NHS Blood and Transplant

NHS Blood and Transplant (NHSBT) Board
31 January 2019

Clinical Governance Report
01 October – 30 November 2018

1. Status – Official

2. Executive Summary

- There has been one new Serious Incident (SI) in Diagnostic and Therapeutic Services (DTS): QI10809 - Discrepancies in Blood Donors – The British Bone Marrow Registry Database (BBMR).
- A probable case of transfusion transmitted Hepatitis B Virus (HBV) infection has been reported to a hospital. The recipient, who had a pre-existing liver disease, received two units of red cells following an episode of bleeding and has sadly subsequently died from liver disease. We have been communicating with the hospital and have offered to meet the family if desired. The donor had an unusual form of HBV infection where a very low level of virus circulates (termed occult infection). No error was made by NHSBT, the virus was circulating at around 250 times lower than is usually detected. This transmission is our first case of HBV transmission since 2012 and the first case from an occult infection. The risk calculation currently is that HBV will be transmitted once in every 2M donations.
- There were no incidents reported to the Information Commissioner's Office (ICO) in this reporting period. Three previous reported incidents have now been closed by the ICO, with no regulatory action taken. One new incident has been reported to the ICO outside this reporting period and whilst we await official confirmation, the ICO have indicated that no action will be taken against NHSBT regarding this incident.
- A total of four clinical audit reports were approved within this reporting period.
- NHSBT is working with the Infected Blood Inquiry (IBI) to deliver 250 boxes of records to a London IBI location, with a review planned to commence on Monday 28 January, and expected to last 6-8 weeks. NHSBT are organising a rota to ensure we are present on site each day to answer any questions regarding the content of the boxes.
- In January, the Executive Team (ET) approved a recommendation to appoint an NHSBT Freedom to Speak up Guardian to supplement existing whistleblowing arrangements.

3. Action Requested

The Board is asked to note the contents of the paper.

4. Serious Incidents (SI)

There has been one new SI in this reporting period in DTS: QI10809 - Discrepancies in Blood Donors – The BBMR. A donor wrote to NHSBT in September to check their details on the BBMR. The donor believed they had joined in 1999 and was checking her details were up to date as she tried to register as a 17yr old blood donor. The donor was informed they were not on the BBMR. The donor expressed concern that other donors may be similarly affected. The donor's daughter is awaiting a stem cell

transplant. The donor wrote to the Department of Health and Social Care (DHSC) expressing concern we may have lost the donor's data and that of other donors, due to IT issues. This is not the case, however at the time NHSBT did not communicate clearly with her about the need for a further sample and that she should register once she reached 18yrs of age. The RCA was that she did not have her HLA type done although a sample was received in the laboratory. The reason for this is not clear and there were a number of contributory factors identified, including our communication with the donor. The final report is being written. We have apologised to the donor who has accepted this and have also communicated with the DHSC.

5. Risk

There are currently thirteen risks recorded within Pentana at a divisional risk level, which have the primary risk impact area recorded as clinical. This is a decrease of two from the previous report. There is currently one high scoring risk (=/>15), an increase of one from the last report. ODT-003: there is a risk that ODT is unable to facilitate organ donation and transplantation caused by peak activity, risk averse behaviours, and or resource constraints, resulting in lower levels of transplantation. This risk currently scores 15 (5x3) and has been reviewed due to the risk of an EU Exit without a deal.

6. Complaints, and compliments

Within Organ Donation and Transplantation (ODT) a total of 27 compliments and 4 complaints were received in this reporting period, three of which were clinical and one non-clinical.

In this reporting period a total of 82 complaints were raised relating to DTS and 89 raised relating to Manufacturing and Logistics (M&L) which were comparable with the numbers in the last reporting period.

Please see the appendix for further details of complaints and compliments in each of the operational directorates.

7. Blood Supply (BS)

Five Serious Adverse Events of Donation (SAEDs) were reported in October and one in November. Three of the SAEDs related to needle insertion, one was a fracture, one related to a hospital admission following a delayed faint, and one event resulted in the donor attending A&E following a citrate reaction during donation.

