Cord Blood Unit Data Checklist: Overcoming Variation in CBU Reports to Improve the Selection Process

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NHS Blood and Transplant

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Introduction and Background

Umbilical Cord Blood Transplantation (UCBT) is an established treatment of many haematological conditions, with a growing role in high-risk leukaemia, especially in paediatric practice. Selection of an optimal, suitable and high-quality Cord Blood Unit (CBU) is a crucial factor in transplant outcome. Meanwhile, the lack of a standardised CBU Report format complicates CBU comparison and selection due to significant variation in length, layout and content.

Aims

The aim of this project was to create a standard form of CBU Report data presentation to:

- Help Transplant Centres (TCs) to compare CBU reports
- Allow rapid assessment of incoming data for suitability
- Identify critical missing and/or alarming information
- Promote best practice for CBU selection
- Reduce turn around time of provisions
- Decrease the number of product-related shipment cancellations

Materials and Methods

The quality and potency parameters included on the checklist, as well as the framework used to interpret these values, was determined using the following:

- FACT-Netcord Standards (7th Edn)
- UK guidelines on CBU selection (Little et al, 2021)
- Human Tissue Authority (HTA) requirements for importing CBUs into the UK
- Internal Anthony Nolan and NHSBT Cord Blood Bank reference points

The Quality Checklist document (figure 1) was developed on Microsoft Excel using a variety of drop-down options, embedded calculations and free text boxes to allow transcription and interpretation of the data.

To test the system a pilot project was run over six months (February 2022 – July 2022) with two H&I laboratories selecting CBUs for three UK TCs. Their comments were collected in regular meetings and via feedback forms showing the effect of the Checklist service on overall confidence in CBU acquisition, satisfaction with the level of information required for decision making, and perceived complexity of CBU selection. The guidance from participants was used to shape the content of the Checklist and logistics of service delivery. We continued to provide Checklists for these two H&I labs beyond the end of the pilot, bridging the gap between the end of the pilot and the implementation of the Checklists into routine procedure.

Results and Implementation

Checklist for CBU (cord support programme)			
Cord blood unit ID:	Example 1	CBB:	UK - Anthony Nolan Cord Blood Bank
Patient initials / ID:	AN/12345	Patient Weight (Kg):	45.0
Select CBB accreditation	FACT		
CORD BLOOD COLLECTION AND PROCESSING ATTRIBUTES			
Collection Date (DD/MM/YYYY):	11/03/2012	Unit age (years)	11
ABO/Rh	B+	Gender	Female
Confirmatory HLA (VT has been performed?)	Yes - on attached segment	Microbial tests	Partial- Bacteria only, Fungi missing
Process Method:	Sepax	red cell and plasma reduced	
Number of Bags Frozen:	1	Frozen Final Volume with cryopreservative (ml):	27
Number of Contiguous Segments:	0	Haemoglobinopathy	Normal
MATERNAL AND FAMILY HISTORY			
Cord Blood Donor Recruitment		**Risk assessed?**	**Comments**
Mother's Declaration/ Travel history: Risk behaviour for contracting and transmitting infectious diseases plus Risk of exposure to infectious diseases		no risk identified	N/A
Family Medical History: Genetic Risk (Incl Cancer, Blood Disorders, Enzyme Deficiencies, Metabolic/Storage Diseases or Autoimmune Diseases identified)		yes, see comments	Maternal grandparent had bowel cancer

CORD BLOOD QUALITY/POTENCY DATA	POST PROCESS	COMMENTS	POST THAW QC DATA	COMMENTS
TNC including NRBC (x10^7)	238.00	Cell dose - OK Suitable for double UCBT AND Suitable for single UCBT	140	59% TNC recovery. AN experience: >60% acceptable; >80% good
Total NRBC (x10^7)	31.00	% NRBC: 13.0% OK		
Haematocrit (HCT) %	27.00	0.16 rbc volume OK No concern		
CD34+ (x10^6)	5.00	Cell dose - OK Suitable for double UCBT -	3.60	72% CD34+ recovery. AN experience: >60% acceptable; >80% good
CFU (x10^4)	211.00	"Good CFU growth"	78	Fact standards require growth
ClonE (CFU/CD34+)	42.63	"Good CFU growth"	15.6	Expected ClonE% value (post-thaw CFU/post processing CD34). AN experience: > 5% is a good indicator.
TNC/ total/ CD45+ Viability	80.00	Less than required by FACT	73	AN experience: >50% acceptable; >70% good
CD34+ Viability	99.00	Good Viability	94	>70% Meets fact requirements

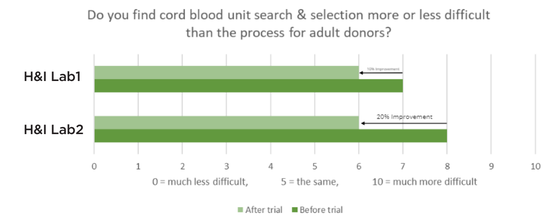
Cell dose recommendations from: Little, A-M, Akbarzad-Yousefi, A, Anand, A, et al. BSHI guideline: HLA matching and donor selection for haematopoietic progenitor cell transplantation. Int J Immunogenet. 2021; 48: 75– 109. https://doi.org/10.1111/iji.12527. Post thaw recommendations are based upon observations made by the teams at ANCTC and NHSBT cord blood bank

