



BORN
LIFESAVER

A LIFESAVING YEAR

**ANTHONY
NOLAN**

saving the lives
of people with
blood cancer

NHS

Blood and Transplant



Welsh Blood Service

BACKGROUND

The second State of the Registry review has been written and produced by the Anthony Nolan and NHS Stem Cell Registry, demonstrating the work, achievements and impact of the UK's stem cell donor registers in 2014.

Anthony Nolan

Founded in 1974, Anthony Nolan was the world's first bone marrow registry. Four decades later, the charity has expanded its reach, saving the lives of people with blood cancer and blood disorders across the UK and beyond with the help of groundbreaking research, dedicated patient support, and a register of more than 500,000 truly remarkable volunteer donors.

Delete Blood Cancer UK/DKMS

Part of the international DKMS family of organisations, Delete Blood Cancer UK/DKMS launched in 2013 as a registered UK Donor Centre. They support patients and their families and raise awareness of blood cancer and the UK Registry, through family appeals, donor recruitment events and focused campaigns.

NHSBT

NHS Blood and Transplant (NHSBT) is dedicated to saving and improving lives through a wide range of services provided to the NHS. It manages the national voluntary donation system for blood, tissues, organs and stem cells, and is also responsible for optimising the safety and supply of blood, organs, stem cells and tissues and matching them to patients. The British Bone Marrow Registry is a division of NHS Blood and Transplant. It holds details of stem cell donors and cord blood donations from England, Scotland, North Wales and Northern Ireland.

Welsh Bone Marrow Donor Registry

Founded by the Welsh Blood Service in 1989 to provide high-quality donor typing, the Welsh Bone Marrow Donor Registry has recruited over 100,000 blood donors to its panel – incredible people who give hope and a second chance to patients throughout the world. The Registry is proud to be working with donors, patients, transplant physicians in Wales, and centres across the globe.

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'It was probably the most important thing I will ever do.'



Stuart's story

Stuart Brooks, 26, is a trainee lawyer from London who gave stem cells via bone marrow donation at The London Clinic in October 2014.

I joined the register 10 years ago while I was studying at the University of Warwick.

My aunt had told me about the shortage of mixed-race donors. My dad's from the UK and my mum's from Dominica; as a result, when there was a donor recruitment event at my university, I was keen to sign up.

Since men who have sex with men can't give blood until 12 months after their last sexual contact, I couldn't donate blood even though I wanted to help. It was refreshing to feel that by donating bone marrow I could make a valuable contribution.

Last year I received a call to say that I was a match for a patient; I spoke to my family, my partner and my

employer, and they were all very supportive. I never felt anxious or afraid. I just felt I had a responsibility and I wasn't going to back out.

I would do it all again; it was just a day of discomfort, really. In fact, I had the most pain from removing the tape from my hairy arms!

I did think about my recipient quite a bit in the days that followed. Whenever I was having a down day, I just thought of that person fighting for their life, and it put everything in perspective. I hope they're doing well and I regularly send out positive thoughts to them.

It was probably the most important thing I will ever do in my life. I did it because I wanted to help, and I need to feel that there are people out there who would do the same for me.

FOREWORD

In 2015, the science of stem cell transplantation continues to advance, offering a chance of life to more patients with blood cancers and other blood disorders than ever before.

The process itself is a remarkable one, testament to the ingenuity of modern medicine – a patient's damaged immune system is wiped out, and replaced by a healthy immune system grown from the 'building blocks' of a volunteer donor's healthy stem cells.

And with the number of potential donors on the Anthony Nolan and NHS Stem Cell Registry now standing at over a million, our enterprise is one that speaks to the informed humanity, generosity and kindness of so many people around the UK. That's something to be truly proud of.

We've seen a promising increase, too, in the quality of the registry make-up, as well as the quantity. Transplant centres have been shown to prefer younger donors, particularly men, which is why the recruitment of more potential donors under the age of 30 is such a vital task for the years ahead – and why our progress over the past twelve months is so encouraging.

But there's still more to be done. Patients from black, Asian and minority ethnic (BAME) backgrounds continue to have difficulty in finding a stem cell transplant, due to a disproportionate lack of available donors. This imbalance needs to be addressed; we need to work harder than ever to ensure that no patient's chances of life are limited by their heritage. Meanwhile, it remains the case that not every patient is cured by a transplant and the risk of disease relapse remains troublingly high. A priority for the future, therefore, must be the design and delivery of more effective transplant strategies through collaborative working between our Registry and major clinical centres.

The individual partners of the Registry all do incredible work, each contributing in their own way towards recruiting more donors and collecting more umbilical cord blood units, and I welcome this year's State of the Registry review as proof of their efforts.

This is a partnership that really does save lives, every day of the year – and in the years to come, I look forward to seeing it accomplish even more.

Professor Charles Craddock
Chairman,
UK Stem Cell Strategic Oversight Committee

INTRODUCTION: THE STATE OF THE REGISTRY IN 2015

It doesn't seem so long ago that we published our last State of the Registry review, the first annual record of a truly pioneering collaboration between the UK's partner organisations in stem cell provision.

But just twelve short months later, in 2015, we've already seen the transplant landscape begin to shift. As of 31 December last year, there were 1,022,329 potential stem cell donors on the Anthony Nolan and NHS Stem Cell Registry, an increase of 14.3% from the year before, and a significant milestone – the most potential donors ever in the UK.

Just as encouragingly, we've seen an increase in both the quality and the genetic variety of potential donors joining the registry: more people aged 16-30 and more young men, as well as more people from black, Asian, and ethnic minority (BAME) backgrounds.

Since transplant centres prefer younger male donors, and because many patients of minority heritage still find it difficult to find a genetic match, this is welcome progress towards our shared goal; a future in which every single person in need of a stem cell transplant can find one.

