NHS
Blood and Transplant

Patient and Donor Safety Incident Response Plan

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Contents

Introduction

This patient and donor safety incident response plan sets out how NHS Blood and Transplant (NHSBT) intends to respond to patient and donor safety incidents over a period of 12 to 18 months. NHSBT is complex in terms of the services provided by each directorate and the way in which the organisation is regulated. As a result, a phased implementation approach is being adopted. This plan represents the first iteration. The first iteration of the NHSBT PSIRF plan aligns with phase 1 of PSIRF implementation. The primary purpose of the first plan is to replace the Serious Incident Framework and includes additional criteria for undertaking a Patient Safety Incident Investigation (PSII) based on NHSBT's incident profile above and beyond the NHS England national requirements. We will remain flexible and consider the specific circumstances in which patient and donor safety issues and incidents occurred and the needs of those affected. For the purpose of the implementation within NHSBT all reference to patient safety will be regarded as also pertaining to donor safety.

The NHS Patient Safety Strategy was published in July 2019 and describes the Patient Safety Incident Response Framework (PSIRF), a replacement of the NHS Serious Incident Framework (2015) which only focused on robust responses to the most serious incidents.

The PSIRF is best considered as a learning and improvement framework with the emphasis placed on systems and culture that support continuous improvement in patient and donor safety through how NHSBT responds to incidents that meet the Patient and Donor Safety Incident (PDSI) definition.

The plan is underpinned by our local organisation policies on incident management. This plan does not supersede any regulatory requirement to undertake causal analysis, investigate deviations and other problems, and implement corrective and preventative actions in response to the investigation.

NHSBT established a PSIRF delivery group and project board to deliver the implementation of the PSIRF.

The PSIRF recognises the need to ensure organisations have support structures for those involved in patient safety incidents (patients, donors, families, and our people), part of which is the fostering of a psychologically safe culture demonstrated by all our leaders and supported by organisation-wide strategies, and associated reporting systems. NHSBT acknowledges limitations in current incident management processes and resources that restrict the organisation’s ability to implement the PSIRF system wide. Therefore, a phased approach has been adopted, this plan represents the first iteration and should be read in conjunction with the NHSBT Patient and Donor Safety Incident Response Policy.

- Phase 1 (April – October 2024):

  Organ & Tissue Donation and Transplantation (OTDT) go live with the full PSIRF process whilst other directorates begin the identification and assessment of PDSI's which will lead to improved understanding of their incident profile. The SI investigations will be replaced by PSI Investigations

- Phase 2 (October 2024 – April 2025):

  PSIRF will be implemented in full across the clinical directorates, with learning response leads undertaking the management of PDSI's. This will also include the development of improvement plans to manage themed incidents and a review of the Clinical Governance oversight structures to ensure their effectiveness in bringing systematic improvement in patient and donor safety.

Our services

NHSBT is a special health authority, sponsored by the Department of Health and Social Care dedicated to saving and improving lives.

