

## **Abstract**

Incentives have been proposed to NHS hospitals to encourage the collection of 'quality' umbilical UCB (UCB) to treat people with blood disorders. As UCB is collected immediately after a woman has given birth, maternity practices have come under scrutiny. Sixty-two interviews were conducted between 2009 and 2010 with those working on maternity wards, and in UCB collection and banking. Ethical approval was granted by the university institution and the NHS Research Ethics Committee. Participants perceived a conflict between acquiring a 'quality' UCB sample for blood disease sufferers and concerns for maternal and neonatal health. Options to overcome the conflict were compromises that demonstrated that those most powerful in the debates are those conducting maternity practices, whilst those involved in the banking of UCB have less influence perhaps as a consequence of the lower priority of 'quality' UCB collection in relation to maternal and neonatal health.

Key words: clinical pragmatism, maternity practices, umbilical cord blood

## **Introduction**

Midwives and obstetricians have longed raised concerns over the implications of umbilical cord blood (UCB) collection on maternal and neonatal health. Their anxieties have predominately focused upon the timing of when the UCB was collected. Maternity staff were fearful that if they were expected to collect UCB they would be distracted from caring for the new mother and baby "at a time of significantly increased clinical risk immediately post-delivery." (Edozien 2006; Regan, Bewley, and Warwick 2008) These fears have been allayed to some extent since the Human Tissue Authority's decision to introduce dedicated personnel to collect UCB (Human Tissue Authority 2008; Machin, Brown, and McLeod 2012) and promotion

by the Royal Colleges for collection to take place following the delivery of the placenta so that collection takes place ex-utero (Royal College of Obstetricians and Gynaecologists 2006).

However, midwives' and obstetricians' long-standing debate surrounding the timing of when the umbilical cord is clamped, and the potential health implications for babies and children as a result, such as neurodevelopment delays and iron deficiencies identified in children up to the age of four years old if clamped 'immediately,' (Mercer and Erickson-Owens 2006; Eichenbaum-Pikser and Zasloff 2009; Andersson et al. 2011; Andersson et al. 2015) or preventing jaundice (Mercer 2001), and lowering cases of anaemia (Andersson et al. 2011) if clamping is 'deferred,' is still on-going (Royal College of Obstetricians and Gynaecologists 2015). The collection of UCB has contributed another layer to the arguments over the timing of when the umbilical cord is clamped, with 'immediate' clamping perceived as facilitating collection (Diaz-Rossello 2006; Brown 2013) and 'deferred' clamping as hindering collection (Andersson et al. 2011; Burgess and Hilton 2012).

Despite their concerns, not only has UCB collection continued, with approximately 20 thousand samples stored in the public bank in England (Pawson 2014), but United Kingdom (UK) Government has recently invested an additional £4 million in order to increase the amount of UCB samples collected and stored in the bank up to 50,000 (Burgess and Hilton 2012). The public bank has recently formed in 2011, after a collaboration between two previously separate banks run by the charity, The Anthony Nolan Trust, and the other by the NHS Blood and Transplant (Williams 2015). Publicly banked units are made available globally through international registries, although the collection of UCB falls within the responsibility of the Human Tissue Authority and is regulated by the Human Tissue Act (2004). Numerous international organisations have been established in an attempt to ensure "high and uniform quality of all UCB units" (Petrini 2012). The accreditation systems available through these organisations, such as FACT and JACIE, are thought to provide reassurance through setting

uniform standards for the collection, processing, banking and transplant elements relating to UCB (Pamphilon 2009).

Umbilical cord blood is used to treat people with blood disorders, such as leukaemia, sickle cell anaemia, and thalassemia, although this is dependent upon a UCB sample with an appropriate immunological type being available from UK public bank (Samuel and Kerridge 2007). Many factors can influence whether 'appropriate' UCB samples are available, including the number of UCB samples collected and stored in banks. So, whilst 112 UCB units were used to treat NHS patients in 2010, proponents of UCB collection argue that approximately four hundred and forty additional patients each year could benefit from treatments using UCB if UK bank of 50 thousand samples were available (UK Stem Cell Strategic Forum 2010).

