakeholders and partners if requested.
- Bring individual opportunities/no regrets decisions to ET
 - SECRO initiative
 - CBB reorganisation
 - London operating model
- Finalise strategy timelines and presentation of full strategy to Board

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Summary: Safe, secure supply

Changes in the ecosystem

- Government ambition to grow UK stem cell capability and infrastructure
- DHSC & UK-SCSF focus on resilience, unmet need and fit for purpose infrastructure
- Government levelling up agenda driving investment in the North
- Lack of northern England infrastructure and access to cellular therapies compared to SE

Existing system strengths to build on

- Adult donor and cord blood units ca 65% of the allograft transplants in the UK
- Remain the only curative option for many patients, particularly patients from BAME communities
- Significant ongoing NHSBT investment in estate to better meet demand and improve compliance
- NHSBT national, licensed, network / capabilities supports 42% (2018) of NHS stem cell transplants and provides cell and gene therapy manufacturing facilities
- Existing close collaborations and partnerships within the UK aligned registry
- Recognised expertise in GMP manufacturing, QA and QP activities.

Changing demographics and consumer expectations

- Growing patient expectation for geographical equity of access to existing / novel cellular therapies

Evolving clinical practice

- Urgent need for a clearly defined process / product delivery pipeline through to clinical trial
- Increasing demand for clinical programmes to join Randomised Clinical Trials (RCTs) and use CAR-T therapies
- Need for UK RCT infrastructure under a sustainable operating / funding model

Emerging technologies

- Adapt to advances in cellular therapies and increasing demand for gene therapy products
- Increasing indications for existing therapies, Immune Effector Cells
- Apheresis collection capacity insufficient to support new therapies i.e. expansion of CAR-T



Overall theme to: Strengthen the UK cellular therapy supply chain in manufacturing and clinical trial delivery

Short term Action-plan

1. Continue to drive the UKSCSF delivery workstreams
2. Commission the additional Barnsley Centre clean room capacity
3. Open a process and product development lab in the North (Barnsley) (DHSC funding request submitted)
4. Complete resilience works at Oxford and Southampton sites
5. Review the roles of CMT sites throughout the NHSBT network
6. Invest in the next generation of cell and gene therapy clinical trials infrastructure (SECRO) and become the preferred cell therapies services supplier, growing NHSBT's stake in future ATMP therapies, increasing the clinical evidence base and patient access to new therapies

Medium to Long Term Action-plan

1. Deliver the UKSCSF outcomes and plans from 2021 onwards
2. Complete (ongoing) construction and commission the CBC extension at Filton
3. Explore collaborative opportunities in cell and gene therapy
4. Develop cell processing prototyping capabilities
5. Develop CAR-T manufacturing expertise in-house
6. Design new operating models to release capacity for ATMP manufacture
7. Pursue CMT (and support TAS) ambition to provide increased laboratory (and collection) capacity for existing and novel cellular therapies within London

Summary: Diverse donor base

Evolving clinical practice

- Over-reliance on overseas stem cell donors within the UK
- Imports growing year on year and a decline in UK stem cell donors being selected for UK patients
- Lack of UK registry FIT panel donors (targeted recruitment of males aged 17-40, 6 loci NGS tested)
- Aggressive donor recruitment by larger scale overseas registries
- Use of Haploidentical transplants as an alternative
- Ageing BBMR donors driving an unsustainable registry; attrition greater than recruitment in 5 years
- Increasing use of CAR-T and EBV specific T cells as routine treatments

Existing system strengths to build on

- Direct access to blood donors and existing relationships with blood donor teams
- Existing close collaborations and partnerships within the UK aligned registry

Changing demographics and consumer expectations

- UK population demographics driving changing requirements for donor ethnicity
- Adult donor and cord blood units remain the only curative option for many BAME patients
- Expectation for patient demographic equity of access to existing and novel cellular therapies
- Opportunity to leverage the COVID19 driven wave of altruism

Changes in the ecosystem

- DHSC focus on equity of access to stem cell services
- c.10% of donors recruited in 2019/20 to the aligned registry were from minority ethnic backgrounds

Emerging technologies

- Growth in cellular therapies requiring additional collection capacity, driving increasing demand for ATMP starting products i.e. CAR-T and manufacturing platforms