It's an incredible challenge, but our aligned UK registries – Anthony Nolan, the British Bone Marrow Registry (run by NHSBT), and the Welsh Bone Marrow Donor Registry will continue to work together towards it.

Our collaboration helps to enable a cheaper supply of transplants for the NHS, and a faster, more efficient search for matching donors.

There's much more yet to be done. We will not become complacent – not while some patients are still unable to find a lifesaving match, face unfair odds of survival based upon their ethnic background, or lack the support they so desperately need in the years after their transplant. Improving quality of life for patients post-transplant is every bit as important as finding the right donor.

Equally, we still lack a full understanding of what makes the most successful donor. Too many patients are at risk of relapse or complications once their transplant has taken place. Combining our donors' genetic information will help us gain a better grasp of the factors at stake, but more research is urgently needed.

And it's vital, too, that we can continue to invest in our cord blood programme in the years ahead, which is particularly important for patients from ethnic minority backgrounds who wouldn't otherwise find a transplant.

But whatever challenges are still to come, we will face them together, looking to save, and improve the quality of, more lives. This review serves not just as our record, but as our collective promise towards that goal.



Henny Braund

Henny Braund
Chief Executive,
Anthony Nolan



Ian Trenholm

Ian Trenholm
Chief Executive,
NHS Blood and Transplant



Cath O'Brien

Cath O'Brien
Director,
Welsh Blood Service

CASE STUDY

'I'm still recovering...
but things are still
on the right track.'



George's story

George Norton, 32, from London, had a stem cell transplant to treat acute lymphoblastic leukaemia in March 2014. He is recovering very well and has now returned to work.

I first developed leukaemia in 2005. For a few months I experienced leg pain, a sore shoulder and a headache; eventually I had a blood test which showed that I had glandular fever. It also showed that I was very anaemic but my iron levels were normal, so I was referred for more tests.

Monday was my appointment with the haematologist, and my father texted me to offer to come along. Of course, I'm so glad he did, as it suddenly all got very serious.

The haematologist brought us back into her room and told me she could see blast cells in my blood: I probably had some form of leukaemia. Kaboom!

I soon began what turned out to be over two years of chemotherapy and radiotherapy, which left me cancer-free and ready to get on with my life.

More than five and a half years after finishing treatment, however, my haematology consultant confirmed the relapse of the blood cancer. So after intensive chemotherapy and an innovative trial using antibodies, I underwent a stem cell transplant in March 2014 to try to stop the leukaemia from returning.

I'm still recovering (though it doesn't always look it), but things are still on the right track.

It's astonishing to think that it's only a year since I was putting my life in the stem cells of an incredibly generous anonymous donor – stem cells, it seems, that have done a pretty fantastic job.

George Norton, pictured with his wife, Mariacristina

'It's amazing to think that it could possibly save a life.'

Anne and Florence's story

Anne Bos, 30, from Brixton in South London, donated cord blood when her baby, Florence, was born on 21 January 2015.

I heard about the possibility of donating the cord blood very early on in my pregnancy – I think it was at my first midwife appointment.

It was the first time I'd heard about cord blood donation, as Florence is my first child.

I was given a leaflet about it and it seemed silly not to do it as it isn't intrusive.

I asked more about the process, and was happy to sign up before Florence's birth at King's College Hospital in January.

I have no recollection of anyone coming in to collect the cord blood – I was so absorbed in my new baby that I didn't notice. In fact, the most time-consuming thing was signing the consent form!

The midwife who collected the cord blood was very friendly and she came to say 'thank you' later, when I was on the recovery ward.

I'd absolutely do it again; I've told my friends about it and they're all really keen too.

It was so unobtrusive that I'd recommend it to anyone, and it's amazing to think that it could possibly save a life.

THE REGISTRY TODAY

This year's demographic data backs up the achievements of the Anthony Nolan and NHS Stem Cell Registry, and its goals for the future: more patients helped, more potential donors recruited, and a younger, more diverse database sought out by our partners.

In 2014, 396 transplants were facilitated for UK patients using UK stem cell donors. This is an 8% increase from the previous year, when 367 UK patients were helped by UK donors (itself a 7% increase from 2012). This steady growth from year to year is evidence that transplant centres are continuing to choose home-grown donors, and that the Registry is continuing to supply them.

Of these 396 donors, 65.5% were aged 16-30, and 77.5% were male, indicating that the Registry should continue to prioritise these demographics.

Of the 136,476 new potential donors made active in 2014:

- 63% were aged 16-30
- The most common age of joining was 19 years old
- 76% were from British, Irish, and Northern European backgrounds, and 24% were from minority ethnic backgrounds.

Meanwhile, 3,226 new umbilical cords were banked in 2014: 65% from British, Irish, and Northern European mums, and 35% from mums with minority ethnic heritage. 34 UK cord blood units were used in donations, making up 3% of the total stem cell provision for UK patients this year.

Currently, there are 1,022,329 potential donors listed on the Anthony Nolan and NHS Stem Cell Registry. We divide our age data into two categories: 16-30 and 31-60. Donors under the age of 30 are preferred by transplant centres, so their recruitment is measured as a key performance indicator each year.

As in 2013, our ethnicity data shows that the majority of potential donors come from British, Irish, or Northern

European backgrounds. While close to a quarter of potential donors are from minority ethnic backgrounds, there continues to be an inadequate supply of stem cells for minority patients that needs to be addressed.

The regional spread of the past year's recruitment roughly aligns to the Registry as a whole, with significant numbers of potential donors being signed up from London, Scotland, the North-West, and the Midlands, likely in part as a result of targeted patient appeals and associated press coverage.

Historically, potential donors have been tissue typed (HLA typed) to varying levels. A recent focus on the highest possible level of typing – using a combination of six HLA alleles – means that these potential donors now make up 15% of the total Registry, a significant increase from the previous year. Potential donors typed to the second-highest level (with a five-allele combination) come to 20%, meaning that more than a third of all those on the Registry are now typed to the highest standards.