However, even if an immunological matched UCB sample is available in the bank, this does not guarantee it is deemed 'appropriate' for transplantation. Those using UCB samples to treat patients have questioned the 'quality' of some of the samples collected (McCullough et al. 2005; Picardi and Arcese 2010; Querol et al. 2010). In particular, the volume of UCB collected in each sample can influence whether it is useful for treatment or not (Ballen et al. 2001; Jones et al. 2003; Bart et al. 2013). A stored unit typically contains a sufficient volume of blood to treat a small child, therefore multiple units are needed to treat an adult. In order to drive 'quality', some public banks are setting a minimum volume – ranging from 70ml to 100ml - of UCB to be within each sample stored, although no universal standard currently exists across all banks (Diaz-Rossello 2006). As a result, transplant teams may choose to import a UCB sample from an overseas bank, which can prove costly (approximately £16,000 - £30,000) (Brown, Machin, and McLeod 2011; Williams 2015).

Reports in 2010 from the World Marrow Donor Association, which track the activities of UCB banks globally, stated that the percentage of UCB units crossing international borders was increasing (Foeken et al. 2010). In particular, European countries, such as Hungary, France,

and Italy, had imported more UCB units to meet clinical need compared to using UCB units collected within their own country (Katz and Mills 2010). Some countries have attempted to overcome this economic burden by introducing policies that constrain public freedoms in UCB banking choices, such as France prohibiting commercial banking (Katz and Mills 2010; Dickenson 2011).

Between 2011 and 2012, 80 percent of all UCB samples used for UK patients were imported (Burgess and Hilton 2012), and therefore in an attempt to reduce the UK's reliance on imported UCB samples, the All Party Parliamentary Group (APPG) on Stem Cell Transplantation at Westminster has proposed a number of incentives to NHS hospitals in order to encourage the collection of 'quality' UCB (Burgess and Hilton 2012). As UCB is collected immediately after a woman has given birth, maternity practices, such as cord clamping and management of the third stage of labour, have come under scrutiny from those keen to generate 'quality' UCB samples through increasing the volume of UCB collected (Jones et al. 2003; Brown 2013). Consequently, midwives, obstetricians and neonatologists, who conduct maternity practices, have found themselves embroiled in the debates surrounding 'quality' UCB samples (Diaz-Rossello 2006). It is of interest therefore to explore how these emerging and existing stakeholders in UCB collection and banking discuss maternity practices in light of the recent drive for the collection of 'quality' UCB samples. In particular, a focus upon the interplay between these stakeholders in UCB collection and banking offers insight into the conflicts and compromises that are shaping the debates surrounding the collection of 'quality' UCB.

### ***Conflicts and Compromises within Cord Blood Debates***

The field of cord blood collection and banking is rife with conflicts and compromises, not least because of the attempt to combine commercial activities within a public healthcare system. The early debates surrounding the introduction of commercial banks dominate past

research (Querol 2007), with the ethical and legal considerations, such as rationing of resources, staffing shortages, and fear of litigation, raised by those involved in UCB banking and maternity practices (Edozien 2006; Hollands 2006). More recently, academic researchers have identified aspects of the UCB collection process that are significant, such as gathering consent from the pregnant woman (Busby 2010), or potentially controversial, such as ownership of the UCB (Kline 2001). Reflexively, researchers have explored the sources of conflicts within the field of UCB collection and banking, but few have done so explicitly or considered how the application of compromise literature can inform our understanding of the debating surrounding UCB. Specifically, it is rare for the relationships between those involved in UCB banking and maternity practices to be explored by researchers (Fisk and Atun 2008; Fox, Chervenak and McCullough 2008). Yet, researchers do acknowledge the significance of the relationships when contemplating the realities of introducing commercial UCB banks in the NHS, in particular, the power that midwives and obstetricians have to “help overturn entrenched professional opposition to commercial banking” (Fisk and Atun 2008). This paper will attend to this gap by applying a method designed to explore the ethical conflicts within clinical practice (discussed below), and focusing on the compromises reached between those involved in UCB banking and maternity practices, and interpreting these findings within the compromise literature discussed next.

