Northern Ireland Blood Transfusion Service

Annual Quality Report

1. Introduction

NIBTS are fully committed to the provision of high quality products and services. This is detailed in the NIBTS Quality Policy Statement which is included in the NIBTS "Site Quality Manual"

Quality is regarded as of paramount importance at the Northern Ireland Blood Transfusion Service (NIBTS). This Quality Policy Statement applies to all services provided by NIBTS

- Collection, processing, testing, storage and issue of Blood Components
- Collection, processing, testing, storage and issue of Umbilical Cord Blood Cells
- Procurement and provision of Plasma Products
- Provision of Patient Testing Services – Blood Group Serology and Virology Screening(HIV, HbsAg, Syphilis and Rubella Immunity),for Antenatal Patients, and Reference Services to Hospital Blood Banks in N Ireland for Blood Group Serology and Platelet Serology.

This commitment to Quality is demonstrated by the development of a Quality Management System, which will ensure the provision of safe, efficacious and timely delivery of blood products and services for both patients and donors. This system complies with all relevant legislation including Blood Safety and Quality Regulations, Human Tissue Quality and Safety Regulations, Environmental legislation, and CPA/UKAS Accreditation standards

The Quality Policy Statement rests on the following principles:

- NIBTS' definition of quality is 'conformance with requirements'. We will carefully specify the requirements for our suppliers and our processes and will comply with the requirements of our users. Performance against these specifications is monitored

- The training and education of staff shall be of a level to ensure that all staff recognise their responsibility to maintain and improve quality through awareness of this Site Quality Manual and compliance with relevant procedures. Staff are committed to good professional practice.

- The health and welfare of staff and visitors.

- The quality objectives set will maintain and improve quality through a planned system of quality management, which covers every part of our activity. An essential part of this system is audit and review procedures.

This quality policy statement is communicated to all staff and reviewed annually for suitability and effectiveness.

2. Engagement with Q2020

The NIBTS Quality Manager represented the Service on the Q2020 Implementation Team during 2014/15 and provided information to the wider Agency. To date the activities undertaken by the Team have been focused on Trusts and medical staff with a limited direct relevance to NIBTS. Future NIBTS representation on the team will be the NIBTS Regulatory Affairs & Compliance Manager.

3. NIBTS Quality Systems and Improvement

Each of the processes listed below contribute to quality improvement; by the identification of:

- non-conformances
- observations, suggestions etc. (opportunities for quality improvement)
- risks

These in turn drive the process of Root Cause Analysis through to the implementation, monitoring and review of corrective and or preventative actions.

NIBTS has developed and maintains processes, which ensure effective management of:

- Internal Audit –Assessment of User Satisfaction
- Processing of Complaints
- External Quality Assessment Schemes
- Quality Incidents
- Assessments by external bodies
- Change Control
- Risk Management
- A Staff Suggestion Scheme also exists.

A brief explanation of each process is detailed below:

'NIBTS Quality Audit Programme'

Internal audits are carried out by NIBTS staff or by contracted staff, these measure performance against the range of standards with which NIBTS must comply. These audits identify non-conformances, which are then addressed by the completion of corrective action/s and/or observations (improvement opportunities). Observations or improvement opportunities are considered and may be addressed by completing preventative actions to reduce the potential for further non-conformances.

'Participation in External Quality Assessment Schemes'

This involves the participation in external quality assessment schemes relating to the various testing processes performed by NIBTS. This comparison of NIBTS results with national standards allows the identification of less than satisfactory results and/or scope for improvement. Poor performance in such schemes results in the logging of Quality incidents (non-conformities, which in turn drive corrective and/or preventative action).

'Procedure for the Reporting and Management of Quality Incidents (*including Serious Adverse Events***)'**

This procedure facilitates the logging of Quality Incidents (non-conformities), their investigation to root cause and completion of remedial corrective and or preventative action as necessary.

'Change Control Procedure'

This procedure ensures that changes to processes, facilities and equipment are delivered in a controlled way. The controlled delivery of such changes is key to the implementation of many quality improvements. The expected benefit of each change is stated in the Change Proposal and delivery against this is assessed at review and sign-off. It is often the means of delivering corrective and or preventative action.

'Procedure for the Management of Assessment of NIBTS by External Bodies'

This process sets out how NIBTS manages external assessments. It facilitates the opportunity to identify any common issues highlighted by external bodies. It also sets out how corrective action plans are developed and managed.

