



Images: **Monsterful Photo**

# BLOOD, SWEAT AND TEARS

**Natasha Cowan** visits **NHS Blood and Transplant** to discover why quality and safety are intrinsically linked and how the quality team is developing a pioneering agile QMS





**On 26 September 2016** the NHS celebrated 70 years of blood donation and the birth of the National Blood Transfusion Service. Beginning with a mere 270,000 blood donors in 1946, the service now sees just under a million volunteers donate blood each year in England, helping to save and improve lives every day.

The birth of blood donation was the start of a national health journey that would evolve into NHS Blood and Transplant, a service that is crucial in supplying blood components to English hospitals on a day-to-day basis. However, the organisation is responsible for more than just the supply of blood. It sources and supplies tissues and stem cells across England and sources and allocates organs for patients across the UK, while also providing a diagnostic testing service for hospitals.

NHS Blood and Transplant plays a crucial role in regenerative medicine in the UK. As a contract manufacturer of small-scale GMP compliant cell therapy products, the organisation is leading the way with cutting-edge work on stem cell therapies.

Director of quality Ian Bateman describes NHS Blood and Transplant as a ‘biological manufacturer’ of a number of materials, including blood, tissues and stem cells. The service collects biological material from donors, which is tested and processed into a number of life-saving or life-enhancing products, and are then used to help cancer patients recover from chemotherapy and to treat serious burns.

“We work in a range of areas including transfusion, transplantation and regenerative medicine to save and improve the lives of patients,” Bateman tells *QW*. “One area we have done work in is cardiac tissue repair to help people who have experienced damage to heart tissue through, for example, a heart attack.

“We have also worked with collaborators to develop a knee bandage which is impregnated with autologous stem cells to assist cartilage repair, and developed decellularised tissue which is used to lower the risk of tissue rejection.”

**Through Zika and beyond**

One of the greatest risks for NHS Blood and Transplant is the danger of transmitting an infection from a donor to a patient and the quality management system is at the heart of minimising this

risk from both an operational and policy perspective.

The organisation is well respected for its high standards thanks to its stringent quality processes, which have been crucial in building professional and public confidence in the service, despite domestic and global epidemics such as the Ebola outbreak.

In 2015 the Zika virus was detected in Northern Brazil and quickly spread to 14 states across the country, making its way over the Columbian border to North



Image: Blood samples being sorted for testing



America. The mosquito-borne disease is spread through blood and is reported to cause birth defects such as microcephaly (where babies are born with an abnormally small head) and Guillian-Barre syndrome.

As the world began to panic at the prospect of a global epidemic, NHS Blood and Transplant had to act fast. The organisation implemented a 28-day blood donation deferral for potential donors who had travelled from the areas impacted by Zika and wanted to donate blood in England. This significantly reduced the risk of transmitting infection via blood donation.

“We have safety policies in place which dictate whether a person can give blood if they have travelled to certain countries,” explains Bateman. “We’re



taking precautions to ensure the safety of the blood supply. Blood is collected and processed within a closed system, which ensures that it’s not exposed to the environment from the time it’s donated to the time it’s transfused into a patient.”

**470ml**

NHS Blood and Transplant is facing a myriad of challenges. The organisation has to ensure its products are safe while minimising costs to the NHS (which currently has a £2bn deficit). In the past

10 years the service has improved safety measures and saved the health service around £70m a year by improving its efficiency and reducing the cost of red blood cells to the NHS. Now the organisation is delivering further improvements by using Lean and Six Sigma methodologies to develop an integrated supply chain approach and improve the donor journey.

Overall, the blood donation process takes no more than an hour. Volunteer donors are health screened and a single drop of blood is taken from their fingertip to check their iron levels. Next they are taken to a waiting area and once in the chair they donate 470ml of blood. The blood is then sent for testing and processing, where it is divided into components such as red blood cells, plasma and platelets. The components are often processed into specialist products such as cryoprecipitate (a frozen blood product prepared from plasma), or further screened to identify rare antibodies, helping to treat patients who react to certain blood donations.

The blood supply chain is complex, with numerous stakeholders ranging



from the donor to the medical staff, those working on the manufacturing floor and the patient receiving the products. Each part of the process requires robust quality assurance to ensure that products are safe.

