



Implementation of an Allogeneic Serum Eyedrops Service

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Caring Expert Quality



DONATION MANUFACTURING CUSTOMER SERVICE & INTEGRATION PATIENTS



1.7 million donations
900,000 donors
£285m turnover
Declining demand



DONOR



PATIENTS



1,281 donors
21m on ODR
4,415 transplants
£71m grant

STRATEGY
Taking Organ Transplantation to 2020
(UK strategy)

WHO ARE WE?



Diagnostic and Therapeutic Services

12,000 tissue implants
50% UK stem cell transplant market
40% NHS H&I testing market
Team of 750
£85m turnover

Tissue Services

Stem Cells

Customer Services

Diagnostic Services

Therapeutic Apheresis Services

Supporting the NHS

Lean expertise



HR services



Clinical R&D



Transport & logistics



Supporting NHS

Specialist Haematology advice



Bioprocessing facilities



Quality/regulatory expertise

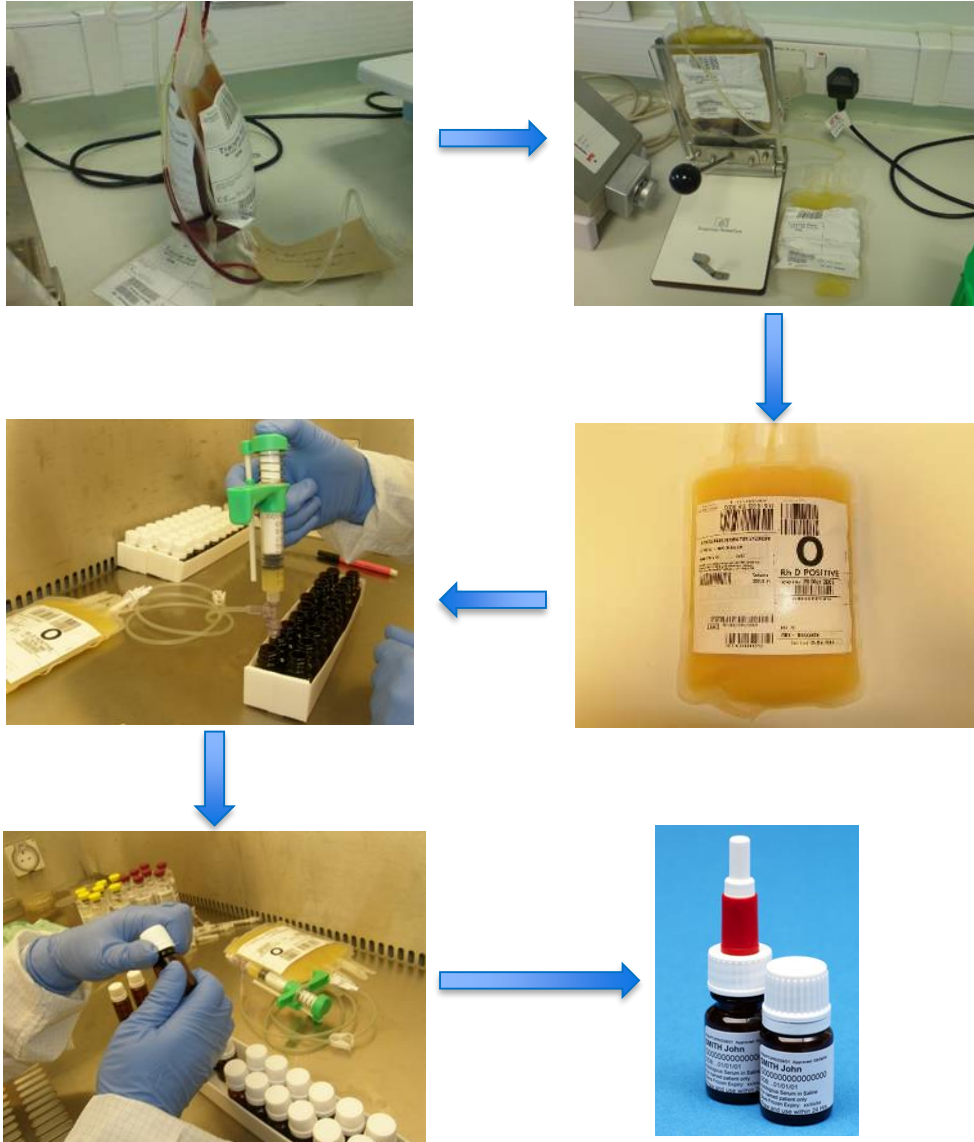


Joint procurement



To find out more about NHS Blood and Transplant visit: www.nhsbt.nhs.uk www.blood.co.uk www.organdonation.nhs.uk

What are serum eyedrops?



- **Autologous Serum (Auto SE) :** SE Prepared from blood donated by patients : First reported in the 1980s

- **Allogeneic SE (Allo SE):** Prepared from blood donated from unrelated voluntary blood donors , relatively new.

In the UK, serum eyedrops are classed as an unlicensed ('special') medicine

Who needs serum eyedrops?

Severe dry eye disease

- May be caused by:
 - Autoimmune diseases (Sjogren's Syndrome, Stevens-Johnson Syndrome)
 - Other immune (Graft vs host disease)
 - Ocular injuries (e.g. chemical burns, post-laser eye surgery)
 - Other medical conditions or medication