'Procedure for the Management of Clinical Service User Surveys'

This procedure seeks assurance from users that their requirements and needs are being met. It also facilitates suggestions for improvement, which are considered for inclusion in planned quality objectives.

'Procedure for Processing Complaints and Other Contacts'

This sets out how NIBTS deals with complaints and other contacts from the public. Compliance with local HSC policies is essential. The procedure ensures investigation of complaints and the completion of corrective/preventative actions

'Risk Management Process'

The NIBTS Risk Management Process is based on Risk Assessments and the identification of mitigating actions: - these may be preventative actions, which will contribute to the overall quality of processes. Such actions are managed via the Change Control process or within the specific risk assessment.

Staff Suggestion Scheme

NIBTS has a staff suggestion scheme. This facilitates recognition for staff who submit suggestions which deliver significant quality improvement.

Outputs and the information arising from these are reviewed and discussed in a range of meetings to ensure they remain effective.

‘Quality Management Review’

This sets out how quality is reviewed throughout NIBTS through to Senior Management Team level. It establishes the principles for Annual Quality Management Reviews with particular reference to CPA and ISO15189

Table 1(page 25) summarises these details and sets out the mechanism and frequency of review. This is further supported by Table 2(page 26) which sets out detailed Quality Indicators used to measure these processes. Each department will tabulate its Quality Objectives; these are subject to regular review within the process above. Quality Objectives are monitored within the framework above.

The detail relating to the quality indicators are specifically included in the Quality Metrics report which is reviewed at the Monthly Quality Improvement Review meeting attended by SMT members and as required other representatives from the Quality Department.

This review meeting is key to the monitoring and management of the Quality System ensuring that operational managers account for Quality Management System compliance within their departments. It is at this meeting that escalation of any shortfall in compliance is reviewed and escalated in keeping with the relevant SOPs

Definitions:

- **Non-Conformity**
  Non-fulfilment of a requirement

- **Corrective Action –**
  Action to eliminate the cause of a detected non-conformity or other undesirable situation.

- **Preventative Action –**
  Action to eliminate the cause of a potential non-conformity or other undesirable potential situation

- **Remedial Action –**
  Action taken to mitigate the immediate effects of non-conformity

- **Continual Improvement -**
  Re-occurring activity to increase the ability to fulfil requirements

- **Quality Indicators -**
  Norms, criteria, standards, and other direct qualitative and quantitative measures used in determining the quality of performance.

- **Quality Objectives -**

  A quality objective is a quality oriented goal. A quality objective is something you aim for or try to achieve. Quality objectives are based on and must be consistent with the Quality Policy. They are usually formulated at all relevant levels within the organisation and for all relevant functions. The laboratory objectives/achievements for 2013/14 are included below:

Department	**Activities**	**Key Achievements 2014/15**
Hospital Services	Preparation and manufacture of blood components Hospital issues department Belfast Cord Blood Bank	Deployment of Europack platelet pooling pack (part of European wide procurement of blood packs) following extensive validation. Introduction has improved conformance with quality requirements and reduced wastage.

Department	Activities	Key Achievements 2013/14
Automated Serology: • Blood Donor Grouping Laboratory • Antenatal blood grouping and antibody screening laboratory	Blood grouping of all donations Blood grouping and antibody screening of all donations including medical reporting of at risk pregnancy results	Completion of the tendering process for purchase of new testing platform for blood grouping and antibody screening. This development has potential to deliver cost savings and provides a robust modern test platform.
Blood group reference laboratory	Specialist referral service for hospital blood banks for complex red cell investigations and cross matching red cell units for difficult clinical cases. Includes on call service	Training of additional staff to the level of competence required for participation in the NIBTS On Call rota. This will allow the provision of a more robust service and improve rota viability Implementation of ABO isoagglutinin titres for ABO mismatched sold organ transplantation using gel cassette technology This allows improved service to users.

Department	Activities	Key Achievements 2013/14
Transfusion microbiology laboratory	Testing of all donations for infectious diseases markers Antenatal screening for infectious diseases in pregnancy	Implementation of a software interface allowing linking of Antenatal infectious diseases screening in pregnancy reports from NIBTS LIMS system to HSC NIMATS. This has improved the efficiency with which results are populated within patient records.
Quality control laboratory	Quality monitoring of blood components. Bacteriological testing of platelet components Environmental monitoring of component production areas	Installation of software package required for introduction of improved Statistical Process Control to allow assurance of product quality.