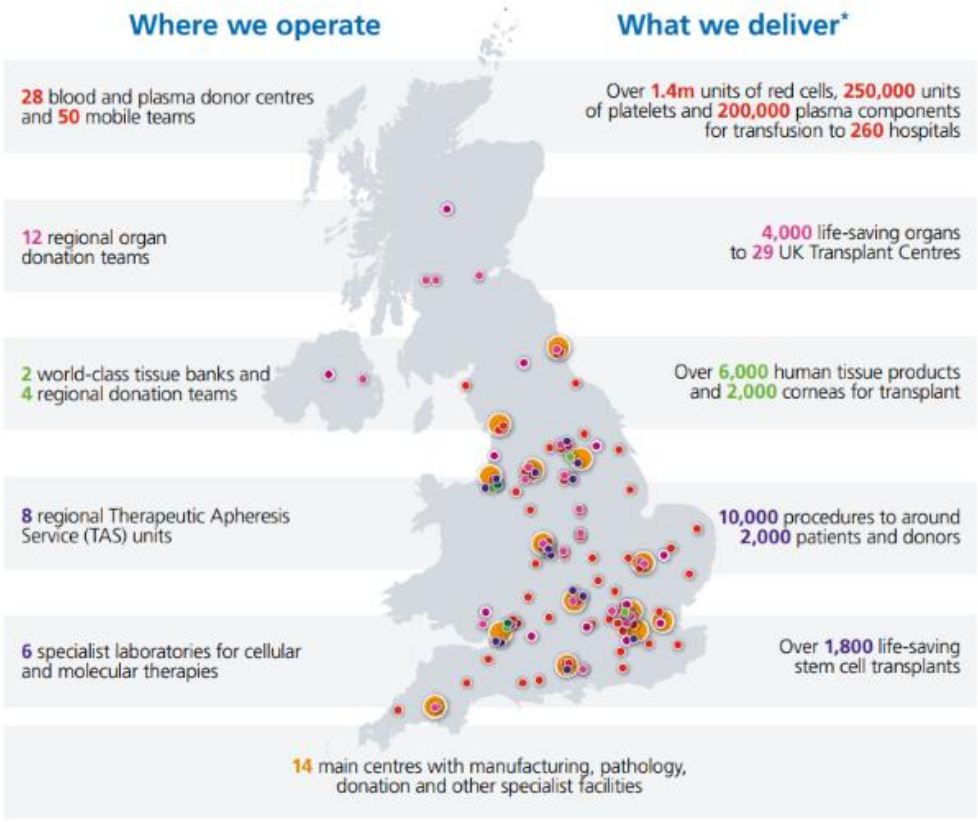

Figure 1: NHSBT Services

NHSBT is governed by a Board of Directors. Day-to-day running of clinical and non-clinical services is delegated to Executive Directors and senior clinicians and managers. The Board has overall responsibility for the activity, integrity, and strategy of the organisation. Its role is largely supervisory and strategic. The Executive team is the senior managerial decision-making body for the Directorates in the organisation.

NHSBT has four operational Directorates each with its individual roles and responsibilities. Each Directorate has its own Director supported by other key personnel, the Senior Management Team (SMT). The Clinical Directorates are:

1) Blood Supply
2) Plasma for Medicines
3) Clinical Services
4) Organ and Tissue Donation and Transplantation

The organisation is supported by the following Directorates:

1) Nursing Directorate
2) Donor Experience
3) Digital, Data and Technology Services (DDTS)
4) Quality
5) People
6) Finance
7) Strategy and Transformation

The Nursing Directorate and Quality Directorate are independent group service directorates with a shared core purpose of assuring patient and donor safety whilst ensuring NHSBT maintains and improves its regulatory compliance. The vision of Quality supports continuous improvement by ensuring donors and patients are at the centre of the organisation's thinking to support a risk-based safety and quality culture. Similarly, the vision of Nursing ensures patients, donors and their families are central to the services we provide and through centralised Clinical Governance, safety and quality is assured and systematic improvement is delivered.

NHSBT is registered with the Care Quality Commission to provide:

- Treatment of disease, disorder or injury at Therapeutic Apheresis Service (TAS) units and the Photopheresis unit
- Management of supply of blood and blood derived products at the blood donor centres.
- Matching and allocation of donor organs
- The supply of tissues or tissue-derived products for transplant, grafting or use in surgery. For example, this will include supply of organs or tissue by NHS Blood and Transplant or any other provider of transplant organs

NHSBT undertakes regulated activities by several external regulatory agencies. The main three regulators are:

HTA - Human Tissue Authority

- Human Tissue (Quality and Safety for Human Application) Regulations 2007 as amended by The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018.
- The key legislation surrounding organ donation and transplantation in the UK are the Human Tissue Act 2004, covering England, Wales and Northern Ireland, and the Human Tissue (Scotland) Act 2006, covering Scotland, together with various Statutory Instruments arising from

those Acts. This legislation specifies the arrangements for donor consent or authorisation, how organs and tissues may be acceptably used, and the data that must be recorded to ensure compliance.

- The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) set the standards for the quality and safety of organs intended for transplantation. For the purposes of licensing by the Human Tissue Authority (HTA), there are two separate groups of activity detailed in the Regulations - procurement and transplantation.
- There is also legislation arising from the EU Organ Donation Directive and the EU Tissues & Cells Directive. These regulations are principally concerned with organ donation, testing, characterisation, procurement, preservation, transport and transplantation, together with the quality, safety and traceability of cells and tissues.