### ***Some Meanings of Conflicts and Compromises***

The proposition of a compromise suggests that a conflict is possible or in existence (Golding 1979; Nachi 2004) and that it stems from ‘political’ problems (Hallowell 1944). So, whilst the presence of a compromise acts as an acknowledgement of the other stakeholder, and gives ‘significance’ to their place in the debate (Nachi 2004; Menkel-Meadow 2006), not all stakeholders are equal, and instead the balance of power can tip in the favour of some over

others (Arnsperger and Picavet 2004; Menkel-Meadow 2006). Examining the negotiation process therefore can highlight the power dynamics at play (Nachi 2004) and provide insight into whom or what is being negotiated for or over, thereby reflecting the needs or interests of specific parties (Menkel-Meadow 2006). Consequently, insight into the roles and relationships of key stakeholders in cord blood banking and maternity practices is essential, as it enable us to learn how the interactions between the two stakeholder groups are reflected in policy and practice today.

Compromises are unpredictable, rarely fixed or static, particularly if new evidence emerges, and therefore the balance of power can shift between stakeholders (Papilloud and Rol 2004; Hussenot 2010). This is significant for the debates surrounding UCB collection and maternity practices as recent clinical trials in cord blood transplantation, ongoing scientific research to develop techniques to expand small volumes of UCB collected, and current large scale cohort studies into the consequences of cord clamping (Hollands and McCauley, 2009) all bring the potential of new evidence, and in turn, the shifting of power between stakeholders. Therefore, this paper will explore the evolution of a compromise emerging from the debates surrounding the collection of 'quality' UCB, which will provide an explanation for the production and reproduction of policies and practices (Hussenot 2010) in UCB collection and maternity practices in England.

### ***A Closer Look at UCB Collection and Maternity Practices in England***

Umbilical cord blood can be collected for either a public or a commercial bank. There are three fundamental differences between the two types of banks. Firstly, once a baby is born, a woman can donate the blood from the umbilical cord to UK public banks, or pay to store the blood in a commercial bank. Secondly, the donated UCB in the public banks is available to patients worldwide, whereas the UCB in commercial banks is available solely to the family that paid for

the storage. Commercial banks can store units with a lower volume of UCB than the standard set by public banks if families agree. Consequently, commercially-collected UCB for familial use has generated much debate, particularly surrounding the viability of the samples for transplantation (Edozien 2006; Mohr et al. 2012). Finally, UCB can be collected for both types of banks within specific NHS hospitals. However, donor co-ordinators are employed by the public banks to carry out the collections, whereas phlebotomists are contracted by pregnant women to collect the UCB to be stored in commercial banks (Edozien 2006; Machin, Brown, and McLeod 2012).

Despite these differences between the types of banks, the process of collection by the donor co-ordinators or phlebotomists, is thought to be similar. The midwife or obstetrician places the umbilical cord in a dish, which is handed over to the donor co-ordinators or phlebotomists, who may or may not be permitted inside the labour room. Therefore the collection process may be conducted in a sluice or dedicated collection room within the hospital (Machin, Brown, and McLeod 2012). The donor co-ordinators or phlebotomists clean the cord, hang it from a hook, and place a needle in the cord, so the blood is predominately gravity-fed into a UCB sample bag (Jones et al. 2003; Davey et al. 2004).