A case of HBV infection in a recipient has been investigated and concluded to be a probable Transfusion Transmitted Infection (TTI). A 78-year-old patient with pre-existing liver disease alongside other medical conditions, died from liver failure. In their last illness they were found to also have evidence of an HBV infection. Their only risk factor was two transfusions received within the previous year, which had been given following an episode of bleeding. Both donors were investigated, and one was found to have an unusual form of HBV with very low level of circulating virus and an absence of the usual markers of disease. This was only identified following a ten-fold concentration of the donor's blood and testing with a singleton test. Public Health England (PHE) were unable to perform confirmatory testing with their assays nor to

genotype the donor virus. The imputability was defined as 'probable' due to the single risk factor in the recipient, the genotype of the recipient viral DNA being most common in the geographical origin of the donor and the detection of viral DNA at very low levels in a donor of a product received by the recipient. This will be reported to SHOT/SABRE by the hospital. We have communicated with the hospital and offered to speak to the family should they wish to do so. No errors were made in this case; however, we will be looking at our processes to see if there are any changes that should be recommended to testing policy.

Blood Donations (BD) Colleagues have focused their efforts on reducing the number of incidents where Hb screening is missed on session. There have been no missed Hb screening incidents in the last three months.

8. Diagnostic and Therapeutic Services (DTS)

Eleven events were reportable to the Human Tissue Authority (HTA) as Serious Adverse Events and Reactions (SAEARs). There was no evidence of any errors by NHSBT resulting in harm to patients. Nine of the events were in Cellular and Molecular Therapies (CMT); eight were positive results of microbiology testing on donations collected with no obvious pattern to suggest a systematic problem. There was one graft failure which is within the expected rate for such events. Two events were in Tissue and Eye Service (TES) and related to a history of possible herpes infection of the eye. The detail was in the GP record from 12 years previous and was not identified prior to issue of the corneas but was spotted at routine follow up. A fungal infection in a corneal graft following implantation was reported to NHSBT.

9. Organ Donation and Transplantation (ODT)

The British Medical Association's (BMA) ethics committee have provided ODT with a comprehensive report in relation to organ retrieval from pregnant females. ODT will write to DHSC explaining NHSBT intend to adopt the BMA's advice and to request endorsement to adopt the guidance and put a policy in place to operationalise.

10. Information Governance (IG)

The Data Security and Protection Toolkit (DSPT) requirements have been aligned to the General Data Protection Regulations (GDPR), as part of continued planning for compliance by March 2019. The DHSC requested all Arm's Length Bodies (ALB) submit an interim compliance update by 31 December 2018: this was submitted in-line with the request.

There were no incidents reported to the ICO in this reporting period. Three previous reported incidents have now been closed by the ICO, with no regulatory action taken. One new incident in BD has been reported to the ICO outside this reporting period. On the 8 January BD received a complaint from a suspended blood donor, detailing an incident in which a Donor Carer Administrator (DCA) had disclosed, as part of a workplace blood donation session booking, private medical details about the complainant. The complainant was very distressed by this disclosure. NHSBT has apologised to the complainant and undertaken an RCA and as referred to earlier, has reported the incident to the ICO. The ICO have indicated that no further action will be taken and that NHSBT has responded to the incident appropriately. We do however, await official confirmation of this.

11. Clinical Audit

The 2018/19 clinical audit annual programme included fifteen audits which were scheduled to be completed and report within 2018/19. Of those fifteen, nine have now reported and a further three are on track to be completed and report within 2018/19. The previous report outlined two DTS audits which will now report in 2019/2; this was approved at October DTS CARE. A further audit in DTS will now report in 2019/20; an audit of sample acceptance and rejection in Red Cell Immunohaemotology (RCI) has been replaced by an audit of the impact of new drugs on pre-transfusion testing. This will now report in 2019/20, and this programme change was approved at December DTS CARE.

A total of four clinical audit reports were approved within this reporting period, none of which had any high-risk recommendations:

- DTS AUD3210: Re-audit of discrepancies in Histocompatibility and Immunogenetics (H&I). Reporting to ODT.
- BS AUD3738: Confidentiality on Mobile Sessions Re-Audit.
- DTS AUD2843: Audit of sample transfer/receipt processes.
- AUD3454: Audit of Time to Treat Thrombotic Thrombocytopenic Purpura (TTP) Referrals for Therapeutic Apheresis.