MHRA - The Medicines and Healthcare products Regulatory Agency (MHRA).

The MHRA is responsible for the regulation of medical devices and medicines used in healthcare and the regulation of blood establishments. They are regulated under four licences held by NHSBT:

1. Blood Establishment Authorisation
2. Manufacturer's Authorisation- Investigational Medicinal Products
3. Manufacturer's "Specials" Licence
4. Wholesale Distribution Authorisation (Human)

CQC – Care Quality Commission

The CQC monitors, inspects, and regulates our services to make sure they meet fundamental standards of quality and care.

Defining our patient and donor safety incident profile

The PSIRF defines a patient safety incident as:

"Something unexpected or unintended has happened, or failed to happen, that could have or did lead to patient (or donor) harm"

As a result of the regulatory activity, the current NHSBT incident management processes encompass not only incidents that have an impact on individual patients, donors and donor families but also events that have an impact on the system and supply of products and services, these event types are not within the scope of the PSIRF.

During the data analysis it was identified that there was no differentiation in the record keeping within the electronic quality management system, this was a limiting factor in the data analysis process and resulted in a greater reliance on triangulation of findings with local expert knowledge.

All unexpected events are recorded in an electronic quality management system managed by colleagues within the Quality Directorate. A proportionate response is undertaken based on a likelihood and impact assessment that considers the impact of the incident on individuals, the system and supply. Prior to the introduction of the PSIRF, Root Cause Analysis (RCA) has been the most commonly used investigative methodology for all incident types requiring corrective and preventative actions.

Stakeholder engagement

The NHSBT patient and donor safety incident profile which has informed the PSIRF plan has been developed in collaboration with stakeholders across the organisation. Key stakeholders were identified and invited to form the membership of the PSIRF delivery group and PSIRF Project Board. These include:

- Chief Medical Officer
- Chief Nursing Officer
- Director of Quality
- Chief Nurse, Corporate Clinical Governance Lead
- Assistant Director of Quality and Regulatory Compliance
- Directorate Chief Nurses and deputies
- Directorate Heads of Clinical Governance
- Head of Patient and Donor Safety
- National Quality Assurance Manager, ODT
- Regional Quality Assurance Managers
- Medical Director, SHOT and Consultant Donor Medicine

- Clinical Risk Lead
- Clinical Audit Manager
- Head of Health, Safety and Wellbeing Delivery
- Freedom to Speak Up Guardian

Primary Data Sources

A strategic data analysis workstream was initiated by the PSIRF delivery group. In collaboration with a data analyst, multiple sources of information and data were analysed to identify the overarching and key patient and donor safety issues that are contributing to risk at NHSBT (Figure 2). Additionally, conversations were held with representatives from each directorate to identify the key issues affecting patient and donor safety within their service areas. Where available, data was collected from the previous three financial years, dating from 2020/21 through to the present 2022/23.