However, what happens *inside* the labour room immediately prior to this can vary across hospitals. In particular, once a baby is born, the umbilical cord is clamped twice, one close to the new mother and the other close to the baby. In 2010, a survey reported that 74 percent of obstetricians and 41 percent of midwives in the UK clamped the cord within 20 seconds after a baby was born (Farrar et al. 2010). Such practice was conducted as part of a range of activities to facilitate control over the uterus and the delivery of the placenta in the final stages of labour, thereby reducing the risk of the woman haemorrhaging (Regan, Bewley, and Warwick 2008; Downey and Bewley 2012; Duley and Batey 2013; Royal College of Obstetricians and Gynaecologists 2015). Yet, some midwives and obstetricians are waiting to

clamp the cord, leaving it to pulsate between two to five minutes after the baby is born. Midwives and obstetricians are justifying this shift in practice by claiming that it is 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; Royal College of Obstetricians and Gynaecologists 2015).

The decision of when to clamp the cord does not happen in isolation and is both influential of, and influenced by, how the third stage of labour is managed. In particular, a woman in labour may opt for an 'active' third stage of labour. This includes the umbilical cord being clamped within 30 seconds to a minute after her baby is born, and an injection of drugs with the aim of prompt delivery of the placenta (Downey and Bewley 2012; Duley and Batey 2013; Brown 2013). Alternatively, a woman may choose a 'physiological' third stage of labour, which can mean 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; National Institute for Health and Care Excellence 2014).

For the stakeholders in UCB collection and banking, the maternity practices of clamping the cord and management of the third stage of labour have become of intense interest as each are considered as having implications for the collection of 'quality' UCB samples.

## **Methodology**

The data used in this article is the result of a two-year project funded by the [removed for double blind review] to explore the policy and practice implications arising from the introduction of the UCB banks.

## ***Participants***



Potential professional and lay stakeholders were initially identified from the published literature on UCB and were deemed “relevant” due to their existing or emerging role in the debates surrounding UCB collection and banking (Pinch and Bijker 1984) *(for a visual interpretation of the stakeholder groups, see Machin, Brown and McLeod 2012)*. Additional professional and lay stakeholders were identified via interviewees’ suggestions. Lay stakeholders - women and men who had or were considering storing UCB, in either a commercial or public bank in England - were recruited through advertising on local and national websites, in parent and child magazines, and with the assistance of UCB banks.

### ***Ethical Approval***

Ethical approval was granted by the University institution [removed for double blind review] and the NHS National Research Ethics Committee. In addition, the governance requirements for nine NHS hospitals in England were met.

### ***Data Collection***

A total of 68 people were approached to take part in the project. Two declined to participate in the project due to time commitments, and four did not respond to the recruitment email. Sixty two interviews were conducted over 17 months between 2009 and 2010 *with professional and lay stakeholders (see Table 1)*. A focus group with independent midwives (8) was also conducted during this time. *The purpose of this paper is to explore how those working within the UCB sector and on maternity wards discuss maternity practices in light of the recent drive for collecting ‘quality’ UCB. As a result, the interviews from these stakeholder groups are drawn heavily upon throughout the paper. The experiences of pregnant woman and parents of UCB banking are considered elsewhere (see Machin, Brown and McLeod 2011; Machin, Brown and McLeod 2012)*.

Informed consent was obtained from all individual participants included in the study. The interviews were semi-structured in order to provide rich and in-depth data. This also allowed participants and the interviewer the freedom and flexibility to follow up topics that might not initially have been considered on the interview guide (Holstein and Gubrium 1995; Kvale 1996). The interview guide covered the roles and relationships within UCB banking, as well as discussion of maternity practices (see Table 2). Each interview lasted between 60–120 minutes and were recorded, and transcribed in full.