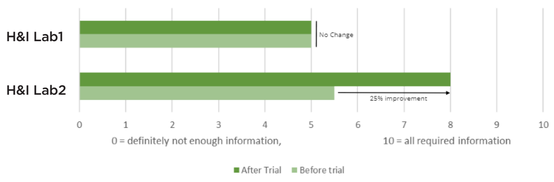
CORD BLOOD SAFETY DATA	MATERNAL BLOOD TESTS DRAWN ON: 11/03/2012			
HBs Ag	NEG			
HBc Ab	NEG			
HBs Ab	n/a			
HIV-1/2 Ab	NEG			
HCV Ab	NEG			
HCV/HIV/HBV NAT	NEG	NEG	NEG	maternal
Treponema pallidum Ab	NEG			
HTLV-I/II Ab	NEG			
HTLV I NAT	n/a			
CMV IgG/IgM	NEG	NEG	OK	
CMV NAT	n/a			

IDM testing key neg: non-reactive, pos: reactive, tbc: to be confirmed, n/d: not done, n/a: not applicable.

Figure 1

147 Quality CBU Checklists were completed for 17 patients served by the two participating H&I labs during the Pilot Project between February 2022 and December 2022. The feedback from the TCs showed an improvement in the level of information provided, reduced complexity in CBU selection and an overall decrease in difficulty related to CBU requests (figure 2).





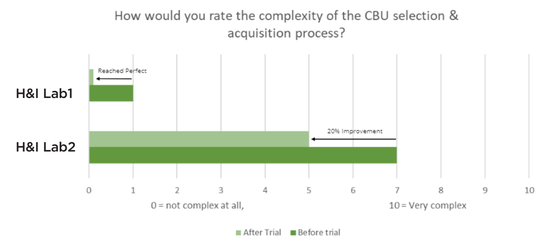


Figure 2

Following the success of the pilot project, from January 2023 the Checklist service was implemented in the routine work of the Anthony Nolan Search and Selection Team for 53% of all UK TCs – those receiving our clinical H&I services and those subscribed to the Cord Support Programme (CSP). In four months of 2023 (Jan–April) more than 300 checklists (5–6 checklists per patient case) were provided, with excellent feedback from the TCs. The number of product–related CBU shipment cancellations in 2022/23 FY (April 2022 – March 2023), when the Checklists were piloted and implemented, was a record low of 3.9%. Overall, we believe that the UK CSP, which started in 2018 with a range of supporting services (CBU shortlisting, Quality Checklists, Post–Thaw Clinic), has played a significant role in reducing product-related CBU shipment cancellations (figure 3).

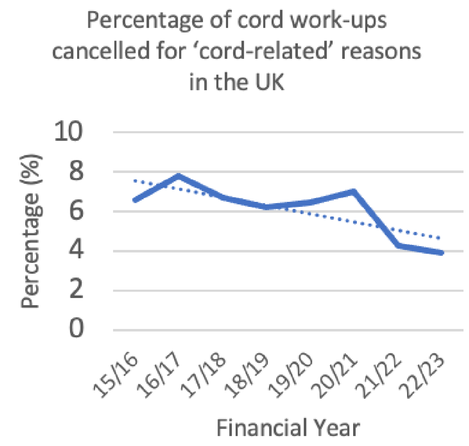


Figure 3

Conclusion and Future Plans

The Checklists have improved TCs' confidence and reduced the perceived level of difficulty in CBU selection. They have contributed to a reduction in the number of product-related cancellations, and thus helped to improve service delivery times and transplant outcomes.

We plan to expand our Checklist provisions to the rest of the UK TCs in this coming FY23/24 with the goal of reducing these cancellations even further. We also work closely with WMDA Cord Blood Working Group to promote this service internationally.

Testimonies

The Quality Checklist produced by the Anthony Nolan Cord Support Team is extremely helpful in counteracting the variability in information provided in the CBU Reports, thus enabling more precise comparisons of units from different banks.

Dr Ann-Margaret Little, Gartnavel General Hospital, Glasgow

References
• Little, AM., Akbarzad-Yousefi, A., Anand, A., Burlinson, N.D., Dunn, P.P.J., Evseeva, I., Latham, K., Poulton, K., Railton, D., Vivers, S., Wright, P.A. (2021). 'BSHI guideline: HLA matching and donor selection for haematopoietic progenitor cell transplantation', *International Journal of Immunogenetics*, 48(2), pp. 75-109. Available at: **https://doi.org/10.1111/iji.12527**
• Seventh Edition NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration (2020). Available at: **https://www.factglobal.org/standards/cbb-standards/**
• HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment (January, 2021) Paragraph 243 onwards-Import

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