NIBTS is one of four Blood Services in the UK. It also has links with other Blood Services in Europe through the European Blood Alliance. Within the UK Blood Services there are a wide range of groups which support bench marking and identify best practice. Two overarching committees are the UK Forum and the UK Blood Services Joint Professional Advisory Committee. Both these committees have a wide range of sub-groups and advisory committees which focus on specialised areas with Blood Transfusion Practice. The UK Blood Service Business Information Committee is one such group and this produces an annual report formally benchmarking comparison data for key processes within the blood services.

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4. Governance

NIBTS has set key performance indicators for quality. The review of these is a fixed agenda item within operational and quality specific meetings. These indicators are designed to provide information to SMT and the Board on quality related matters and are presented routinely at meetings attended by these staff members.

5. Leadership/Culture

NIBTS has clearly defined Mission and Vision Statements within which are a commitment to maintaining and improving quality. These are shared with all staff and commitment to these is reinforced by all senior staff.

Mission

NIBTS will strive for excellent results in transfusion. This applies to the donors we receive and care for, the patients we serve and our staff whom we wish to develop to their full potential.

Vision and Service Domains

The following statements set out the vision and strategic direction for NIBTS based on five domains.

The corporate goals, service improvement plans for individual departments and individual staff development reviews are linked to these themes:-

- **Quality** – Patient Safety and maintenance of Licences
- **Donor/Customer** – Improving the Donor/Customer experience
- **Improvement** – Constantly seeking to improve our service
- **Resources** – Maximising the use of resources allocated to us and minimising waste
- *People – Engage, Empower and Encourage learning and development*

A quality-focused culture has been enhanced through the following actions:

- The Board, Chief Executive and Senior Managers all demonstrate commitment to quality by promoting and pursuing quality objectives. In addition and due to the specific services provided by NIBTS the organisation has in place a formal Quality and Regulatory Affairs and Compliance Function lead by a member of the Senior Management Team.

- Systems both formal and informal exist within NIBTS to encourage and facilitate staff input to decision making, problem solving and innovation at all levels. In respect to business planning input from staff at all levels is sought through meetings with the Chief Executive which are open to all staff, team meetings and the input of the Board and SMT. The procedures in place relating to risk management and the investigation, correction and prevention of quality incidents requires investigation and input from the full range of staff as appropriate. NIBTS has in place systems both formal and informal for staff to make suggestions. During 14/15, 3 suggestions received - all considered however none was feasible to implement. Feedback and justifications re reasons for non-implementation were provided to the initiators.

- Team working across departments, professions and at all levels is essential in the delivery of routine services and quality improvement. NIBTS continues to develop communication processes with continued use of team briefings, e mail and screensavers to provide up to date information to staff. Training specifically focussed on communication was delivered to 49 managers with generally positive feedback.

6. Staff

The development and maintenance of a safe and secure working environment for staff remains a priority. NIBTS' Health and Safety Committee continued to make encouraging progress on a range of issues in 2014/15 including its planned programme of risk assessments. The environmental management controls assurance standard was externally verified as substantively compliant. As in previous years 2014/15 witnessed another year of a very low number of recorded health and safety incidents with no serious incidents recorded. This bears testimony, once again, to the efforts of the Committee and indeed to the general vigilance of staff throughout the organisation.

No fire safety incidents were recorded during 2014/15. The Health and Safety Committee continued to discuss fire safety governance arrangements and there were also dedicated fire wardens for the organisation. Fire risk assessments were reviewed during the year with no adverse findings.

NIBTS is committed to maintaining security of the facilities and staff at all times. NIBTS positively promotes the objectives and principles of equality of opportunity and observes all of its statutory obligations in relation to all of the Section 75 groups in the Northern Ireland Act (1998).

Promote staff health and wellbeing - In 2014/15 NIBTS conducted a number of health and well-being events in which staff participated. These ranged from vaccination clinics for influenza, to a health fair designed to promote and advise on healthy living. World Diabetes Day, World Sight Day, Men's' Health Week and Depression Awareness were promoted by NIBTS. The Agency continues to provide a full occupational health facility to staff who can self-refer at any time as well as a continuing service level agreement with 'Carecall' which provides a range of services to staff

7. Service User Engagement

NIBTS engages with users in a number of ways. There is limited direct contact with patients however hemochromatosis donors do attend NIBTS by way of treatment through blood donation and currently NIBTS have initiated a project to improve access to this service by increasing venues for donation as a result of feedback from users.