Effects of severe dry eye disease

- Extreme pain
- Sensitivity to light
- Eye infection
- Loss of visual acuity

Management of severe dry eye disease

- Improve local environment; remove the source of the problem
- Use over the counter pharmaceutical eyedrops
- Surgical options; punctal occlusion

Severe cases of dry eyes have a major effect on patient's quality of life - If none of the other treatments work, serum eye drops may be considered

History of the Service 2003- 2014

2002

- Study performed in Leeds

2003

- Continued provision to trial patients; Service established

2003-06

- New patients referred through word of mouth, other centres – London, Newcastle, Oxford, Bristol, Liverpool

2003-06

- Donations at 4 Therapeutic Apheresis (TAS) units & 2 Blood donor centres (BD).
- Processing done at local blood centres

2003-06

- Dispensing centralised where clean rooms were available initially in Leeds, then Sheffield, Bristol and Colindale before moving to Liverpool in 2006

2013

- Donation sites moved from TAS to BD static sites.
- Processing centralised in Liverpool & Central Administration Hub established
- TES overall management responsibility -

Why AlloSE?

- 50% patients are not healthy enough to donate enough of their own blood
- Children cannot donate blood
- Poor veins, anaemia and adverse events such as fainting associated with blood donation – may lead to exclusion
- Urgent treatment, hospital inpatients requiring treatment
- Patients do not have to travel to donate blood

NHSBT CAN ADDRESS THIS UNMET CLINICAL NEED!!



How was the service implemented?

Planning (2012)

- Literature Review
- Establish clinical advisory group
- Develop a business case