### ***Data Analysis***

Each transcript was coded for themes using the qualitative data package, Atlas ti. Initially, codes reflected very broad themes, such as ‘portrayal of UCB banking’ and ‘portrayal of UCB,’ and were refined with each reading of the transcripts, for example ‘priorities for UCB.’ On average, each transcript was read three times, with new codes emerging with each reading, such as ‘portrayal of maternity practices’ (see Diagram 1). Importantly, any “unexpected issues” (Seale and Kelly 1998) that emerged during the reading of the data, for example ‘compromises’ and ‘conflicts,’ were also acknowledged and resulted in further refinement of the codes. Throughout the project, analytical summaries and interview transcripts were compared and discussed between the research team to enhance the data analysis.

### **Findings**

#### ***Structure of the Article***

It became apparent from the emerging coding that participants perceived a number of ‘problems’ when discussing the collection of ‘quality’ UCB and maternity practices that they were trying to reason through. For some participants, the problems were presented as conflicts, or involving a negotiation between competing priorities, or requiring a compromise.

It would therefore be appropriate to frame the findings of this article within a decision-making tool that aims to “facilitate answers to the question ‘what should I do?’ in the specific context of institutional health care delivery” (Steinkamp and Gordijn 2003).

This is a novel approach to the field of UCB collection and banking as it is designed to be used by health care practitioners to consider clinical and ethical matters jointly. Clinical pragmatism is a flexible method of problem solving through a process of inquiry, discussion, negotiation and reflective evaluation (Fins, Bacchetta, and Miller 1997). Clinical pragmatism is not a point of view, but rather a way of understanding and responding to complicated ethical issues in health care (Fins and Bacchetta 1995). Crucially, the method focuses upon the nuances of the problem, which in turn “illuminates the thinking of practitioners, the expectations of patients...and the clinical and institutional forces...” at play (Fins and Bacchetta 1995). It is democratic in its approach, with no stakeholders’ viewpoints being considered more significant than others (Fins, Bacchetta, and Miller 1997).

For its critics (Jansen 1998), the purpose of clinical pragmatism may only be to augment clinical thinking to a dilemma. Yet, it still provides insight into the interplay between stakeholders (Steinkamp and Gordijn 2003) and therefore how this plays out in policy and practice development. Therefore, this article follows stages of the clinical pragmatism approach, from the ‘problems’ emerging for stakeholders, their assessment of the relevant facts, through to the options and negotiation throughout the problem-solving enterprise, concluding with an evaluation of the results.

### *Diagnosing the (Moral) Problem*

From a clinical pragmatist perspective, a moral problem in health care is evident when people are conflicted over how to proceed in response to patient care (Fins, Bacchetta, and Miller 1997; Steinkamp and Gordijn 2003). There were three ‘patients’ apparent during participants’

interviews: the new mother; the newborn baby; and the blood disease sufferer. How explicit each 'patient' was referred to varied across participants' interviews and offered insight into their priorities for the UCB. Participants presented a number of conflicts around the care of these three patients, which were at various stages of resolution. In particular, when participants discussed the clamping of the umbilical cord, the conflict existing between acquiring a 'quality' UCB sample for the blood disease sufferers and concerns for maternal and neonatal health was presented as unresolved. For example, a paediatric haematologist at a hospital based in the North of England claimed that clamping immediately after a baby was born meant a larger volume of blood remained in the umbilical cord. As a result, more blood was available to collect for the UCB sample, in comparison to postponing clamping that led to less blood in the cord to collect. For this participant, the *timing* of when the umbilical cord was clamped influenced the 'quality' of UCB samples, but also acknowledged "the only issue that we might have a concern about is the impact (of clamping) on the mother and the baby..." (P87). Therefore the timing of clamping also had the potential to influence the well-being of new mothers and neonates. For this haematologist, there was a restricted amount of blood within the umbilical cord and therefore an optimal time to clamp the cord existed according to which 'patients' were considered a priority – the new mother and neonate, or the blood disease sufferer.