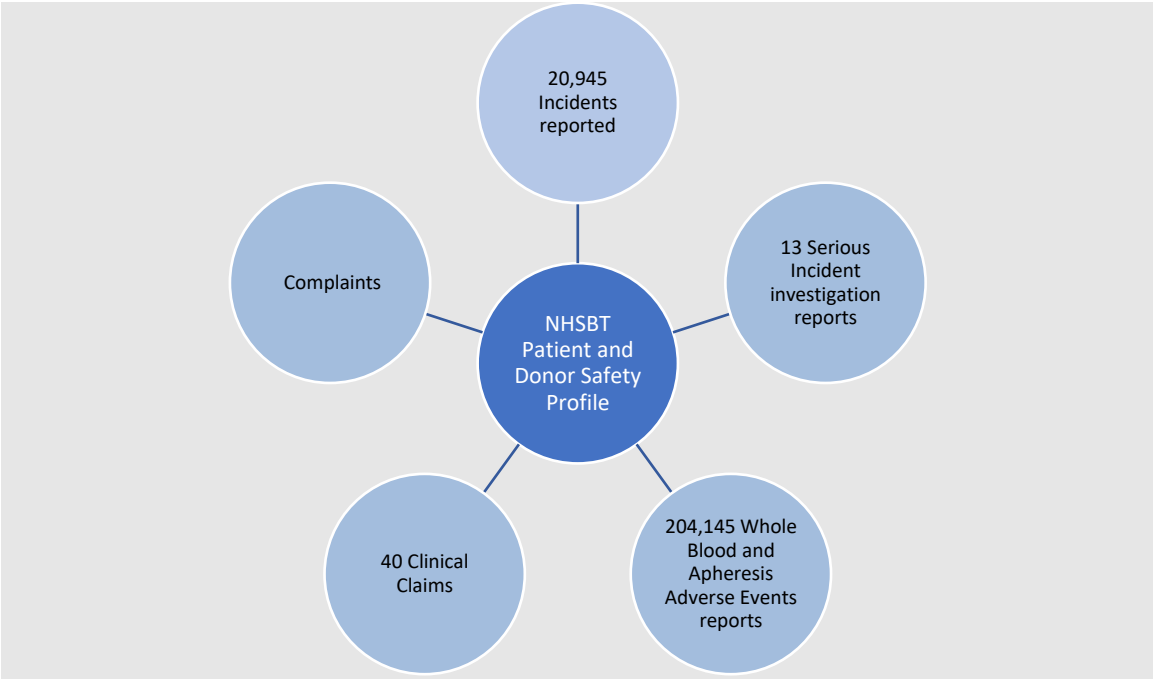

Figure 2: Primary data sources

Complaints

Across NHSBT compliments and complaints are encouraged from hospitals, blood donors, from organ donor families and from Therapeutic Apheresis patients. These are managed separately in four areas.

Organ and Tissue Donation and Transplantation

The OTDT Clinical Governance team manage approx. 30-40 complaints and 150 compliments a year from deceased donor families, recipients, living donors, members of staff, members of the public and external stakeholders.

Blood Donation – The Donor Feedback Team

The Donor Feedback team manage around 7.5k complaints and 12k compliments a year from blood, platelet and plasma donors, members of the public and external stakeholders.

Therapeutic Apheresis Services

The TAS team manage around 2 complaints and 250 compliments a year from TAS patients and hospitals.

Hospital Services

The Hospital Customer Service team manage around 1000 complaints and 200 compliments a year received from hospital transfusion laboratories.

Whole Blood and Apheresis Donor Adverse Events

Haemovigilance is fundamental to keeping donors and patients safe. 204,145 Whole Blood and Apheresis Adverse Events reports were received. The most commonly reported adverse events are:

- Vasovagal event without loss of consciousness not resulting in injury
- Bruising at the time of blood or component donation
- Re-bleed – Bleeding from needle puncture site after donation has been completed
- Painful arm, without bruise, tendon or nerve injury

Clinical claims

Clinical claims data for NHSBT over a 10-year period (2012-2022) was analysed. A total of 212 clinical claims were reported during this decade. There were 40 incidents relating to patients and donors within the scope of the PSIRF data analysis.

Other data sources considered

- Safeguarding
- Health, Safety and Wellbeing
- Freedom to Speak Up
- Local intelligence

Defining our patient and donor safety improvement profile

NHSBT has been continually developing its clinical governance structures and associated processes to ensure it gains insight from all patient and donor incidents. The first stage of the PSIRF implementation will focus on reinforcing a robust and collaborative corporate Clinical Governance and Quality incident response decision-making process, that meets the proportionate learning response requirements of incidents that fulfil PDSI criteria, whilst maintaining regulatory requirements. This will be achieved through the implementation of a weekly corporate Patient and Donor Safety Incident Review Group (PDSIRG) and Clinical Quality and Safety Oversight Group. A function of these groups will be to proactively examine the patient and donor safety data and inform locally designed patient and donor safety improvement plans.