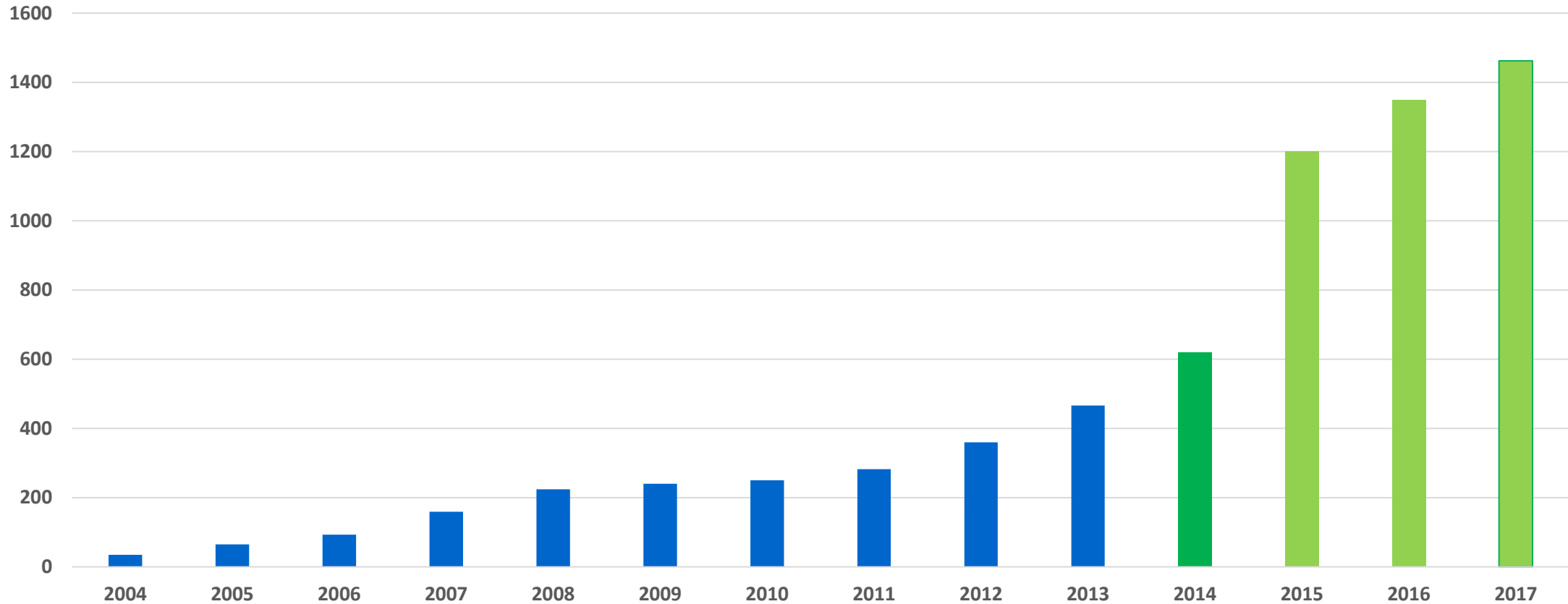
Implementation (2013-14)

- Senior Management & Clinical Governance Approval
- Set up Project Board and Cross-functional Project Team
- Consult with regulatory authority
- Implement change process through Quality Management System
- Communication with internal & external stakeholders (leaflets, newsletter)