During 2014, 2,074 searches were conducted for UK patients, resulting in a donation of bone marrow, peripheral blood stem cells (PBSC) or cord blood for 1,098 patients – or around 53% of the total.

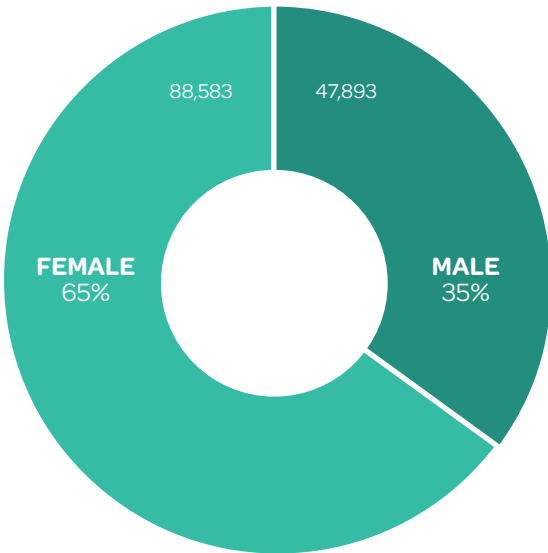
In conclusion, this data demonstrates the continued development of the Registry by recruiting more young people who have a much higher chance of being called upon to donate; however, it indicates that more work is required to target young males. Equally, the Registry must keep focusing on the recruitment of potential donors from minority ethnic backgrounds, and maintain a robust and well-provisioned cord collection programme to help address any gaps.