NIBTS medical team plays a leadership role in the Northern Ireland Transfusion Committee. We work closely with our colleagues and agree priorities and annual work plan. The committee has met on 3 occasions during 2014/15 with a further educational day held during February 2015.

The NIBTS medical team works closely with the Public Health Agency on implementation of antenatal screening programme for infectious diseases in pregnancy.

NIBTS also support innovations in medical practice such as ABO titration studies for ABO mismatched renal transplantation and the provision of autologous serum eye drops for patients attending the ophthalmic service at Royal Victoria Hospital.

The Blood Transfusion Communities Partnerships are very active in relation to improving the service for donors in terms of information, development of our website and changes to our session profile and operational practices where appropriate. NIBTS engages the users of its clinical services, i.e. Haematologists, Biomedical Scientists, Haemovigilance Practitioners, Midwifes and Obstetricians through meetings such as the Regional Transfusion Committee, Pathology Network groups, surveys, and user meetings.

This clinical interface is very effective and is key to improving services. For example, the haemovigilance function in Northern Ireland is recognised as being particularly strong. This is reflected in restrictive red cell transfusion practice which is within appropriate clinical practice guidelines. Annual issues of red cells in 2014/15 of

49,302 represent 27.22 per 1,000 capita Northern Ireland population, a ratio which compares favourably with the EU.

Northern Ireland is the only region in the UK and Ireland which has mandatory competency testing for the essential elements of the blood transfusion chain which include sampling, labelling, ordering and requesting, delivery to the clinical area and administration of a blood component. This follows on the National Patient Safety Agency safer practice notice and also coincides with a reduction in the number of reports of serious adverse events to the haemovigilance reporting scheme known as Serious Hazards of Transfusion (SHOT UK).

NIBTS hosts the Northern Ireland Transfusion Committee which oversees individual hospital transfusion committees which support hospital transfusion teams which deliver the haemovigilance function on the ground. The committee has in 14/15 completed an audit of appropriate use of platelet transfusions confirming a high percentage compliance with clinical practice guidelines and progressed regional standardisation of some processes notably the bloodless pathway document and request form for Kleihauer test. The committee continues to provide valuable educational opportunities for clinical staff.

There are a wide range of forums where representatives from NIBTS meet with other stakeholders such as other Blood Services, Regulatory Bodies, HSCB and DHSSPS representatives on a wide range of topics e.g. Information Governance, Emergency Planning and Public and Patient Involvement

8. Learning from experience

As noted elsewhere NIBTS has in place comprehensive systems for the logging, investigation of errors, incidents and risks. These include both the completion of corrective and preventive actions across the organisation and discussion of incidents at an incident management forum with representatives from across the organisation, thus facilitating shared learning. These procedures also include a process of review

which triggers escalation to external bodies such as Northern Ireland Adverse Incident Centre (NIAIC) or Regulators if appropriate.

These procedures relating to logging and investigation of errors, incidents and risk encourage a no blame culture to provide a supportive environment in which staff feel comfortable reporting such events. Corrective and preventive actions will include the provision of training or retraining and competency assessment to provide assurance that staff continue to work within their level of competency and not negligently.

NIBTS utilises a Quality Management Systems software tool – Q-Pulse which supports management and analysis of errors, and incidents.

NIBTS has in place a Staff Development Review process based on the Knowledge and Skills Framework. As part of the SDR process, all staff must:

- Be reviewed against the Post Outline for their post to determine strengths and areas for development.

- Have a Personal Development Plan (PDP) developed indicating, where applicable, in what areas they are expected to develop over the coming 12 months.

- Be supported in learning and development by their appraiser/manager, remembering that learning and development does not mean attending courses.

- Have their learning and development evaluated, the outcome of which helps the cycle commence again.

- Agree objectives in line with the Agency's Business Plan.

The key to an effective SDR process is the principle of 'no surprises'. Issues that arise during the year should be addressed immediately and not left to a scheduled formal review time. During the formal review, individuals should know what the key issues will be through effective routine management.

