Deciding ‘quality’ surrounding umbilical cord blood treatments in Japan and the UK

Takuya MATSUSHIGE, National Institute of Public Health, Japan
Laura MACHIN, Lancaster Medical School, United Kingdom

This research received a research grant from Great Britain Sasakawa Foundation
Background

• Hematopoietic stem cells obtained from umbilical cord blood
  ◆ Used for the treatment of blood diseases such as leukemia and aplastic anemia
  ◆ Burden on donors is relatively small
  ◆ Transplant possible even if there is partial discordance of HLA

• Cord blood bank networks have been established in many countries
The way of managing bank networks varies from country to country

- Private / Public, Legislation? Regulations? Quality management?
- How to provide stem cells to medical institutions

No international single criteria about “how do they ‘know’ what constitutes a ‘quality’ cord blood unit?”

The present study
- explores the perceived ‘quality’ of a cord blood unit among professionals
- considers how differences in the perception, if any, affect the practice of collection, preservation and transplant, ethical challenges?
Method

• Semi-structured interviews in the UK and Japan
• with those who are engaged in either of cord blood collection, preservation and transplant (hematologist, oncologist, immunologist, obstetrician and others)
• 10 interviews in each country, totally 20 interviews will be conducted

◆ Perception about the quality of cord blood unit?
◆ What to do to maintain the appropriate level of quality?

• Each face to face interview lasts approximately for an hour and a half
• Recorded with the informed consent
• Transcribed data are analysed using the MAXQDA

* This study obtained ethics approval from NIPH.
Focus for discussion

“How do you evaluate the quality of cord blood unit?”

“trust underpinning the judgement”

◆ Many procedures involved in cord blood stem cell transplants; collection, component separation, inspection, storage, typing and transplants

“How they collect and preserve cord blood. Of course, it is an important issue. However, we, transplant practitioners, do not necessarily have detailed information about the whole procedures. All the cord blood units available to us are from the banks with governmental approval. At the time of authorisation, the banks have already passed a number of inspection items.” (Transplant surgeon)

“plural indicators unable to prioritise”

◆ Multiple indicators exist and it is impossible to prioritise them for judging the quality of cord blood unit

◆ One indicator has importance at some point; however it can become less important after a little while

“Whether or not HLA is crucial, whether or not TNC is critical, varies delicately with disease trajectory and pathological condition.” (Haematologist)
“CD34 is very important and I always confirm it. However, the thing is the accuracy of the measurement. Unfortunately there are large variations in the way in which the number of CD34 is measured. So you cannot accept it without questioning.”

‘CD34-positive cells’
- Many transplant surgeon of umbilical cord blood give much weight in evaluating the quality TNC (total nucleated cells)
- An older indicator than CD34, shows smaller variation in measurement because its method has more established

- In the decision of ‘quality’ surrounding cord blood transplants, there are two uncertain issues that are intricately intertwined with each other.
  - Decision of the ‘quality’ by placing trust on other agency based on existing approval systems
- The level of importance of each indicator varies according to the stage of disease and pathological appearance
  - Experts must consider and compare multiple variables surrounding the disease at each stage of treatment, which makes it extremely difficult to illustrate the diagram of quality decision making