ALIGNED REGISTRY DEMOGRAPHICS

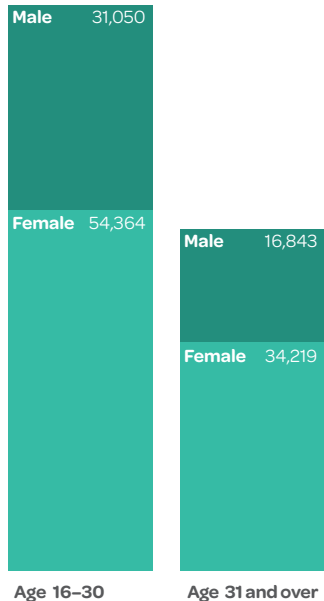
NEW DONORS MADE ACTIVE IN 2014

GENDER

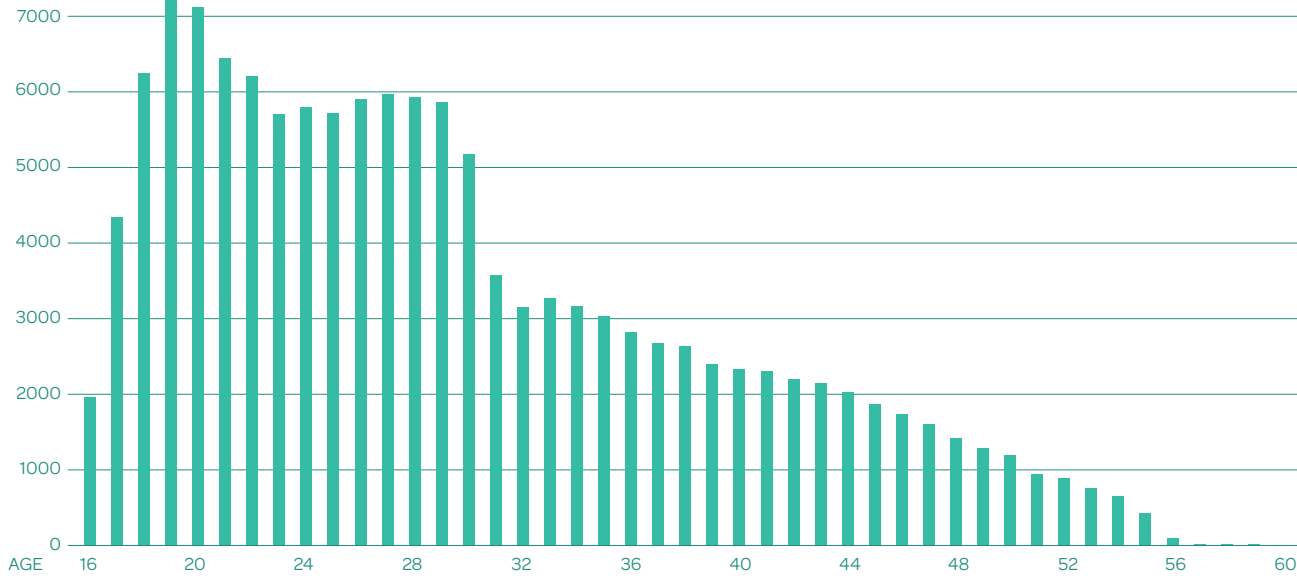
TOTAL 136,476



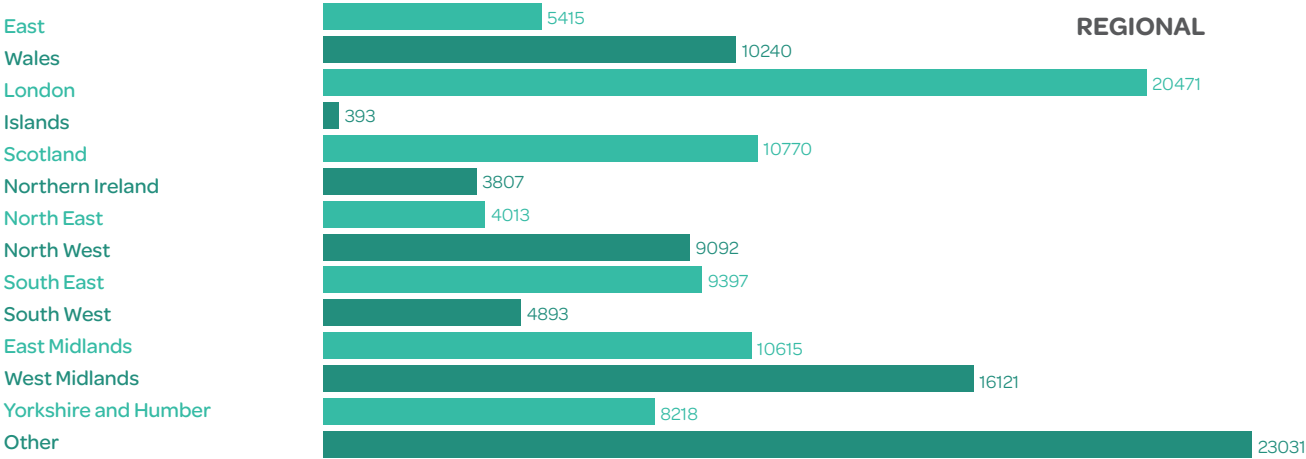
AGE & GENDER



AGE



REGIONAL

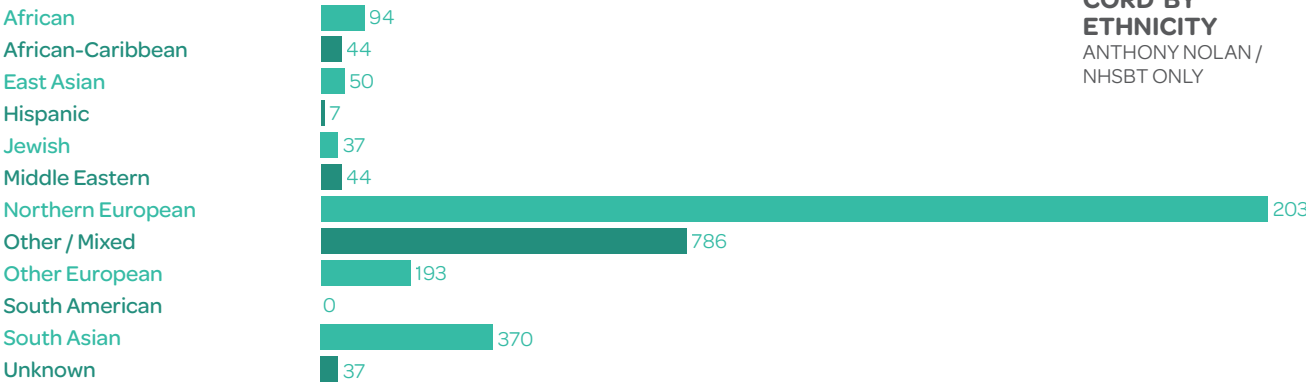


ETHNICITY



CORD BY ETHNICITY

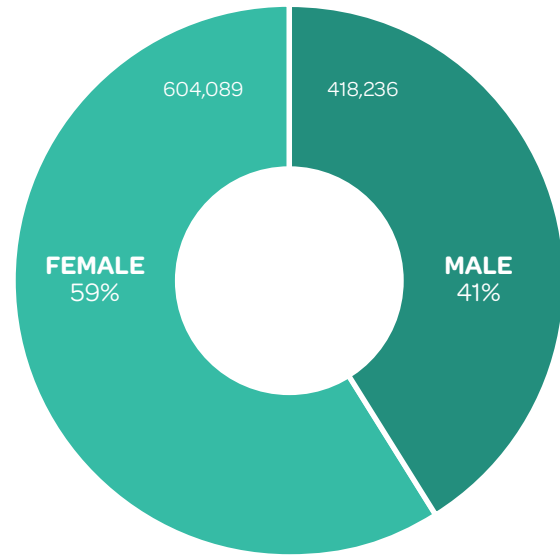
ANTHONY NOLAN / NHSBT ONLY