Existing System Challenge

- Historic development of the Cord Blood Bank resulted in a high volume of lower quality, C grade cord blood units; the units issued for patient care are from the A/B grade pool



Overall theme to: Strengthen the UK cellular therapy supply chain for donors and donor products

Short term Action-plan

1. Increase the annual growth in the BBMR FIT panel from 10k donors to 30k through investment in recruitment and typing increasing patient access to optimal UK donors
2. Continue to deliver key CBB operating targets (>40% BAME mothers donating) to ensure sufficient diversity in cord HLA collection, driving equity of access for patients
3. Become the ATMP starting material provider of choice by developing an aggressive cellular therapy NCI programme
4. Activity to drive collection of A/B grade units through raised TNC thresholds
5. BBMR support to TAS healthy donor panel activity and donation for ACT trials

Medium to Long Term Action-plan

1. Deliver the UKSCSF outcomes and plans from 2021 onwards
2. Coordinate donor recruitment more effectively with the new Donor Experience Directorate
3. Work with Anthony Nolan to improve speed and quality of service provision
4. Co-develop a BBMR donor portal / CRM with Blood Donation to provide improved analytics and access to donors

Summary: Modernised service model

Changes in the ecosystem

- Leverage the accelerated pace of change in the NHS driven by COVID-19
- Push a more systemic NHS approach through the Integrated Care Systems (STPs)
- Second CV-19 wave (& beyond) impacting NHS SCT programmes / inbound supply chain fragility
- NHSE move to provide funding allocations through integrated healthcare systems
- Funding environment post COVID-19 may impact on demand and supply capacity in hospitals

Existing system challenges

- Perception that NHSBT is difficult to do business with and lacks agility
- Initiatives / policies are frequently siloed vs holistic
- Lack of clarity within the UK stem cell arena; opportunity to propose new commissioning models
- No internal SCT funding for process / product development
- CMT prices are mis-aligned with costs across the portfolio
- Current SCDT financial deficit results in reliance on central government funding (GiA)
- Limited self marketing resource
- Although now engaged in several academic partnerships, our previous historical reluctance to enter academic lead collaborations, means we are still playing catch-up

Existing system strength

- Significant proportion of NHS England activity already under NHSBT
- Opportunity to expand further into key regions i.e. London
- NHSBT seen as key partner for risk mitigation in cellular therapy (and TAS) services (NHS)



Overall theme to: Develop optimal cellular therapy operating, commissioning and financial models

Short term Action-plan

1. Work with NHS Trusts to develop operating models to support London
2. Deliver new SCDT sustainable operating model (BBMR & CBB)
3. Scope centralised hub/spoke model for autologous processing with NHSE to expand NHSBT market share and increase ATMP capacity in close to patient programmes
4. Develop alternative proposal for bag storage pricing, reducing financial risk
5. Rebrand and relaunch the Pathfinder service - focus on ATMP market share growth, NHS contract opportunities and streamlined NHSBT cellular therapy programme offer
6. Initiate a viral vector platform for CBC ahead of the move to Filton (ongoing CBC programme)

Medium to Long Term Action-plan

1. Explore new commissioning models for stem cell transplantation with ICS and NHSE
2. Develop plans to build internal cellular therapy pump prime development funding into SCT prices
3. Deliver the UKSCSF outcomes and plans from 2021 onwards
4. Increase plasmid production and introduce viral vector manufacturing after the move to Filton (ongoing CBC programme)
5. Increase data capture and analysis to improve service delivery

Summary: Optimise resources

Changes in the ecosystem

- DHSC priority to understand the unmet demand in stem cell transplantation
- UK-SCSF, NHS Digital, NHSE/I focus on greater data sharing and integration in the NHS

Evolving clinical practice

- NHS genomics programmes capturing whole patient genome data with potential to create risk / outcome stratification and complication of Tx prediction

Emerging technologies

- Greater safety through electronic data interchange, product tracking, product identification
- Availability of ICT equipment to support paperless operations across SCT
- Adapt to advances in cellular therapies i.e. CAR-T, IEC
- Explore and deploy technology such as artificial intelligence, machine learning