This process is confidential between Reviewer and Reviewee, however, in exceptional circumstances the Reviewee has the option to refer the document to a Senior Reviewer for comments.

The relevant documentation to undertake this process is stored by the line manager. If reviewers and staff wish to keep paper copies, this is at their own discretion but will be additional to the information stored by the line manager, not instead of.

For this process to be effective, it is essential that all reviewers/managers are trained on how to use this process and attend any updates where appropriate. It is the reviewer/manager's responsibility to ensure their training is up to date, and the staff they are responsible for, understand the SDR process.

Staff are encouraged at all stages to report risks and any potential failures in service. This is re-enforced in procedures for reporting Quality Incidents. Within NIBTS the vast majority of paperwork is controlled by formal quality processes which include regular reviews of all documents and forms which ensure that any paperwork is required for regulatory reasons or adds value to the processes.
NIBTS continue to implement its Risk Management Strategy which includes the development of quarterly corporate and departmental risk registers. The registers detail the factors used to control and mitigate risk within the organisation. Risk Management is also incorporated into the Incident Management and Validation Procedures within NIBTS.

NIBTS has within its Quality system a range of processes that ensure processes keep delivering the expected results. These include setting targets and standards and regular monitoring against these. e.g.

- Blood Component Specifications and routine Quality Monitoring. – All blood components produced by NIBTS have either European or locally defined specifications. Compliance with these specifications is assessed by testing a representative sample of products. Compliance with these specifications is part of the NIBTS Governance process.

- The NIBTS Internal Quality Audit system also provides assurance of control. This is managed through the NIBTS Quality function and involves completion of audit by NIBTS staff against both external regulations and standards, and internal policies and procedures. These audits are also designed to facilitate free and open dialogue between operational staff where concerns and risks can be identified.

- NIBTS also is subject to audit by the Business Services Organisation Internal Audit function which completes an annual review of financial management, governance and risk management. In each case in 2014/15 satisfactory assurance was reported and the linked controls assurance standards externally verified. Any weaknesses in control have been identified and are the subject of detailed action plans which will be followed up by the auditors at their mid-year and end of year reviews. The Chief Executive prepares a governance statement for the Permanent Secretary which is supported by an opinion from the Head of Internal Audit. This was completed for both the mid-year and end of year accountability review meetings both of which had satisfactory outcomes.

9. Regulation and Accreditation

NIBTS is regulated and accredited by a number of bodies:

- Medicines and Healthcare Product Regulatory Agency – Blood Establishment Authorisation and Pharmaceutical Wholesale Dealers Licence
- Human Tissue Authority Licence for the Belfast Cord Blood Bank licence
- Accreditation of patient testing laboratories by Clinical Pathology Accreditation UK Ltd. , now a wholly owned subsidiary of UKAS. UKAS is currently managing the transition of all CPA accredited laboratories to UKAS accreditation to *ISO 15189:2012, Medical Laboratories – requirements for quality and competence*
- Investors in People Accreditation

The regulatory and accreditation standards are based on quality management systems which include a focus on Quality Improvement e.g. CPA accreditation requires the setting, monitoring and delivery of key quality objectives. Such systems require the embedding of a quality approach to all aspects of the service. Working in keeping with IIP and systems that meet IIP requirements enhances staff input to enhancing compliance with standards.

10. Workforce

NIBTS is committed to Learning and Development for all staff including support for appropriate post entry qualifications. Facilitating CPD and training is key to the success of the organisation. All professional groups are encouraged to undertake specific CPD activities. This includes the provision of lunchtime seminars.

NIBTS operates in compliance with many regulations and as such have a significant mandatory training commitment which includes regular training for all staff on aspects such as Good (Pharmaceutical) Manufacturing Practice, Health and Safety, Information Governance. E-learning packages are now being used to deliver much of this training. This is further supported by extensive ongoing training on detailed standard operating procedures

All medical staff are subject to GMC Revalidation procedures. The Revalidation process it up to date with two doctors progressing in 2015. Dates for Revalidation for other staff are 2016 and 2018.

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Middle managers attended training sessions on the “Equipping our Leaders Programme”.

11. Public and Patient Involvement:

NIBTS is a member of the Regional Personal and Public Involvement Forum (RPPIF) and its Blood Transfusion Service Communities Partnership (BTSCP) is very active in relation to improving the service for donors in terms of information,

development of our website and changes to our session profile and operational practices where appropriate.