Proposed quality improvement focus for the 12 month period covered by this plan includes:

1) Optimising venepuncture practices and addressing preventable factors for nerve injuries
2) Improving arm cleansing during blood donation
3) Reducing incidents associated with Hb testing during the blood donation process
4) Reduction in primary graft failures (corneas)
5) Reducing transplant delays in Tissue and Eye services
6) Reducing drug errors in Therapeutic Apheresis service
7) Improvement in contemporaneous record keeping in Therapeutic Apheresis service
8) Reducing incidents associated with manual transcription

In NHSBT there are a number of patient and donor safety improvement initiatives in progress, this includes:

- National commissioning of histopathology services for organ donation
- Sustainability and Certainty in Organ Retrieval (SCORE) programme
- Coroner working group (ODT)
- Donor Adverse Events Severity grading working group
- Transfusion 2024 Programme
- Digitise, automate and streamline processes to improve resilience, reduce risk and increase efficiency, including:
    - Therapeutic Apheresis Service digital development
    - Automated Results Transfer Programme (ART)
    - UK Living Kidney Sharing Scheme (UKLSS) digital transformation

NHSBT will review reports including but not limited to, SHOT Annual Report, Donor Epidemiology Annual Report, Biovigilance Annual Report, the Infected Blood Inquiry Report, national inquiry reports related or patient or donor safety, Infection Prevention Control guidance and national alerts to triangulate with internal data and consider any further associated improvement activities.

Our patient and donor safety incident response plan: national requirements

Incidents meeting the Never Events criteria (2018) and deaths thought more likely than not due to problems in care will always require a locally led PSII to learn and improve.

Some events in healthcare require a specific type of response as set out in national policies or regulations. These responses may include review by or referral to another body or team, depending on the nature of the event.

Table 1 below sets out the local or national mandated responses. As NHSBT does not directly provide acute, maternity, mental health or custodial services it is more likely that the organisation will be a secondary participant rather than a lead for those incident types (7-11).

National Requirements			
Event		**Approach**	**Improvement**
1	Incidents meeting the Never Events criteria (2018)	PSII	Create local organisational corrective and preventative actions and feed these into the quality improvement strategy
2	Death thought more likely than not due to problems in care (incident meeting the learning from deaths criteria for patient safety incident investigations (PSIIs))	PSII	Create local organisational corrective and preventative actions and feed these into the quality improvement strategy
3	Deaths of persons with learning disabilities	Refer for Learning Disability Mortality Review (LeDeR). Locally led PSII (or other response) may be required alongside the LeDeR. NHSBT to liaise with this review.	Respond to recommendations from external referred agency/ organisation as required. Feed actions into quality improvement work
4	Safeguarding incidents in which: • Babies, children, or young people are on a child protection plan; looked after plan, or a victim of	Refer to Local Authority Safeguarding Lead via the NHSBT named Safeguarding Lead. NHSBT named Safeguarding Lead will contribute towards domestic independent inquires, joint targeted area inspections,	Respond to recommendations from external referred agency/ organisation as required. Feed actions into quality improvement work

	wilful neglect or domestic abuse/ violence. • Adults (over 18 years old) are in receipt of care and support needs from the local authority. • The incident related to FGM, Prevent (radicalisation to terrorism), modern slavery and human trafficking, or domestic abuse/ violence.	child safeguarding practice reviews, domestic homicide reviews and any other safeguarding reviews (and inquiries) as required to do so by the local safeguarding partnership (for children) and local safeguarding adult boards.	
5	Child deaths	Refer to Child Death Overview Panel (CDOP) review. Locally led PSII (or other response) may be required alongside the CDOP review. NHSBT to liaise with the CDOP	Respond to recommendations from external referred agency/ organisation as required. Feed actions into quality improvement work.
6	Incidents in NHS screening programmes	Incidents in NHS screening programmes See: Guidance for managing incidents in NHS screening programmes	Respond to recommendations from external referred agency/ organisation as required. Feed actions into quality improvement work.
7	Deaths of patients detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies, where there is reason to think that the death may be linked to problems in care (incidents meeting the learning from deaths criteria)	PSII	Respond to recommendations from external referred agency/ organisation as required. Feed actions into quality improvement work.
8	Maternity and neonatal incidents meeting the Healthcare Safety Investigations Branch (HSIB) criteria or Special Healthcare Authority (SpHA) criteria when in place	Refer to HSIB or SpHA for independent PSII.	Respond to recommendations from external referred agency/ organisation as required. Feed actions into quality improvement work.