12. Research update

CRYOSTAT – 2 is a multi-centre, Randomised Controlled Trial evaluating the effects of early high-dose cryoprecipitate in adult patients with major trauma haemorrhage. In this reporting period there has been a further serious breach of protocol following the previous reported breach. A participant was treated with Factor VIII rather than cryoprecipitate. This was due to an issuing error by the transfusion laboratory. Recruitment was temporarily halted and commenced again January 2019.

13. Infected Blood Inquiry (IBI)

NHSBT has recently confirmed to the IBI team that they will be responsible for the Serious Hazards of Transfusion (SHOT) Team. Rule 9 Requests have now been received for information held by both SHOT and for the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) and to review around 2500 boxes from Iron Mountain (IM). We have been requested to deliver an initial 250 boxes, 86 of which are from the AR archive to an IBI location in London, with the review of the boxes planned to commence Monday 28th January. It is expected this work will take approx. 6-8 weeks and we are devising a rota to enable NHSBT to have someone present each day to answer any questions the IBI team may have regarding the content of the boxes.

A visit for NHSBT external legal teams to Filton has been held and a date in February or March is being set up for the IBI team to visit Filton. The format for a day for infected and affected people is still being explored. We would like to publish this prior to the hearings commencing in April 2019.

The Heritage Database work is now progressing. In November ET it was approved that NHSBT will commission IM to conduct a full box review of the 14,797 unallocated boxes. The review has now been scheduled to run from January to March 2019, and we are currently working with IM to commence the review.

14. Freedom to Speak Up Guardian (FTSU)

The appointment of a FTSU Guardian was a recommendation made by Sir Robert Francis following his review of how concerns are managed within the NHS. This recommendation was accepted, in principle, by the Department of Health, 2015, and the 2016/17 NHS Contract was amended to include the role.

NHSBT has not yet introduced this position within the organisation. A paper, which included detail of the FTSU Guardian role, was submitted to the September Executive ET in 2017, and a decision made that this was not required in addition to NHSBT's whistleblowing team and arrangements.

The FTSU Guardian role supports employees who wish to raise a concern. The role supports NHSBT's commitment to a culture of safety and openness. The role also contributes towards demonstrating cultures and commitment during Care Quality Commission (CQC) inspections.

It is felt that it is becoming increasingly important that NHSBT appoints a FTSU Guardian to ensure we remain in-line with other NHS organisations and demonstrate the organisation's commitment to a culture of openness and transparency. A failure to listen to colleagues' concerns was also highlighted by a recent review of the Core Systems Modernisation programme.

January ET approved a recommendation to appoint a FTSU Guardian within NHSBT. Actions will be now taken to implement this decision.

13. Safety Policy Matters

The donor selection guidelines for the human T-lymphotropic virus (HTLV) have been changed to provide discretionary testing for repeat donors who have had sexual contact with a person with HTLV. The operational steps required to implement this are being developed.

The UK Forum approved funding for a piece of work by the joint NHSBT/Public Health England (PHE) epidemiology team on individualised risk assessments of donors. As part of this we will conduct a donor survey in 2019, with around 14,000 donors expected to participate. Donor and patient focus groups are being set up and co-ordinated through the University of Nottingham.

Authors
Louise Cheung, Assistant Director,
Governance and Clinical Effectiveness

Gary Mallinson, Safety Coordinator
January 2019

Responsible Director
Dr Gail Miflin
Medical and Research Director

Appendix One: Complaints

There was a request at the Board for further detail regarding operational complaints to understand better the narrative of the complaints in each area and not just the numbers, and the different routes by which they come into NHSBT.