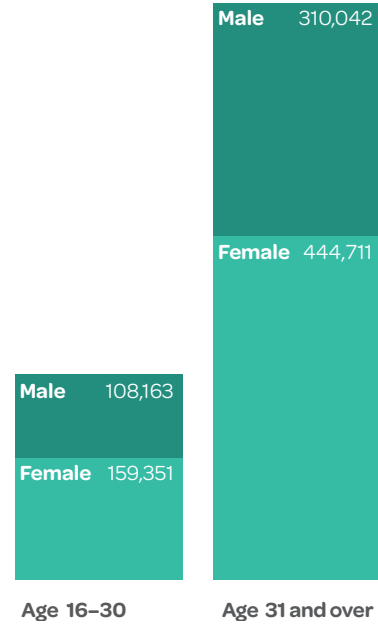
ALIGNED REGISTRY DEMOGRAPHICS

ALIGNED REGISTRY DEMOGRAPHICS: FIGURES AS OF 31/12/2014

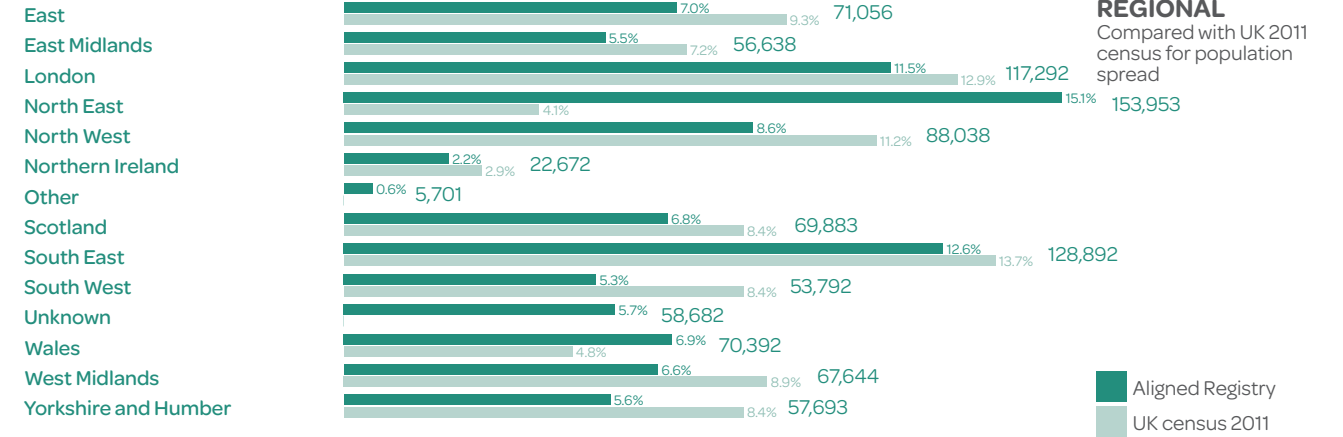
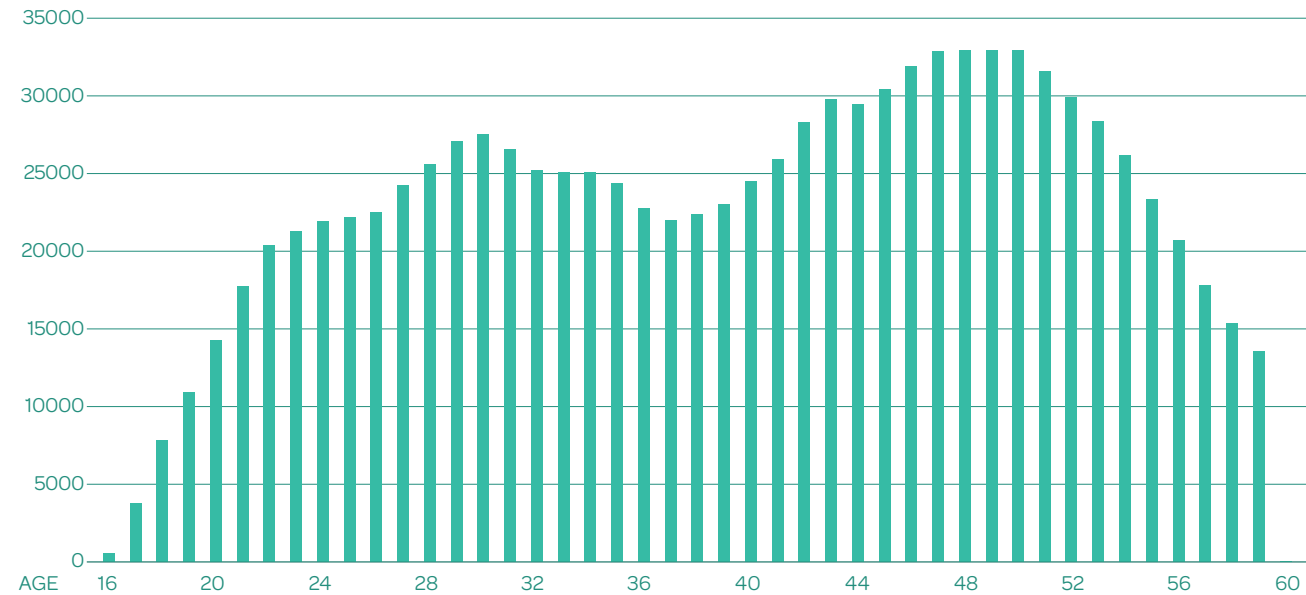
GENDER



AGE & GENDER



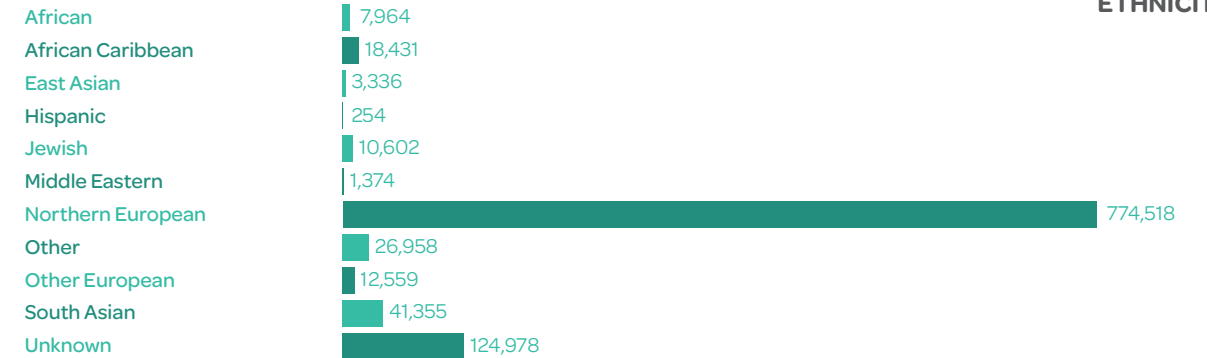
AGE



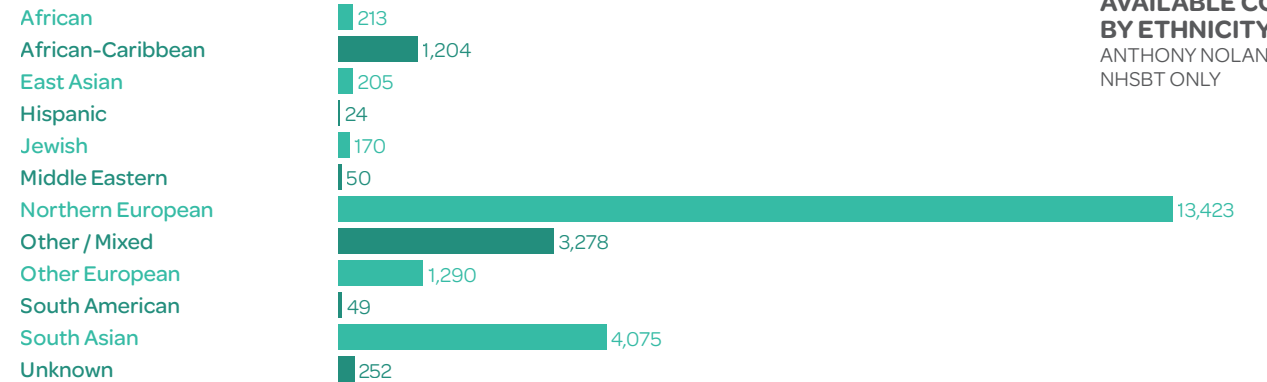
REGIONAL
Compared with UK 2011 census for population spread