Debbie Richards is head of continuous improvement at NHS Blood and Transplant. She tells *QW*: “One of the hardest things is trying to streamline the process to ensure it doesn’t impact adversely on someone else in the system by making it more wasteful or time consuming.

“Everyone working on the collection sessions during the blood donation wants to do the best job for their donor and patient but sometimes it’s about making those links across the value stream. Often the manufacturing team will request a particular blood type to use in specific products and it’s up to the blood donation teams to make sure that happens. We have to cultivate a real sense of understanding that there is a patient out there who needs one of our blood products quickly and if we don’t do things correctly this could mean that the blood can’t be used.”

To improve the process Richards needed to exhibit a combination of technical prowess and an understanding of the challenges the blood collection team was facing. She used Lean methodology and a Kaizan approach, including ‘rapid improvement events’ to improve the system.

Her team chose to employ ‘A3 methodology and thinking’, based on



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PDCA (plan, check, do, act), to improve the processes. Drawing a nine-box grid on an A3 piece of paper, they steered the blood collection team through the problem and then asked questions to determine the current situation, the context and what needed to change.

Crucially, Richards' team does not own the process and instead choose to act as facilitators ensuring that staff are thinking critically. For example by using the '7 ways' technique, which includes picture diagrams and Lego modeling, facilitators have helped NHS Blood and Transplant imagine the best possible outcome for different processes. Finally, her team carried out a gap analysis to determine how far they were from their goals.

"You aim to have everything done in a set period of time and have monthly reviews to check everything is on track,"

she says. "My team acts as 'the coach' but the process is owned by the business, so we have to make sure it can be sustained when we aren't there. The blood donation teams can look after it better than us because they work on the blood donation sessions every day."

#### Agile against the odds

The quality team, led by Bateman, are involved in the entire process – from the research and

development of regenerative medicines and the donation of blood, tissues and organs, to working with the licensed facilities and ensuring the right regulatory compliance and quality management systems are in place.

During the past 12 months Bateman's Quality Assurance team has worked with the organisation to redevelop and improve the quality management system, while



Images: (clockwise) blood being tested on automated equipment; processing platelets; director of quality Ian Bateman; and cold storage.



ensuring a safe and sufficient supply of blood, tissues and organs.

The organisation has embraced the concept of a scaled agile framework (SAFe) within the business transformation programme, which has challenged the current quality management system and regulatory understanding. The quality team worked with internal and external stakeholders to map and reconfigure the current quality management system to accommodate the new SAFe practices.

"This is a move from the previous waterfall approach, where there was a danger that by the time you've delivered results your stakeholder requirements have changed," Bateman explains. "The agile development approach is based on specifying and developing smaller chunks of requirements, so you have a better chance of delivering results rapidly and more efficiently."

During the research phase Bateman and his team searched for other organisations using a similar agile technique within a complex and highly regulated environment.

"We could not find anyone in a highly regulated industry with a significantly more developed process, making it difficult to benchmark and verify the effectiveness of our approach. We had to revisit several elements of the QMS such as user requirement specifications, change control and validation, to redesign them and ensure we could maintain compliance in using this new approach."

regular meetings to inform them of our progress and make sure what we're doing is compliant and safe from their perspective."

#### Understanding human error

Meanwhile, Fidelma Murphy, assistant director of quality and regulatory compliance worked with Richards' Continuous Improvement team to tackle the problem of human error – a crucial risk for NHS Blood and Transplant. Simply mislabeling a bag of blood could mean the difference between life and death for a patient.

Rather than fighting against human factors, the team embraced them and captured the potential for error in every process. The teams set out to identify the elements of their processes which were susceptible to human factors and redesign them to eradicate, where possible, the risk of human error. Murphy set up a

project team with the aim of learning as much as possible from other organisations and focused her efforts on speaking to experts in the field. She even built relationships with the National Air Traffic Services to understand how human error was accounted for in the airline industry.

Murphy explains: "National Air Traffic Services are using a tool called 'Day to Day Observations', which has been really effective in their hands. Staff are trained to design and use checklists to review their colleagues' practice in manufacturing and

diagnostics laboratories and over time they build up cumulative feedback on how well processes are being completed.