Yet, indirectly, by participants discussing the implications of cord clamping on UCB collection, an additional, related problem emerged, whereby maternal health was pitched as in competition with the neonate's health, as the following quote from a senior policy maker illustrates;

There is the question about clamping itself...It's there for very practical reasons to stop mothers bleeding to death. However, there's still a debate to be had around what that

means for the child and when is the optimum time to clamp and if you clamp early what effect that has on the child in later life. (P13)

The policy maker presented the purpose of clamping as to avoid new mothers haemorrhaging, but created the possibility that the practice could have negative implications for the long-term health of babies. As a result, it can be inferred that the participant did not accept that the stated purpose of cord clamping to protect new mothers from haemorrhaging overruled newborn babies' needs. However, the participant avoided prioritising either 'patient' when claiming that an 'appropriate' time to clamp the umbilical cord remained unknown.

The uncertainty around the timing of cord clamping was at the heart of the conflict for the care of blood disease sufferers, new mothers and their babies. Such uncertainty was reflected in the varying terminology participants used when discussing the timing of clamping i.e. early, delayed, immediate, postponed, as well as how these clamping practices were categorised. Yet, participants still presented it as not being possible to clamp the umbilical cord at a time that was mutually beneficial to all three 'patients.' In essence, to acquire the volume for a 'quality' UCB sample to treat the blood disease sufferer, it was claimed that the umbilical cord needed to be clamped at a time that was also beneficial for the new mother to avoid her haemorrhaging, but the long-term impact on the newborn baby's health was unknown. Therefore, the problems surrounding cord clamping were discussed as unresolved. The lack of resolution appeared to stem from the disputed 'facts' surrounding the practice, in particular the purpose of cord clamping, which is discussed next.

### *Assessing the Relevant Facts*

In clinical pragmatism, the 'facts' can relate to an individual patient's case, as well as taking into account the norms that exist around a specific problem (Fins, Bacchetta, and Miller 1997). These norms may derive from health care professionals' opinions, the wishes of patients and

their families, as well as “issues of power or conflict, and institutional factors.” (Steinkamp and Gordijn 2003)

When discussing the problem of acquiring the volume of UCB for a ‘quality’ sample and protecting maternal and/or neonatal health, participants critically evaluated the relevant ‘facts’ of umbilical cord clamping within the context of the management of the third stage of labour. In particular, participants queried the norms surrounding cord clamping and the management of the third stage of labour, which in turn enabled them to cast doubt over the purposes of the practices. For example, a focus group with independent midwives based in the North of England discussed the rationale underlying clamping the umbilical cord ‘immediately’ as part of ‘active’ management of the third stage of labour, which can also include women receiving an injection to facilitate the delivery of the afterbirth,

iv1: 30 years ago they started routinely bringing in clamping and they said, babies become over-transfused. Well, they weren’t over-transfused before millennia up until that point...

iv2: I heard them [midwives] say to women do you want an injection that stops you from bleeding heavily when we deliver the afterbirth. I mean, who is going to say no to that...

iv1: And now a reason cited that women give for why they want to have the injection is to speed it up. Now, that’s got to come from a convenience of staff. You can’t have a woman hanging around on a labour ward for five hours. (P16)

The first participant implied that clamping the umbilical cord was a relatively new phenomenon when she stated that the practice was introduced “30 years ago,” and reinforced this portrayal when she compared it to practices “before millennia up until that point.” The division in time that the independent midwife constructed in the quote enabled her to create the image of clamping within active management as lacking ‘evidence.’ As a result, the purpose