Aligned Registry
UK census 2011

ETHNICITY



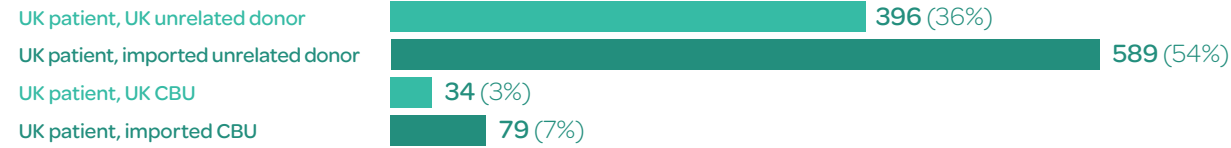
AVAILABLE CORD BY ETHNICITY
ANTHONY NOLAN / NHSBT ONLY



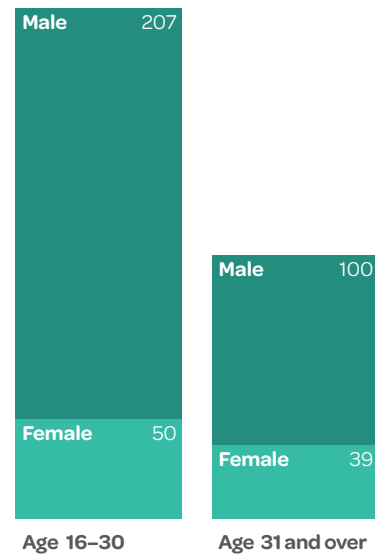
ALIGNED REGISTRY SUMMARY

PROVISIONS FOR UK PATIENTS (MARKET SHARE)

TOTAL 1,098



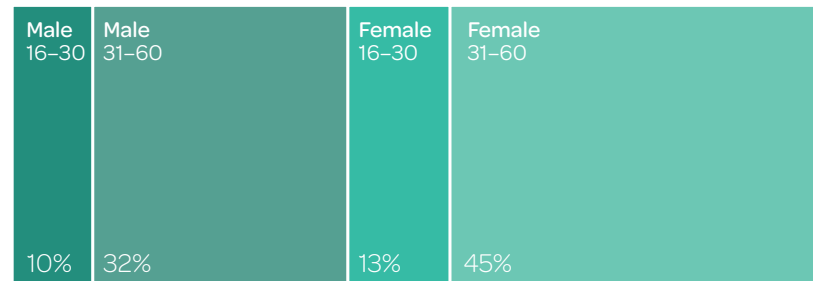
UK DONORS FOR UK PATIENTS 2014



DEMOGRAPHIC OF UK TO UK DONATIONS 2014

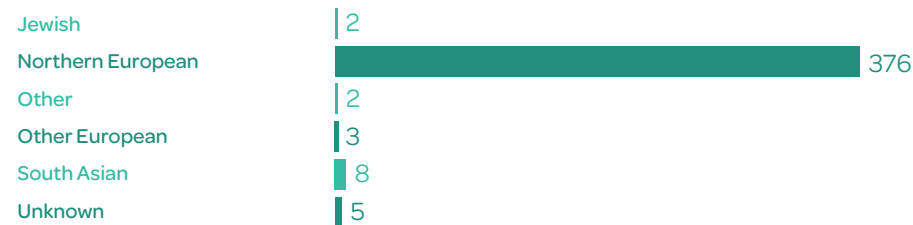


DEMOGRAPHIC OF ALIGNED UK REGISTER

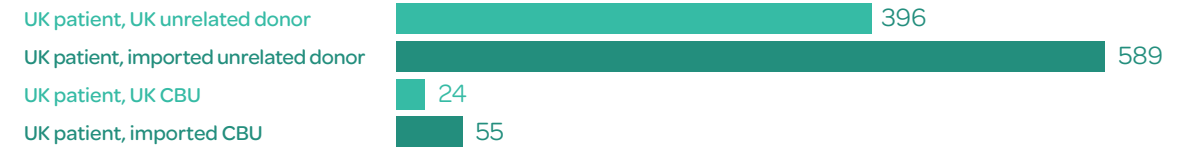


UK DONORS FOR UK PATIENTS 2014 BY ETHNICITY

TOTAL 396



UK PATIENTS HELPED 2014



UK DONORS FOR UK PATIENTS

SEARCH REQUESTS V MATCHES FOUND 2014



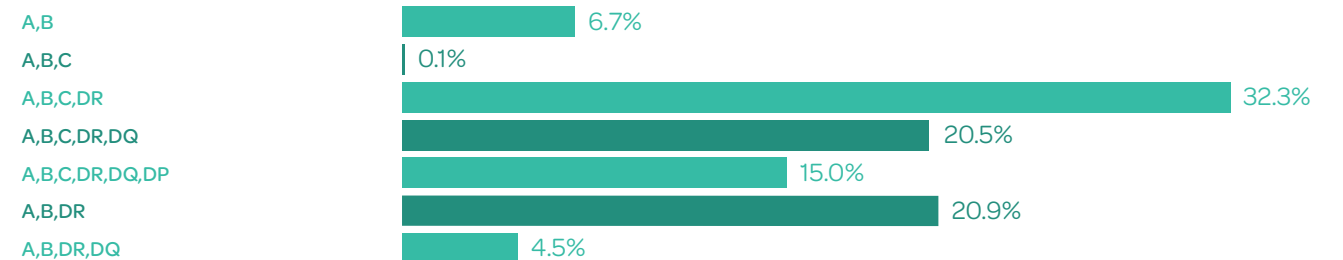
Note: around 50% of searches result in the patient receiving a donation from either an unrelated adult or cord blood unit. There is no correlation between the number of searches and donations in 2014.