9	Deaths in custody	Any death in prison or police custody will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the Independent Office for Police Conduct (IOPC) to carry out the relevant investigations. NHSBT will fully support these investigations where required to do so.	Respond to recommendations from external referred agency/ organisation as required. Feed actions into quality improvement work.
10	Mental health-related homicides	Refer to the NHS England Regional Independent Investigation Team for consideration for an independent PSII. Locally led PSII may be required	Respond to recommendations from external referred agency/ organisation as required. Feed actions into quality improvement work.
11	Domestic Homicide	Identified by the police usually in partnership with the Community Safety Partnership (CSP) with whom the overall responsibility lies for establishing a review of the case. Where the CSP considers that the criteria for a domestic homicide review (DHR) are met, it uses local contacts and requests the establishment of a DHR panel. NHSBT will contribute as required by the DHR panel.	Respond to recommendations from external referred agency/ organisation as required. Feed actions into quality improvement work.

Our patient and donor safety incident response plan: Organisational focus

In addition to the national requirements listed above there are also incidents, that we have agreed within NHSBT, will always require a PSII. These are listed in the table below.

As NHSBT transitions to phase 2 of PSIRF, the PSIRF plan will be updated to include incident types that do not meet the threshold for a PSII and the planned response for these.

This plan does not supersede any regulatory requirement to undertake causal analysis, investigate deviations and other problems, and implement corrective and preventative actions in response to the investigation.

Patient and donor safety incident type or issue	**Planned response**	**Anticipated improvement route**
Patient or Donor Safety incidents relating to patients from the devolved nations	Refer to specific national incident categories. Locally led PSII may be required	Create local organisational corrective and preventative actions and feed these into the quality improvement and patient and donor safety strategy
An event leading to major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or NHSBT	PSII	Create local organisational corrective and preventative actions and feed these into the quality improvement and patient and donor safety strategy
Post-mortem loss of an organ; removal, disposal or retention of an organ or tissue without consent; post-mortem examination or release of the wrong body	PSII	Create local organisational corrective and preventative actions and feed these into the quality improvement and patient and donor safety strategy
An unexpected Patient or Donor safety incident which signifies a catastrophic impact (using grading tool) for donors, patients, families and carers, staff, or organisation where contributory factors are not well understood, and local improvement work is minimal	PSII	Create local organisational corrective and preventative actions and feed these into the quality improvement and patient and donor safety strategy
Ineffective communication of significant new clinical information relating to a patient or donor that has resulted in harm or potential harm where contributory factors are not well understood, and local improvement work is minimal	PSII	Create local organisational corrective and preventative actions and feed these into the quality improvement and patient and donor safety strategy

Confirmed or near miss transfusion or transplantation transmitted infection where contributory factors are not well understood, and local improvement work is minimal	PSII	Create local and national organisational corrective and preventative actions and feed these into the quality improvement and patient and donor safety strategy

All incidents relating to the developing NHSBT PSIRF Improvement workstreams will be included in the improvement activities being undertaken.

Any new incidents or events reported will be included in the workstream for review to understand whether they highlight any new issues that may not have already been identified.

The next phase of the PSIRF will proactively focus on a number of thematic workstreams to ensure resources for investigation are used more efficiently. The learning response methods, advocated by and available from the NHS England PSIRF toolkit, such as After Action Review and Multi-disciplinary Team Review will provide a robust learning response with a more effective use of time, allowing a focus on learning and improvement.

It is anticipated that the number of thematic PSII workstreams being undertaken will increase as the organisational learning response capacity increases. Alongside this, proactive, Safety II horizon scanning will support insight and further support a culture of learning by triangulating with learning from excellence. A phased implementation will give greater opportunity to learn from each implementation phase to enhance safety of all services. Quality improvement methodology will be utilised. This will be reflected in future iterations of the organisation's PSIRF plan, oversight and monitoring will be maintained by the Clinical Quality and Safety Oversight Group and Clinical Governance Committee.

Established Processes

Incidents relating to the specialist areas below will be monitored and reviewed and investigated by the relevant subject matter experts according to organisational policy. The specialist teams will be involved in relevant learning responses and have oversight of these. They may steer the appropriate learning response for specific incidents depending on the level of issues identified.

- Investigation of all suspected Transfusion Transmitted Infections and Microbiology Lookbacks
- British Bone Marrow Registry (BBMR) Concessions
- Clinical Sample Concessions
- Courier Incidents
- Environmental Monitoring
- Ink on Packs
- Temperature Excursions