of clamping within active management i.e. to avoid “babies becom[ing] over-transfused” is brought into question. Furthermore, the first participant claimed that clamping within active management practices were “routine,” which suggested that they were implemented irrespective of new mothers’ individual needs. Instead, the purpose of active management practices, such as clamping and an injection to facilitate delivery of the afterbirth, were implied to benefit hospital staff. Consequently, institutional factors, such as lack of staff and bed shortages, were conjured when the independent midwives described components of active management as convenient for hospital staff and to avoid “women hanging around on a labour ward.” The depiction of the purpose of active management practices as convenient for hospital staff also undermined the implied health professionals’ beliefs of active management practices claimed by the second independent midwife - “an injection that stops you from bleeding heavily...” In turn, the labouring women’s wishes to have an injection “to speed it up” were delegitimized. The independent midwives implied that if women were aware of the ‘true’ purpose of active management practices i.e. convenience for hospital staff, they would be less likely to agree to them taking place. Moreover, if the practices of active management are not carried out to protect maternal health, then doubt is cast over whether they should be conducted at all, and we are led to question what implications they might have for maternal and neonatal health. Such doubt and questioning have the potential to be significant for the collection of a ‘quality’ UCB sample as there would be less blood available in the umbilical cord to collect if active management was not carried out, and the presentation of physiological management of the third stage of labour could be viewed as beneficial to maternal and neonatal health.

When participants were asked about the potential benefits of physiological management practices, which can entail ‘deferring’ clamping the umbilical cord, they frequently referred to the ‘evidence’ surrounding it. Whilst participants acknowledged the

existence of 'evidence' relating to the physiological management practices, they were keen to highlight its limitations, which generated uncertainty over the purpose of the practices. One such limitation was how 'applicable' the evidence was to the context being addressed.

For example, a director of a commercial UCB bank discussed deferring cord clamping when aiming for a 'quality' UCB sample,

There is a view that when baby is born some people will eat the placenta. Some people will take the placenta and bury it in the garden. Some people will insist that the placenta is attached to the baby until it is delivered. Strange things like that. Current medical practice in most of the developed world is that a baby is born, the cord is clamped. (P3)

The reference to the "developed world" in the extract implied that the other practices, such as eating or burying the placenta, were carried out in the developing world, of which deferred cord clamping – "Some people will insist that the placenta is attached to the baby until it is delivered" – was associated with. The participant shrouded the practice of deferred cord clamping in mystic by comparing it to other "strange" actions with the placenta once a baby is born. In effect, deferred cord clamping was something to be viewed as exotic and unusual within the developed world, which created an uncertainty around the purpose of the practice. When the director framed immediate cord clamping – "a baby is born, the cord is clamped" – as within "current medical practice," it positioned deferred cord clamping as outside of it and instead associated it with 'non-medical' or 'outdated' medical practices. The distinction of 'non-medical' or 'outdated' medical practices proved useful for the director of the UCB bank as it positioned deferred cord clamping as lacking a 'medical' basis for its application in the developed world. Conversely, immediate cord clamping was not implied to be detrimental to the health of babies born in developed countries, like UK, and in turn made collecting UCB for blood disease sufferers after immediate cord clamping had taken place, as acceptable. It appeared therefore that when faced with the conflict of caring for all three patients when



clamping the umbilical cord, some participants, such as independent midwives and the UCB bank director, adopted polarised positions i.e. immediate or deferred clamping was deemed to be harmful for either maternal or neonatal health. Yet, when asked how to overcome the opposing viewpoints to the conflict, participants, including the independent midwives and the UCB bank director, proposed a number of options that acted as compromises. A closer look at these compromises provided insight into participants' goals for patient care i.e. which patient's health was considered priority in the conflict, as well as suggest that a series of negotiations had taken place.

#### *Goals, Options, and Negotiating a Decision*

The clinical pragmatism approach proposes that the goals of care are agreed between stakeholders and plausible ways to proceed in the conflict are considered (Fins, Bacchetta, and Miller 1997). Discussions around the collection of 'quality' UCB samples implied the health of blood disease sufferers as a goal of care, and initiated the protection of maternal and neonatal health as an additional goal of care for participants. Whilst these goals of care were agreed between participants, they were also prioritised, as a quote from a mother who had stored UCB in a commercial bank illustrates, "...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..." (P69). For this participant, the hierarchy of goals were the safety of mother and baby, then collecting UCB. UCB for blood disease sufferers as a secondary concern to protecting maternal and neonatal health was also explicitly agreed upon between participants, for example an obstetrician stated, "The most important thing, like most things in life, is actually the baby being born. The UCB banking actually is a secondary issue" (P65) and a director of a commercial UCB bank claimed, "...the priority is to mum and baby" (P4). Echoes of this prioritisation was also apparent in the discourse of those whose work was associated with UCB treatment, as the following extracts from a senior policy maker