Existing system challenges

- No end to end patient management database; data held in silos across several organisations
- Current operational processes are primarily paper based
- Paucity of clinical evidence, particularly for long established therapies
- No data driven performance benchmarking / continual improvement initiatives
- Limited data analysis capability / capacity within SCT
- No defined programme/access to NHS data for R&D / Industrial partners
- Unclear R&D governance to deliver services/products that directly improve patient outcomes
- Lack of shared staffing has slowed knowledge transfer from BTRU's
- External funding increasingly focussed on translation

Changing demographics and consumer expectations

- Greater expectation for data to be leveraged for better patient outcomes
- COVID19 driven wave of altruism to participate in R&D

Existing system strength

- NHSBT data / statistics expertise and reputation; OTDT national programme
- NHSBT R&D programmes and BTRU focus delivering cutting edge research across the estate
- NHSBT has a track record in manufacturing cell and gene therapies under MHRA licenses



Overall theme to: Drive innovation to deliver better outcomes for patients through optimised use of data and aligned R&D

Short term Action-plan

1. Explore and develop a proposal for a centralised NHS Cellular Therapies data centre, leveraging patient pathway and outcome data to develop best practice and new therapies
2. Commission an international NHSBT cell and gene therapy Scientific Advisory Board (SAB)
3. Develop a new BTRU therapeutics programme focussed on transformational changes in treatment for patients; optimising existing and accelerating new therapies
4. Ensure tech transfer from existing BTRU programmes
5. Align process / product development life cycle and intellectual property protection / exploitation policy

Medium to Long Term Action-plan

1. Deliver the UKSCSF outcomes and plans from 2021 onwards
2. Leverage SCT data for operational, BI and research applications
3. Develop paperless processes across SCT; reduce transcription errors
4. Develop a BBMR donor portal / CRM with Blood Donation
5. Develop a CMT CRM to support (a rebranded) Pathfinder Service
6. Work with NHSBT Diagnostic Services to develop an advanced sequence based typing proposal for Stem Cells & Therapeutics
7. Maximise the manufacturing of Advanced cell therapies to enhance the NHSBT offering to NHS patients

Summary: Great place to work

Changes in the ecosystem

- Government ambitions for UK capability, scientific skills and careers
- Government HMT levelling up agenda pursuing greater science, maths and engineering opportunities in the North of England

Existing system challenges

- Increasing demand for trained cell and gene therapy staff both internally and across the system
- Access to clinical and scientific training in cell and gene therapies a challenge
- Initiatives often held up due to staffing levels; ongoing recruitment challenges and retirements
- Current data is underutilised, unlinked and staffing skill sets reflect this
- Paucity of scientific staff local to key strategic sites i.e. Barnsley

Existing system strength

- Core competencies of NHSBT Cellular Therapies, QA and OWD teams
- Initial NHSBT/ATTC training programmes are in place for cell and gene therapy manufacturing and delivery

Emerging Technologies

- Adapt workforce to advances in cellular therapies / increasing demand for gene therapy products
- Increasing indications for existing therapies IEC across increasing range of indications
- Opportunity to use Artificial Intelligence & machine learning to better understand donors / donation

Changing demographics and consumer expectations

- UK population - growing expectation for geographical equity of access to existing and novel cellular therapies - lack of access to cellular therapies as a career in the North



Overall theme to:

Drive the development of the future cellular therapy workforce

Short term Action-plan

1. Development programme for SCT leadership to challenge dogma and drive agility
2. Align SCT to corporate programmes on diversity and inclusion, health and wellbeing, staff survey response plans
3. Link into Medical staff work-plan review
4. Pursue training initiatives and external funding in cell and gene therapies

Medium to Long Term Action-plan

1. Deliver the UKSCSF outcomes and plans from 2021 onwards
2. Deliver an apprenticeship to clinical scientist/ consultant clinical scientist career pathway in the cellular therapies
3. Further develop and deliver a training pathway to support UK cellular therapy initiatives
4. Work with the Royal College of Pathology and AHCS to explore the development of an RCPATH examination in the cellular therapies
5. Develop and implement the ACGT Skills Academy
6. Scope and develop an HEE funded cellular therapy clinical academy
7. Implement VR training
8. Support STP / HSST in clinical informatics / bioinformatics

Appendix