DONORS SELECTED FOR STEM CELL DONATION

V REST OF REGISTER 2014



ALIGNED REGISTRY BY TYPING LEVEL



2010-2015 AND BEYOND

The UK's strategy for unrelated donor stem cell transplantation was first created in 2010 by the UK Stem Cell Strategic Forum – established at the request of the Minister of State for Public Health, and led by NHSBT, with the participation of key stakeholders, including Anthony Nolan and senior clinicians.

The Strategic Forum's report¹ made 20 recommendations to improve the provision of adult donor stem cells, to increase the UK's cord blood inventory, to advance clinical practice, and to standardise commissioning processes.

A vital step towards achieving these aims would be the alignment of the UK's three stem cell registries, in order to make provision simpler and more straightforward for UK transplant centres.

In 2011, the Forum's recommendations were endorsed by the Minister of State, and the UK Stem Cell Strategy Oversight Committee was established to coordinate and monitor implementation of the recommendations across the UK.

In 2014, the Oversight Committee updated the original recommendations.² This work has since been endorsed by the Minister for Life Sciences and the Minister for Public Health.

STREAMLINED STEM CELL PROVISION FOR UK TRANSPLANT CENTRES

In 2010, the UK had three stem cell donor registries, with a combined panel of more than 770,000 adult donors: Anthony Nolan, the British Bone Marrow Registry (BBMR), and the Welsh Bone Marrow Donor Registry (WBMDR).

In January 2012, to maximise efficiency and keep delivering improvements in stem cell provision, Anthony Nolan and the BBMR began operating as a single registry.

In September 2013, the WBMDR joined the Anthony Nolan and NHS Stem Cell Registry collaboration. This alignment of UK registries created a streamlined service for NHS transplant centres, which now searches just once before receiving a consolidated listing of all donors who've been potentially matched to individual patients.³

In 2013, Delete Blood Cancer began recruiting potential donors in the UK.

The progression of a patient's blood cancer or disorder while they wait for the identification of a suitable donor remains an important, and preventable, cause of treatment failure and death. The UK Stem Cell Strategic Forum advised that taking steps to increase donor reliability, and decreasing the time taken to select and test registry volunteers before donation, would lead to improved patient outcomes.

As a result, the Strategic Forum recommended the creation of a 'fit panel' of young and committed adult donors, HLA typed at high resolution, to provide the best matching information possible.

This strategy has exceeded all expectations; 'fit panel' donors are now eight times more likely to be selected compared to other registry volunteers.

Registry turnaround times and donor reliability have also improved. In 2014, 80% of samples for confirmatory typing were provided within 15 days of the request; this compares with just 35% in 2010.

IMPROVING EQUITY OF ACCESS TO STEM CELLS FOR BLACK, ASIAN AND MINORITY ETHNIC PATIENTS

HLA types are related to ethnicity, and donors from ethnic minorities are under-represented on adult registries. As a result, patients from ethnic minorities have been historically at a disadvantage in terms of unrelated donor stem cell transplantation.

In 2010, the Strategic Forum reported that around 90% of white Northern European patients would typically find a match, whereas the matching rates for BAME patients were estimated to be around 40% or lower.

The Strategic Forum recommended that increasing the UK's cord blood inventory to 50,000 donations offered a cost-effective means to address this inequity. Cord blood donations account for a significant proportion of transplants for this demographic; in one large prospective study,⁴ 21.3% of BAME patients received a cord blood transplant, compared to 3.8% of white Northern European patients.

In its 2014 report, the Oversight Committee noted that the chances of BAME patients receiving a stem cell transplant have substantially improved since, with more than 60% of patients able to find a well-matched donor.

Most of this improvement was the result of improved access to UK-sourced cord blood donations. In 2011, UK-sourced cord blood donations were accounting for less than 10% of all cord blood transplants in the UK; the rest were imported. By 2014, however, over 25% of UK cord blood demand was met by the UK inventory.⁵

A DUAL APPROACH TO IMPROVE EQUITY OF ACCESS AND SAVE MORE LIVES

In its 2014 report, the Oversight Committee reflected on the effectiveness of the UK's interlocking approach towards adult donor provision and cord blood banking. Since 2010, the number of patients in the UK able to receive a potentially lifesaving unrelated donor transplant has increased by over 30%.

Against the growing number of UK patients now eligible for a transplant, the Oversight Committee estimated that around 355 patients⁶ each year are still unable to find a well-matched donor at the right moment and in a timely way.

The strategy outlined by the Oversight Committee remains one of 'quality rather than quantity'. For adult donors, this involves expanding the UK's 'fit panel' of young donors to 150,000, ensuring that every donor is HLA typed to the highest resolution. For cord blood banking, this involves the establishment of a 50,000-donation inventory, banking only those donations with a 1% likelihood (or better) of being issued each year.

These complementary approaches will continue to strike the best balance between the need to achieve financial sustainability, and the need to improve patient outcomes.

HEALTH ECONOMICS

In its 2014 report, the Oversight Committee confirmed that a UK cord blood inventory of 50,000 donations is the best way to meet the needs of UK patients, and has the potential to save the NHS valuable funds.⁷ To meet this goal, the committee recommended that the expansion of the UK cord blood inventory should be achieved in two phases.