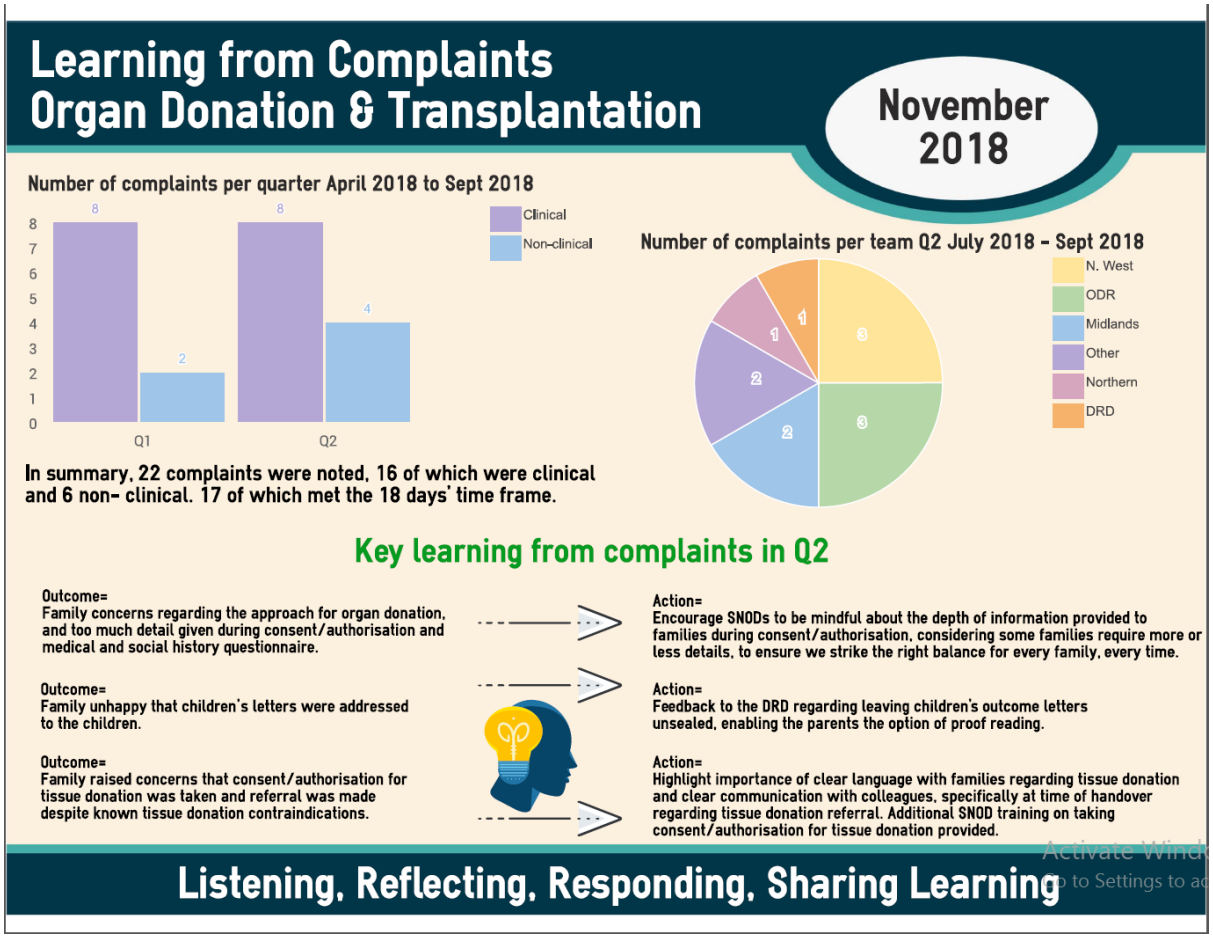
Outlined below is the information regarding the current complaint management processes in each area.

1. **ODT:**

Within ODT all complaints are reported centrally, and they can be reported into NHSBT via several different routes, which include; Contact with the caring Hospital/Health Board, direct to the CEO/Director, Service evaluation survey, complaints and compliments email, direct to the organ donation services team, National Call Centre, and the enquiries email. ODT review and discuss complaints bi-monthly at each ODT CARE. Complaints are logged and managed as quality incidents.

In addition, ODT undertake quarterly reviews of complaints and produce and circulate a quarterly infographic, to share data, actions and key learning from complaints across the directorate.

Below is an infographic of the complaints review of data from Q1 and Q2.