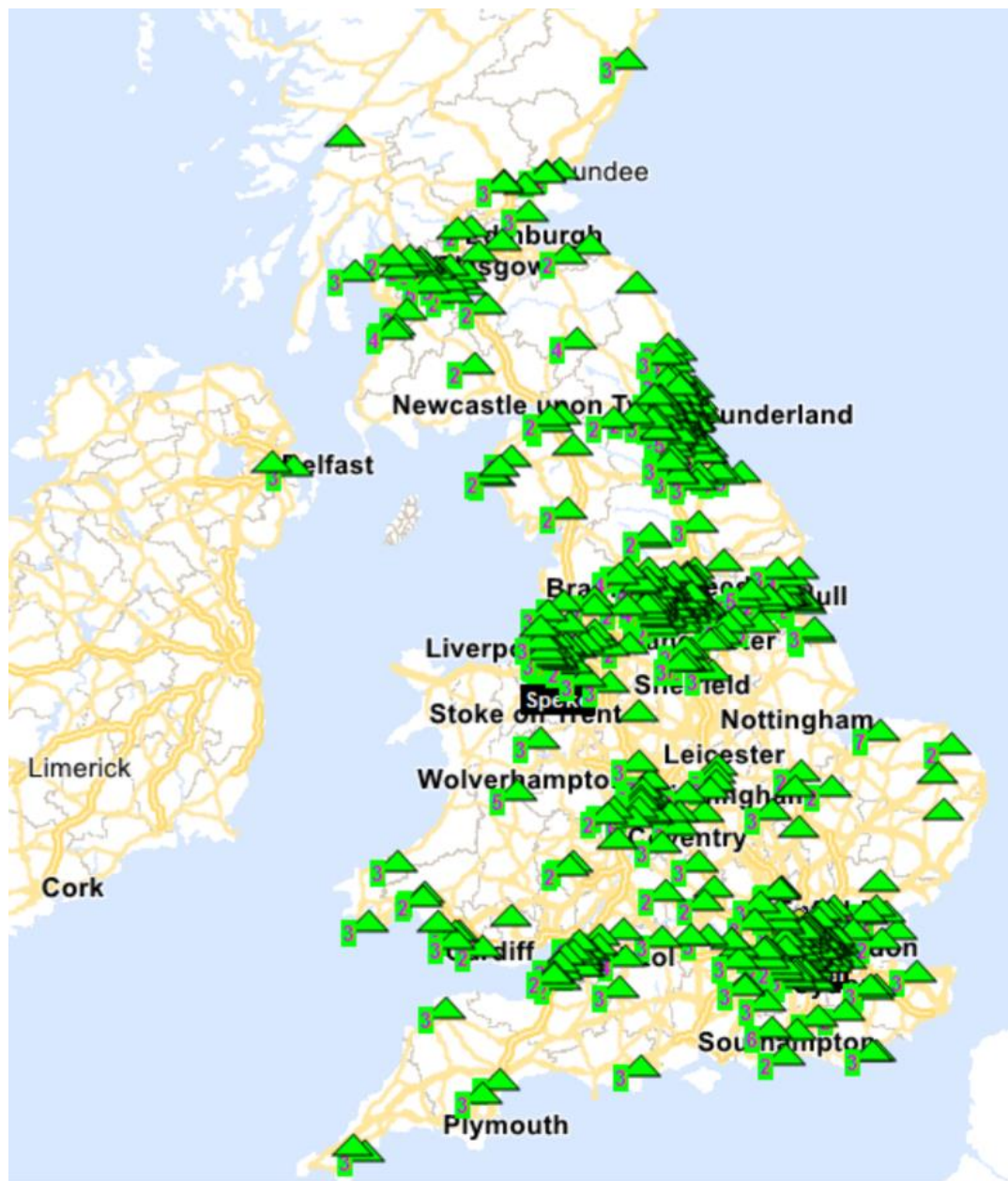
Monitoring (2014 →)

- Regular activity monitoring
- Clinician satisfaction survey
- Patient Reported Outcome Measures recording
- Clinical outcome monitoring

Improved Access to the Service



2004-2013 – Figures for AutoSE only
2014 – AutoSE for the whole year + AlloSE from July-December
2015-2017 – Figures for both AutoSE and AlloSE



Consultant Feedback....

Hello Akila

Hope you are fine. I just wanted to let you know that the allogenic blood worked like a charm and the epithelial defect has healed very well. Thanks for all your help

Kind regards

XXXXXX

Patient Feedback....

But Mr. [REDACTED] saw the answer and prescribed your miracle eye-drops. Their use has transformed my very existence. I hope so fervently that this spectacular service is not withdrawn by the N.H.S.

Congratulations to each one of you working in such an efficient way. And it's wonderful to be able to speak to the Team members, who are always eager to help.

Key Learning Points

**Careful
planning and
execution**

**Early stakeholder
involvement**

**Collaborative
leadership**

**Accurate
projections as to
how the service
will develop**

**Put the patient
at the centre**

**Patience and
perseverance**

**Celebrate
every success**

**Good and timely
communication,
both internal and
external**

**Resources to
support growth**

Strengths

Established QM systems for blood collection & processing

Ability to scale up to meet increased demand due to access to voluntary blood donors

Link between hospitals and blood services – easy access to service

Weaknesses

Active components not defined

No defined specification /standard manufacturing protocols

Varying regulatory approach

Labile – cold storage required

Lack of quality clinical data

Serum Eyedrops

Opportunities

International collaboration to share expertise (ABO/BEST)

Research and development

Collection of clinical outcome data

Changes in the regulatory framework

Threats

Changes in the regulatory framework impacting on ability to provide the service

Healthcare funding restrictions



Acknowledgements

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- Patients
- Blood donors

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Thank you!

