Exploring Perceptions of 'Quality' Cord Blood for Stem Cell Treatments

Dr Laura L. Machin, Lancaster Medical School, UK; Dr Takuya Matsushige, National Institute for Public Health, Japan; & Dr Richard A. Williams, Lancaster Management School, UK

Today

- **Political and Moral Economy of Umbilical Cord Blood Banking (2009 – 2011)**
  - Project website: https://www.york.ac.uk/satsu/stem-cell-banking/
  - Research aims: explore new forms of consumption, parental responsibility and the changing balances between public and commercial bioscience that are emerging as a result of cord blood banking
  - 62 Interviews with: midwives, obstetricians, neonatologists, donors & depositors, policy makers & regulators, activist, genetic and professional interest groups, phlebotomists & donor co-ordinators, Royal Colleges, commercial & public bankers.
- **Exploring Perceptions of 'Quality' Cord Blood in Stem Cell Treatments (2013 – 2016)**
  - Project website: http://www.lancaster.ac.uk/shm/research/projects/cord-blood-quality/
  - Research aims: what makes a 'quality' cord blood unit for those working in transplant centres and what factors influence their perceptions?
  - A review of policy and practice surrounding cord blood collection, banking, and treatments in Japan and the UK
  - 20 interviews with haematologists, immunologists, and oncologists in Japan and the UK
  - Survey 'factors of influence' for those using cord blood in treatments in Japan and the UK

Influential Factors for 'Quality' Cord Blood: Knowns

- 'Known' factors affecting the 'quality' of cord blood
  - Cell counts (TNC / CD34+ cell)
  - HLA (type / typing techniques)
  - Length of storage / Age of unit
  - Bank
    - Method of storage (red blood cells)
    - Accreditation
    - Methods of measuring cell counts
    - Red blood cells included in count?
    - Bag storage
    - Maternal and infant follow up testing

Influential Factors for 'Quality' Cord Blood: Unknowns

- Clinical Expertise
  - Location of the cord blood therapy
  - Who conducts the cord blood therapy
  - UK Stem Cell Forum and the introduction of 'regional centres of excellence'
    - Success of cord blood therapies dependent on inherent properties of the cord blood?

Influential Factors for 'Quality' Cord Blood: Unknowns

- Collecting cord blood and 'transplant quality'
  - Donor co-ordinators and Phlebotomists
    - Medically qualified?
  - Obstetricians
    - Timing of collection

(Machin, L.L., Brown, N. & McLeod, D. (2012) 'Two's company—Three's a crowd': The collection of umbilical cord blood for commercial stem cell banks in England and the midwifery profession' Midwifery, 28(3):358-365)

Influential Factors for 'Quality' Cord Blood: Unknowns

- Maternity practices and 'transplant quality'
  - Timing of when the umbilical cord is clamped
    - 'Delayed': *leaving the cord to pulsate between one to two minutes after the baby is born. Beneficial for the baby to continue to receive the blood within the cord after s/he is born* *(Downey and Bewley 2012; Hutchon 2012; Mercer and Erickson-Owens 2014).*
    - 'Early': *clamps are typically put in place between 2 and 60 seconds after the baby is born, in an attempt to reduce the risk of haemorrhaging for the woman* *(Regan, Bewley, and Warwick 2008; Downey and Bewley 2012; Duley and Batey 2013).*

Influential Factors for 'Quality' Cord Blood: Unknowns

- Maternity practices and 'transplant quality'
  - Management of third stage of labour
    - Active: *includes the umbilical cord being clamped within 30 seconds to a minute after her baby is born, and an injection of drugs with the promise of prompt delivery of the placenta* *(Downey and Bewley 2012; Duley and Batey 2013; Brown 2013).*
    - Physiological: *the umbilical cord is left unclamped until it finishes pulsating, and the woman's body expels the placenta without pharmaceutical encouragement* *(Downey and Bewley 2012).*

(Machin. L.L. (under review) 'The collection of 'quality' umbilical cord blood for stem cell treatments: Conflicts, compromises, and clinical pragmatism' Journal of Bioethical Inquiry')

Conflicted Practices

- Acquiring a ‘quality’ cord blood sample for the blood disease sufferers and concerns for the maternal and neonatal health
  - Not possible to clamp the cord at a time that was beneficial to all three patients i.e. blood disease sufferer, new mother, and neonate
    - ‘early’ = more blood available in cord = more blood available to collect = beneficial for blood disease sufferer
    - ‘early’ = lower risk of labouring woman haemorrhaging = beneficial for mother
    - ‘delayed’ = more blood available to neonate = beneficial for neonate

- Timing of Clamping = Volume = ‘Quality’ cord blood

Purpose of Practices

- Goals of 'care'
  - New mother and neonate
  - Blood disease sufferer

"…at the end of the day, you're in labour and it's the safety of the mother and baby that is the first priority…" (Depositor)

"The most important thing, like most things in life, is actually the baby being born. The cord blood banking actually is a secondary issue" (Obstetrician)

"…the priority is to mum and baby" (Commercial banker)

Compromised Practices?