"They discovered that a high percentage of the time the staff are working really well. By concentrating on the positives they were able to illustrate that most of the processes were working really well but the areas

that weren't working could be improved by working collaboratively," she reveals.

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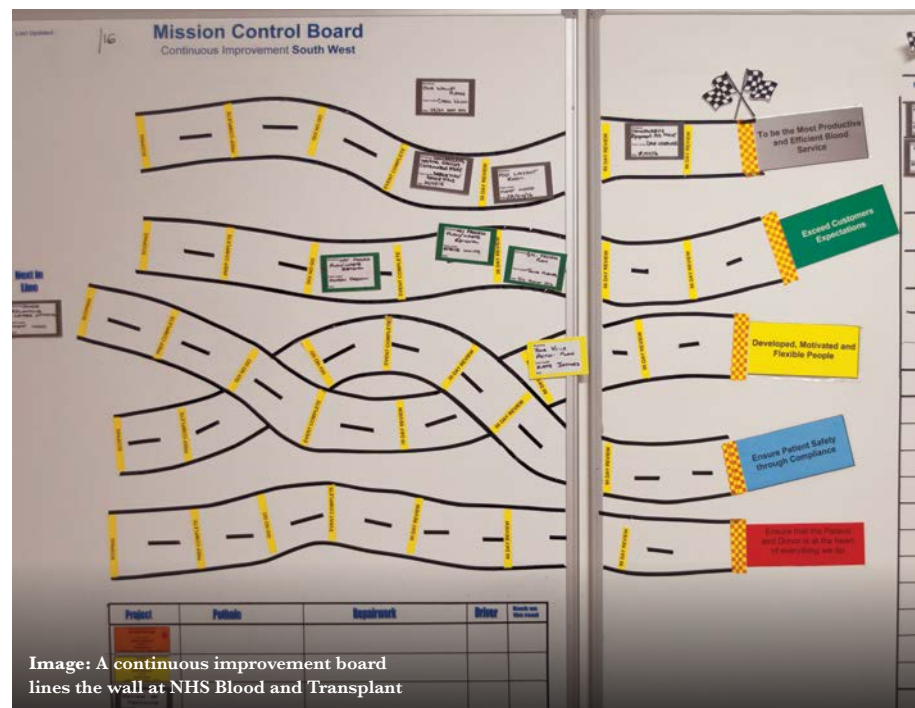
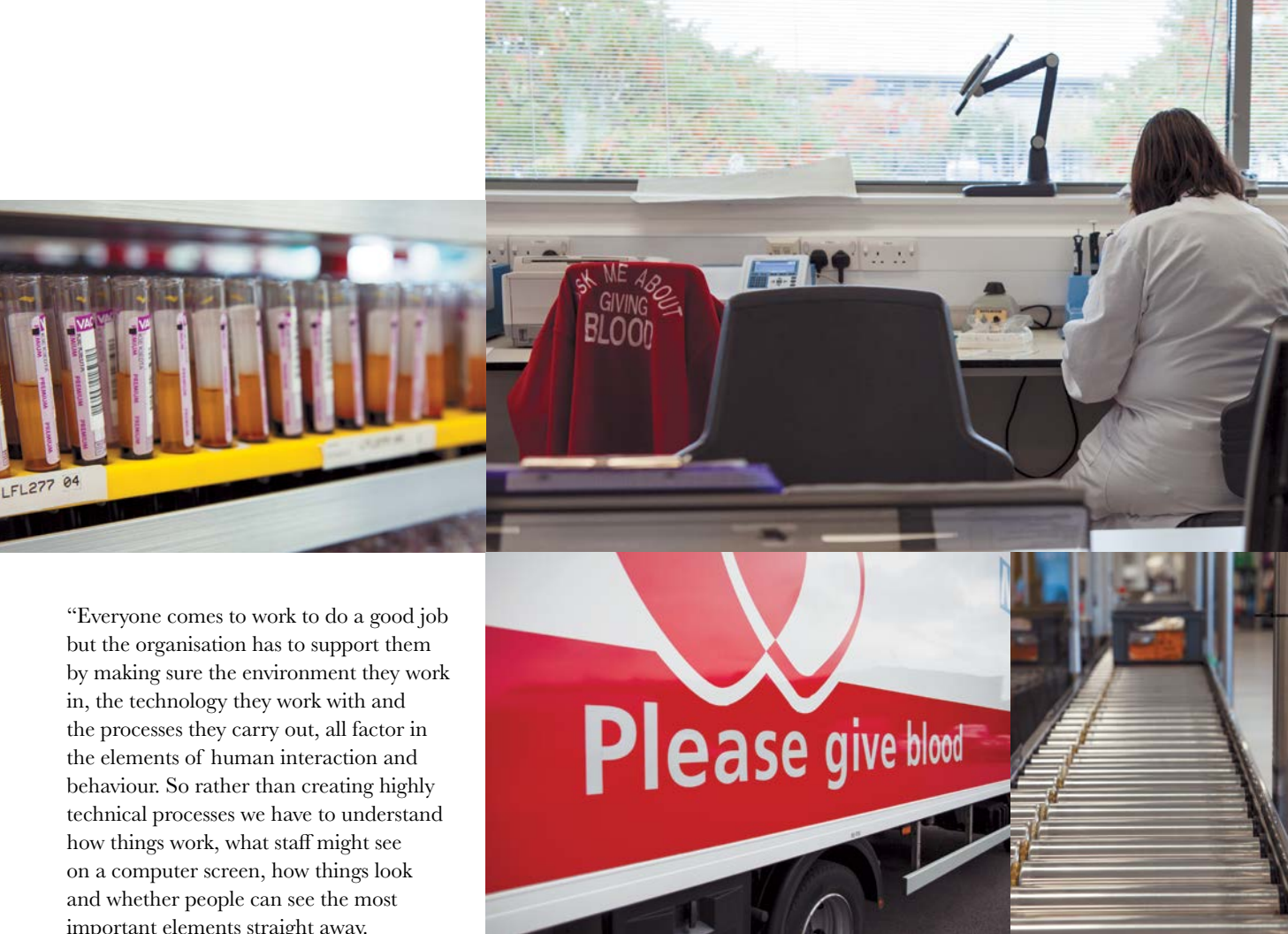