In phase one, continued investment over three years would achieve an inventory of 30,000 donations by 2018, expected to deliver a cost per additional quality-adjusted life year (QALY) of around £10,400.

In phase two, beyond 2018, the inventory would be financially sustainable (providing it achieved 1% utilisation per annum), generating the income needed to fund ongoing inventory growth of up to 50,000 donations.

The Oversight Committee also reported on the cost-effectiveness of expanding the UK's 'fit panel' to 150,000, suggesting a cost per additional QALY of around £8,500⁸ – again, significantly better than the threshold used to evaluate the effectiveness of NHS spending decisions.

2014 OVERSIGHT COMMITTEE RECOMMENDATIONS

The Oversight Committee made 12 recommendations. Those relevant to the Anthony Nolan and NHS Stem Cell Registry are summarised below:

- The Anthony Nolan and NHS Stem Cell Registry should continue to expand the UK’s ‘fit panel’ to 150,000 donors. There should be a continued emphasis on recruiting young, male, ethnically-diverse donors, predominantly aged between 16 and 30. Donors should be typed at high or allelic-level resolution.
- The Anthony Nolan and NHS Stem Cell Registry should continue to develop evidence-based strategies to further improve the availability of donors when they are approached for donation. Stem cell supply organisations should undertake or commission research to better understand donor behaviours in relation to stem cell donation.
- The Anthony Nolan and NHS Cord Blood Bank should establish an inventory of 30,000 cord blood donations by 2018. Beyond 2018, inventory growth to 50,000 donations should be funded via income generated through donation provision. The inventory’s efficiency should be improved by banking only those donations likely to contain a clinically useful dose of stem cells (equivalent to 14×10^8 total nucleated cells before processing); 30–50% of donations should include BAME parentage.
- Anthony Nolan and NHSBT should work with midwives and community groups with direct access to families, especially those from ethnic minorities, in order to raise awareness of the medical benefits of unrelated donor stem cell transplantation.

- UK stem cell supply organisations should continue to implement next-generation DNA sequencing platforms for unambiguous HLA typing of selected adult donors and cord blood donations.
- Anthony Nolan, NHSBT, WBMDR, The British Society of Blood and Marrow Transplantation (BSBMT) and the British Society for Histocompatibility and Immunogenetics (BSHI) should collaborate to improve the selection and provision of adult donor and cord blood stem cells, by gathering and sharing performance data, providing expert guidance, and supporting education.
- The Anthony Nolan and NHS Stem Cell Registry should continue to develop and implement IT platforms to facilitate the rapid import and export of stem cell donations.
- The resources and funding which currently support regenerative cell therapies for patients with bone marrow disorders should be fully exploited, with the aim of delivering innovative regenerative cell therapies for other disorders.

IN CONCLUSION

The last five years have seen the benefits of investment in stem cell transplantation, targeted recruitment of donors, and most recently the alignment of all the UK registers, resulting in improved patient outcomes.

While there is still much more to be done, the real and quantifiable progress in stem cell therapy since 2010 is demonstrably saving more lives, every year.

EXECUTIVE SUMMARY

In 2015, the momentous collaboration behind the Anthony Nolan and NHS Stem Cell Registry continues to save lives, both in the UK and overseas. Our combined efforts have resulted in faster matches, more cost-effective stem cell transplants, and a better quality of life for patients afterwards.

This report demonstrates the breadth and significance of our achievements. In a single year, we found 396 UK adult donors for UK patients, a notable increase from 2014. We also grew the Registry by 127,615 new potential donors; an impressive figure, particularly since we have maintained a focus on recruiting younger males, who are more likely to be chosen by transplant centres to donate, despite being harder to engage.

In 2015 and beyond, we look forward to improving on these results, working together to deliver better outcomes for patients, vital research into the science behind stem cell transplantation, and a more efficient service for the NHS.

A major priority for our work is addressing the difficulty faced by so many patients from ethnic minority backgrounds in finding a lifesaving transplant. We need to keep building the Registry, with a priority towards recruiting more donors with diverse heritage. Equally, we need to maintain our cord blood programme to fill the gaps, and ensure that nobody in need of a transplant dies without finding a suitable match.

To these ends, the investment of £3 million from the Department of Health in spring 2015 is warmly welcomed. This funding will allow us to carry out more high-resolution typing, particularly for donors from BAME backgrounds; it will also ensure that we can keep collecting and banking high-dose cord blood units, in line with the Oversight Committee’s recommendations.

We will also invest in research, in the hope of improving outcomes for patients once their transplants have taken place. While valuable progress has been made towards understanding the factors that make a transplant successful, too many recipients are still at risk of relapse or long-term complications. Finding a matching donor is only the first stage of a long journey – and we must support the patient all the way to a successful outcome.

New challenges await; but in the years to come, our groundbreaking partnership will continue to inform our decision-making, our science, and our strategy, resulting in better outcomes and a better quality of life for every patient in need of a stem cell transplant.

1. The Future of Unrelated Donor Transplantation in the UK. A Report from the UK Stem Cell Strategic Forum (2010).
 2. Unrelated Donor Stem Cell Transplantation in the UK. Effective, Affordable, Sustainable. UK Stem Cell Strategy Oversight Committee (November 2014)
 3. In February 2013, the German stem cell donor centre (Die Deutsche Knochenmarkspenderdatei; DKMS) started recruiting UK donors. These are listed on the Anthony Nolan and NHS Stem Cell Registry in addition to ZKRD.
 4. RN Lown (2013) Presentation to the American Society for Hematology.

5. Data from Anthony Nolan.
 6. In 2010, the Strategic Forum estimated unmet need to be around 440 patients per annum.
 7. We estimate that a 50,000 donation inventory will meet around 83% of unmet demand for optimally-matched stem cells in the UK.
 8. Based on costs provided by NHSBT.

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M1521

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