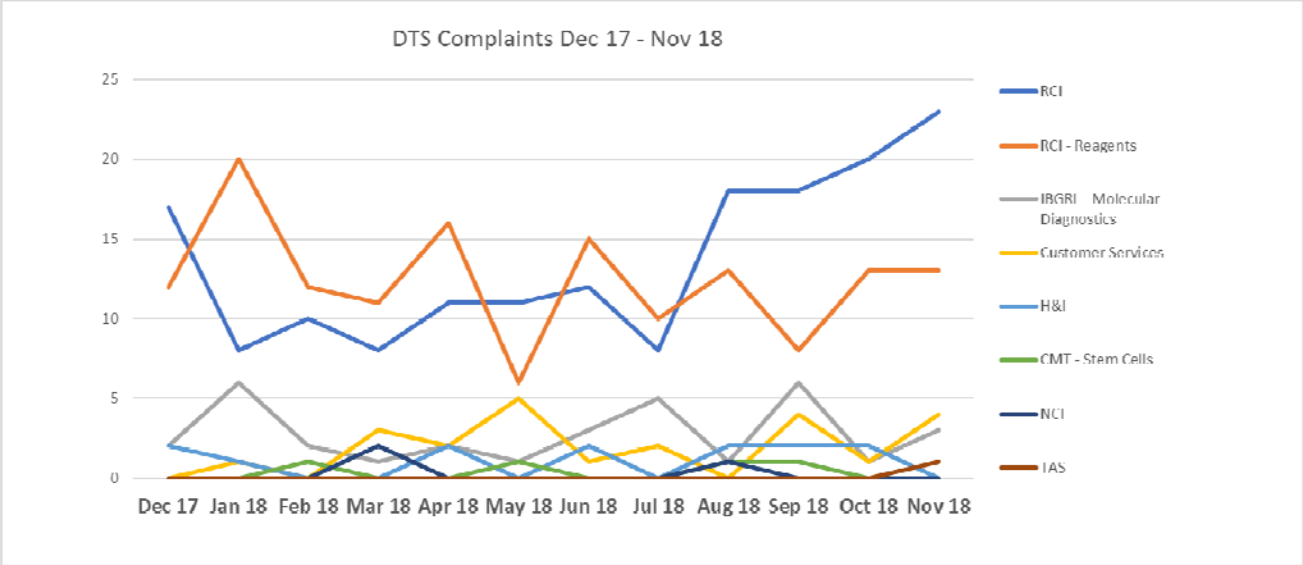


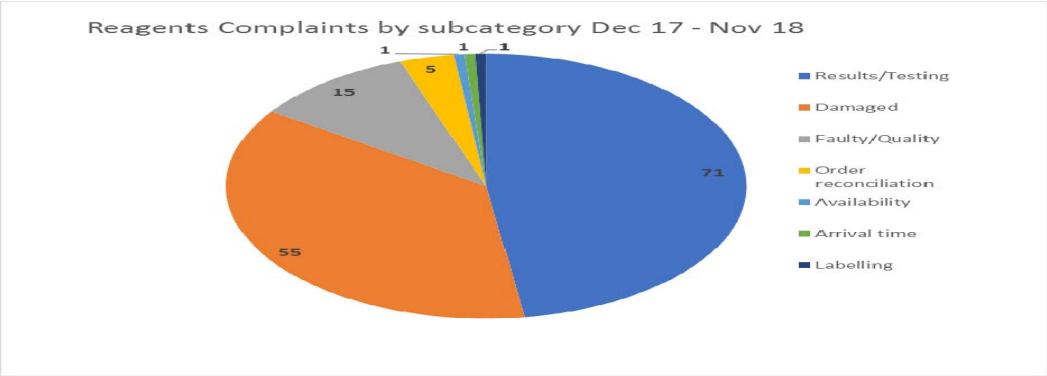
2. DTS complaints

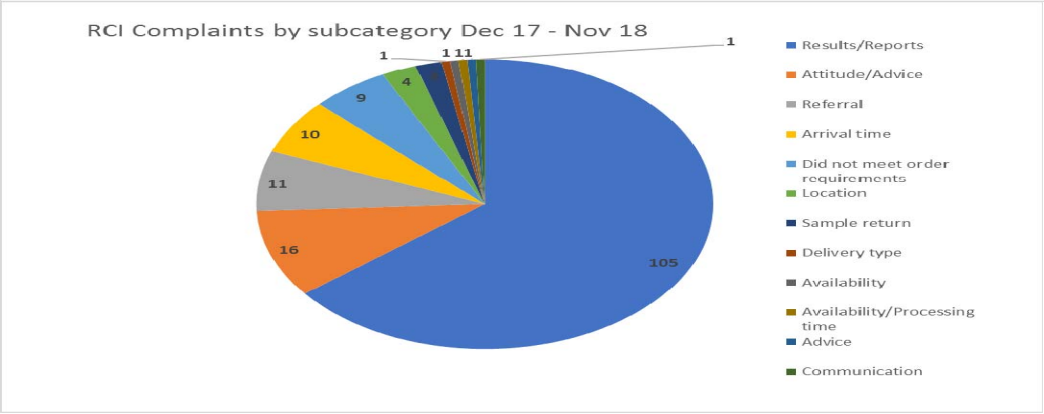
Hospital customer services collate the complaints coming into NHSBT regarding DTS, these are almost exclusively from hospitals and may relate to a complaint in DTS or, indeed, in M&L if related to a blood product. The DTS complaints lead regularly reports these to both the M&L and DTS SMTs. Complaints are also discussed and reported through the DTS CARE route including to CARE. Complaints are logged and managed on our Quality Management System.