Blood Transfusion Service Communities Partnership (BTSCP) met on seven occasions. Central to discussions at BTSCP were session organisation, donor recruitment (including donor selection issues), and communication across a number of areas of interest to donors and the general public.

NIBTS also took further steps to promote PPI amongst all staff via the use of personal computer screensavers and the introduction of the new standards tabled for discussion at team meetings.

The Partnership continues to play an important role in the monitoring of our services to donors and key to this was the quarterly and annual review of complaints. Reports on this area are also circulated to the Patient and Client Council (PCC).

NIBTS complaints are processed through procedures compliant with current DHSSPS guidance. Appendix 1 and 2 set out the standards set out for interaction with donors and summarises our performance against these standards.

12. Best Practice/Standards/Guidelines

As noted elsewhere NIBTS representatives sit on a wide range of committees, these include:

- The Joint UKBTS/HPA Professional Advisory Committee(JPAC) and its Standing Advisory Committees
- Blood Components
- Care and Selection of Donors
- Clinical Transfusion Medicine
- Immuno-haematology
- Information Technology
- Transfusion Transmitted Infection

JPAC and its advisory committees play a key role in the development of improving standards and guidelines in transfusion practice both for Blood transfusion Services and Hospital Blood Bank

NIBTS plays a key role in the audit of Transfusion Practice both directly and through the Regional Transfusion Committee. The Regional Transfusion Committee undertook an audit of platelet transfusion in 2014/15 confirming a high percentage compliance with clinical practice guidelines and provided input.into a National Comparative Audit on patient conformed consent for transfusion.

13. Commissioning and Performance Management

NIBTS has a definitive supplier approval process applied to all services obtained by NIBTS. This includes aspects such as accreditation and licensing to a wide range of quality standards were each standard is applicable to the service obtained e.g. Laboratory testing services are only obtained from laboratories accredited by Clinical Pathology Accreditation UK Ltd or the UK Accreditation Service. In such cases the provider must provide continued evidence of accreditation requirements and if necessary NIBTS will audit/inspect providers against relevant standards. Service provider performance is reviewed on a regular basis e.g. annually dependent on the criticality of the service provided.

Appendix 1

Commitment to care and partnership

... our standards

- Your donation is voluntary and non-remunerated. You should not feel pressurised in any way.

- The Health and Safety of our donors and patients are of primary importance to us. On some occasions it may be better not to donate.

- Acceptable donations will be made available to all those in need.

- Your donation will remain anonymous upon subsequent distribution.

- Information given by you will not be used for any purpose other than that intended and will be treated in confidence.

- Information about you that is held by us will be made available on request. However, not all information will be available at the donation session.

- We ask you for personal information as part of our Health Check screen. Please answer the questions as accurately as possible.

- You are asked to sign your Health Check questionnaire. If as a result of your contact with the Service if we detect anything that may affect your health, we will let you know.

- It is best if you can attend your donation session during the earlier part of each session period. This should prevent undue waiting for you and allow your donation to be returned to our headquarters for laboratory processing without delay.

Appendix 1 contd

Commitment to care and partnership

... our standards

- If you are unhappy about any aspect of our service, you are entitled to comment and seek an explanation. If you have a complaint, it is better if you raise the matter with staff at the earliest possible opportunity. Alternatively, you may telephone or write to one of the people noted on the Information Point that is available at each donation session. An advice leaflet: ***Complaints - Can We Help?*** will provide further details. It should take us no more than 20 working days to deal with your complaint.

- Our aim is to make your visit to a blood donation session a pleasant and relaxing experience, and for this year we have set a donor satisfaction target of 95%.

- Blood donation sessions will not finish before the stated closure time. However on occasions it may be necessary to end sessions early due to advice from local organisers or where large numbers attending may prevent blood being returned to our laboratories for processing.

- 98% of sessions will start on time.

- Average waiting time should be less than 30 minutes. Where an appointment has been made, average waiting times should not exceed 15 minutes

Appendix 2

Commitment to care and partnership

... our performance

Session waiting time

- Average waiting time (from reception until donation venepuncture) was 27 minutes, and this is an increase on the 25 minute average in 2013/14 – due to a reduction in staffing, unfilled vacancies, and long term sickness absence.