Image: A continuous improvement board lines the wall at NHS Blood and Transplant





“Everyone comes to work to do a good job but the organisation has to support them by making sure the environment they work in, the technology they work with and the processes they carry out, all factor in the elements of human interaction and behaviour. So rather than creating highly technical processes we have to understand how things work, what staff might see on a computer screen, how things look and whether people can see the most important elements straight away.

“It’s about accepting we are all human and we all have the potential to create error so we have to set up systems, processes and environments to make sure we minimise this risk as much as possible.”

Richards’ team began to reengineer the processes to establish where the human errors were likely to happen, from the way equipment is designed down to the nuances of a particular piece of kit.

“In the Blood Banks we looked at the labels – how the text was written, as well as making each label error-proof so people can’t put in the wrong information. We examine everything,” she explains. “We are reinvigorated training packages and standard operating procedures to help the people doing the job day in day out to make sure the processes are as error-free as possible. We wanted to make it as simple

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as possible so people could do their jobs to the best of their ability,” Richards says.

### Ahead of the game

The quality team is helping NHS Blood and Transplant to move beyond a mere focus on compliance, ensuring the QMS adds real value and assists the organisation in reaching its strategic objectives.

Now, the emphasis is on patient safety and delivering a robust continuous improvement culture, while ambitiously staying ahead of regulatory trends and pushing the boundaries in terms of regulatory compliance and continuous improvement. Murphy says: “In the past we would have focused on compliance

and maintaining our licenses, but we have moved past that. So what does that move

mean? It means we are working with the rest of the organisation to make sure we deliver safe blood, tissues and organs for the patients who need them, and at the best value for the NHS.

“It’s not just about us, the quality team, it’s about everyone in the organisation understanding the impact of their actions – we’re maintaining the safety of the product, that’s the crux of it. We’re trying to make sure colleagues understand their role, whether it’s the person cleaning the laboratory or the person releasing the blood. After all, everyone has a role in keeping the patient safe.” ■

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