- Options
  - Mix management of the third stage of labour

"We ended up going for a compromise of feeling the cord pulses when the baby had started breathing and then clamping, which is obviously slightly mixing management which sometimes can increase the chance of bleeding [for the woman]" (Midwife)

"…we're looking at doing a halfway house on the management of the third stage of labour…delay clamping if the baby is okay and the mother is okay…" (Midwife)

Compromised Practices?

- Options
  - Cap the volume of cord blood collected

"...in fact you might be able to get to some kind of compromise that we clamp for a minute and then you get 40mls" (Obstetrician).

"...we are taking time to clamp the cord...i think it's enough blood to have a clinical unit for transplant to a patient (Public banker)

"...she didn't allow them to clamp it too early. She let basically a flow go through for a few minutes so that the baby got the essentials and then clamped it after that" (Depositor)

"...You drain as much [cord blood] as you like into that baby. There's plenty. That placenta puts out an enormous amount. We only need 40ml" (Commercial banker)

Emerging Conclusions

- Key stakeholders involved in the collection of cord blood are positive regarding the protection of maternal and neonatal health, whilst those conducting maternity practices are not opposed to facilitating the collection of ‘quality’ cord blood.
- Some ‘delayed’ cord clamping practices and cord blood collection are not mutually exclusive
- Maternal, neonatal, and blood disease sufferer’s health and well-being are not necessarily in conflict with each other
- The perception that the volume of cord blood as determining ‘quality’ cord blood is undermined (more blood = increased volume = quality)
- However, maternity practices are influencing perceptions of ‘quality’ cord blood units (capped cord blood collected = quality)

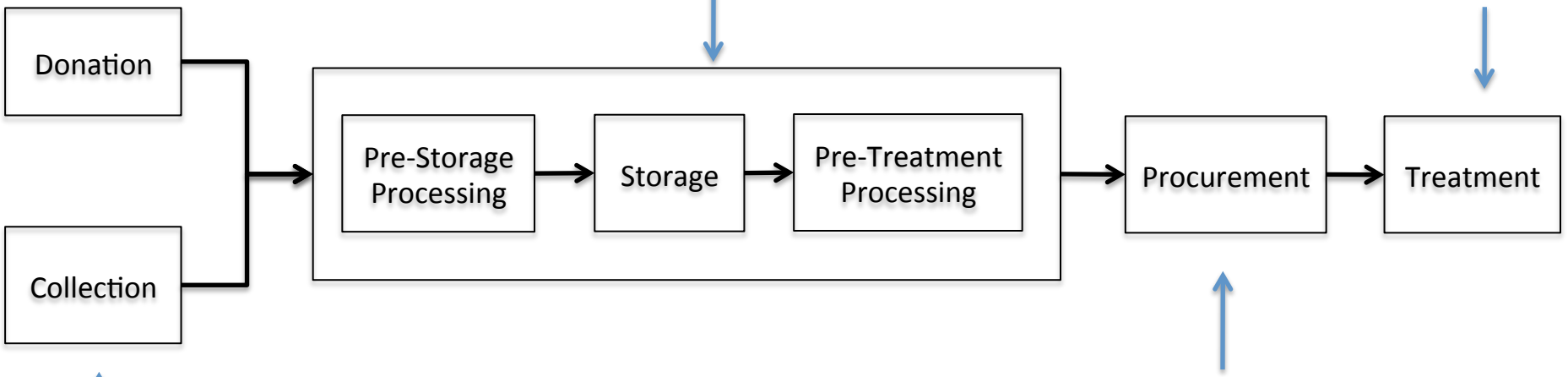
Cord Blood Treatment Process

Lancaster University

Demographic background of Mother,
Location of physical donation,
Volume of physical sample,
TNC count of sample,
Other biological markers of blood

Commercial v Public bank,
Storage practices,
Different blood-typing techniques

Degree of local clinical expertise on Cord Blood



Benefits of Cord Blood v Other Stem Cell lines,
CB quality markers – e.g. age, bank, country of origin,
Policy re: Cord Blood Search

Role/Job of Collector,
Medical Training of Collector,
Different collection processes,
Timing of CB clamping,
Ex-Utero v In-Utero collection