Donor Satisfaction

- 184 comments cards were returned in this year (202 in 2013/14)

- Despite a lengthy period of sub-optimal staffing levels, an overall satisfaction rating of 97.2% was achieved (98.6% in 2013/14). As part of this monitoring programme the Service also endeavours to establish which factors are of most importance to donors, and it is once again confirmed '*Staff*', was the top criterion, closely followed by '*Reception'.*

Complaints Monitoring

- 2014/15, despite some of the challenges referred to earlier, was reasonably satisfactory when measured against the incidence of complaint. A total of 22 complaints were received (31 in 2013/14), with waiting time and staff-related problems counting for over half this number.

Year	Total	Staff-related	Waiting	Venepuncture-related	Turn- away	Other
14/15	22	7	7	2	1	7
13/14	31	7	9	2	4	13

Note: Complainants may cite more than one problem area.

TABLE 1

Doc. No.	Title	Actions Identified	Monitored by	Frequency
SOP:QA:003	NIBTS Quality Audit Programme	Nonconformity, Corrective and Preventative	Departmental Meetings/Quality Improvement Review	Monthly
SOP:QA:045	Participation in External Quality Assessment Schemes	Nonconformity, Corrective and Preventative	Departmental Meetings/Quality Improvement Review	Monthly
SOP:QA:070	Procedure for the Reporting and Management of Quality Incidents	Nonconformity, Corrective and Preventative	Departmental Meetings/Quality Improvement Review	Monthly
SOP:QA:081	Change Control Procedure	Manages Corrective and Preventative action and may as part of planning identify preventative action	Departmental Meetings/Quality Improvement Review	Monthly
SOP:QA:095	Procedure for the Management of Clinical Service Surveys	Usually preventative, occasionally nonconformity, corrective	Departmental Meetings/Annual Quality Management Review	Monthly
SOP:QA:096	Procedure for the Management of Assessment of NIBTS by External Bodies	Nonconformity, Corrective and Preventative	Departmental Meetings/Quality Improvement Review/ Governance and Risk Committee	Monthly
SOP:BD:017	Procedure for Processing Complaints and other contacts	Nonconformity, Corrective and Preventative	Departmental Meetings, Governance and Risk Committee	Monthly
SOP:RM:001	Risk Register Process	Preventative	Departmental Meetings/Governance and Risk Committee	Monthly
	Staff Suggestion Scheme	Corrective and Preventative	Departmental Meetings	Monthly
POL:QP:001	Quality Management Review Policy	Nonconformity, Corrective and Preventative	Departmental Meetings/Quality Improvement Review	Monthly

Table 2 **Quality Indicators**

Objective	Measurement	Target	Frequency of Monitoring/Review	Where/How
Review all documents in keeping with the specified period.	% documents beyond review	0% outside review	Monthly	Lab. Management meetings and Quality Improvement Review meetings
Incident investigations will be completed in a timely fashion	Number of completed investigation proforma submitted to Quality beyond 30 days	Nil >30 days	Monthly	Lab. Management meetings and Quality Improvement Review meetings
Implementation of agreed corrective and preventative actions arising from incidents are completed in a timely basis	Time to incident closed(all corrective and preventative actions closed)	75% >30 days	Monthly	Incident Management Meetings, Lab. Management meetings and Quality Improvement Review meetings
Changes are planned and implemented in a timely basis	Changes are delivered on time i.e. the date specified	<10% past target date for implementation	Monthly	Change Management meetings, Lab management meetings, Quality Improvement Review meetings
Complete Internal Audits in a timely fashion.	Audits are completed no later than one month after that scheduled	No audits overdue	Monthly	Lab management meetings, Quality Improvement Review meetings
Internal Audits are closed in a timely fashion	Audits will be closed within 3 months of an audit being completed	No audit closure overdue	Monthly	Lab Management meeting Quality Improvement Review
Equipment is maintained correctly	Maintenance/Calibration records confirm neither is overdue	No equipment calibration or maintenance greater than 2 weeks overdue	Monthly	Lab Management Meeting, Quality Improvement Review
GMP training refresher training delivered annually	All staff receive relevant GMP training at least once in a twelve month period	100% of available staff receive GMP training annually	Monthly	Quality Improvement review.
Deliver Testing Services provided as specified	Measurement of Turn – round times	98% reports within 3 days	Monthly	Lab Management meetings