Outlined below is some further detail regarding the complaints received within this reporting period (1 October – 30 November), that relate to DTS. This provides some further context to the services in which complaints are received and the patient impact of some of those complaints. A total of 82 complaints relating to DTS were recorded within this reporting period. The complaints received broken down by DTS function are as follows:

- 42 RCI; 3 resulting in delayed transfusions, 1 requiring the patient to be sent home and 2 led to patients needing to be re-bled.
- 26 Reagents
- 5 Hospital Customer Service
- 4 H&I
- 4 International Blood Group Reference Laboratory (IBGRL)
- 1 TAS







Outlined below is further detail regarding patient impact of the DTS complaints:

Department	Patient Impact	Cause	Resolution
RCI Colindale (INC77049 MAJ)	Delayed transfusion/Treatment	Delay in supply due to high work load out of hours in RCI. Hospital not informed of delay. Patient received 1 unit less than planned due to delay. No clinical impact reported. Linked to RPT23411, INC77048, INC77050, INC77051.	Better working patterns currently under consultation with staff side. Being managed under the NHSBT HR Change policy
RCI Colindale (INC77051 COM)	Delayed transfusion/Treatment	Delay in supply. Occurred on same day as above complaint.	As above.
RCI Colindale (INC77129 COM)	Delayed transfusion/Treatment	Based on antibody results provided the hospital agreed to cross-match in house. This decision was not shared between hospital staff leading them to believe RCI were cross-matching.	Delay due to hospital internal error.
RCI Colindale (INC76942 OTH)	Patient Re-bled	Sample returned to hospital in error. Multiple boxes/samples received. One box not checked, sample missed.	All staff reminded of process.
RCI Liverpool (INC77089 OTH)	Patient Re-bled	Multiple GDP failures across RCI, H/S and Transport lead to sample being misplaced. Sample finally found in fridge that was out of use.	Cross departmental CAPA and process review on-going.
RCI Liverpool (INC77092 MAJ)	Patient sent home.	3 units requested, 2 prepared. Decision made to hold back 2 units whilst 3rd prepared. Resulted in delay to supply.	CAPA on-going

RCI Tooting (INC77041 OTH)	Unsuitable units received	Incorrect d.o.b used. Hospital relabelled in house. 3 labelling discrepancies found on sample the d.o.b was unfortunately missed.	Discussed with member of staff.
RCI Colindale (INC77091 MAJ)	Unsuitable units received for	Verbal result given to hospital as Anti-D plus non-specific and advised to transfuse 2 x D-C-E-K- units. Hospital issued units. Later hospital informed patient had anti-Jk^a. Units recalled/not transfused as both Jk^a+.	CAPA on-going. (Reported to Sabre:2018/011/002/HV1/003)

3. Blood Supply:

Complaints about Blood Donation come into the organisation in a wide variety of ways. They may come direct from donors on session, through the National Call Centre, by email or letters to Customer Services or other, particularly senior, members of the organisation or via MPs etc. Because of the numbers of complaints these are logged and managed on our Clientele system. If complaints relate to a serious adverse event or error in processes they are also dual logged on our QMS. Because with both of these systems there is no link to the donor record in Pulse where it is important that colleagues can have site of a letter sent or knowledge of the complaint is it common for the clinical support teams to also reference the complaint and append the letter to the medical history notes of Pulse.

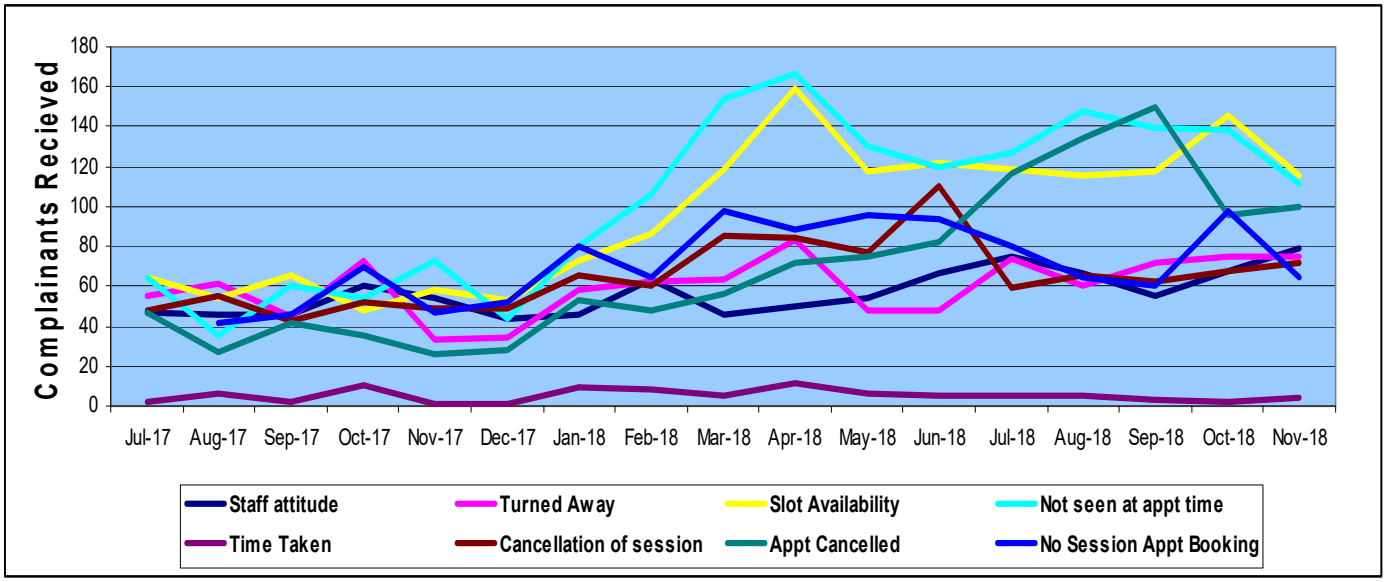
Blood Supply (BSCARE) provides clinical governance review across both BD and M&L directorates. The review of complaints and compliments across BS is currently managed through the operational teams, as follows:

Blood Donation:

Complaints and compliments are reviewed through two main pathways:

1. Complaints relating to donation (and clinical issues) are reviewed by the BD Regional CARE meetings. Significant issues are referred on to BSCARE for further discussion and are reported in the BSCARE minutes and our report to CARE. Complaints requiring a change of process or increased monitoring or analysis of a safety aspect of care are managed through the QMS sometimes as an NQI usually by a team of nurses, clinicians and lead QA specialist.
2. A review of all complaints relating to BD is also produced for the BD SMT by the head of Donor Services monthly and is reviewed by the operational Leadership Team. Actions are determined on the basis of analysis of complaint types (see below).

The complaint Subcategory Analysis is reported below (Top Subcategories)



December BSCARE discussed and made recommendations around a specific issue relating to access to Blood donation for a hearing-impaired donor as a key clinical complaint.

Manufacturing and Logistics:

Complaints relating to M&L are collated through DTS Customer Services as described about and are reviewed by the M&L Regional Operational Leadership Teams and by the Senior Management Teams.

Those complaints that relate to significant clinical issues are reported to BSCARE for further discussion and are reported in the BSCARE minutes and the BSCARE report to NHSBT CARE.

Between April – December 2018 M&L received 443 complaints in total (via Customer Services) 51 of which were classed as majors. The categories of complaints relate to delivery (226), to components (177) and service (40). Across all categories there was potential or actual patient impact in 259 cases.

Future Plans for Review of Complaints and Compliments at BSCARE:

BSCARE is in the process of developing a report format that will allow us to review an overview of all complaints and compliments across Blood Supply. We will undertake the review on a twice-yearly basis to ensure that trends in reporting can be identified and compliments highlighted.