and public banker respectively demonstrates, “Plainly the priority of UCB is to service the baby...any guidance on collection has to give absolute priority and primacy to the baby and the mother” (P7) and “...even taking time to do the clamping I think it’s enough blood to have a clinical unit for transplant to a patient” (P1).

In order to achieve these agreed goals, a number of options were discussed, which revolved around the timing of clamping the umbilical cord and the volume of UCB collected. For example, the director of a commercial UCB bank, a public bank member, and two obstetricians at hospitals in Southern England proposed a cap to the volume of UCB collected for a ‘quality’ sample to treat blood disease sufferers. In the data, reference to 40mls as the required value for a ‘quality’ UCB sample to treat blood disease sufferers was accepted by all participants, and as a consequence, created a flexibility regarding the timing of when the umbilical cord could be clamped, as a quote from an obstetrician illustrates, “...in fact you might be able to get to some kind of compromise that we clamp for a minute and then you get 40mls” (P63).

The flexibility appeared to stem from a desire to help blood disease sufferers via UCB collection, as well as the neonate by prolonging the passing of blood through the umbilical cord before clamping it. Yet, clamping would take place to avoid risking the health of the mother. In the quote, the obstetrician implied that the UCB itself might contain beneficial properties for the neonate. This potential in UCB was recognised by a woman who had paid to store UCB in a private bank, and a member of a public UCB bank who both described how the third stage of labour was adapted so that the ‘beneficial’ elements from ‘deferring’ clamping the umbilical cord were generated, as well as the advantages of immediate clamping for UCB collection being established, “...we are taking time to clamp the cord...i think it’s enough blood to have a clinical unit for transplant to a patient” (P1) and, “...she [midwife] 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” (P53).

The idea that the blood inside the umbilical cord could be beneficial to the neonate's health after being born had the potential to portray UCB collection and immediate cord clamping in a negative light, especially when the agreed goal of care between participants was maternal and neonatal health as priorities. Therefore the option to limit the volume of UCB as proposed by a commercial UCB bank director created the image of a 'small' proportion of the available blood being collected, which would not jeopardise the neonate's health, "...You drain as much [UCB] as you like into that baby. There's plenty. That placenta puts out an enormous amount. We only need 40ml" (P4).

However, whilst the option to restrict the volume of UCB collected was universally agreed upon by participants, the option to combine elements of immediate and deferred cord clamping was presented as potentially risky to maternal health as two quotes from midwives illustrate,

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] (P16)

And, "...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..." (P76)

Although mixing management was often proposed by participants, the riskiness of this option made it difficult for participants to fully support it when faced with the conflict to collect 'quality' UCB. In contrast, the option to limit the volume of UCB collected was presented by participants as having little or no interference to maternity practices i.e. midwives and obstetricians could decide whether to conduct immediate or deferred cord clamping, and was therefore presented as the better option.

This difference in acceptance over the two options is significant as both were presented by participants as compromises – "we only need 40ml" and "halfway house" – but only one was

accepted. In essence, these proposed compromises were forms of negotiation over the UCB itself and who should benefit from it i.e. the neonate or blood disease sufferer, between those involved in UCB collection practices and those carrying out maternity practices. The results of these negotiated compromises are evaluated next.

### **Conclusion: Evaluating the Results**

This study has advanced understanding of the current debates surrounding the collection of UCB through adopting a clinical pragmatist approach and interpreting the findings within compromise literature. This is achieved by considering the relationships between those in the UCB banking sector and those conducting maternity practices. The clinical pragmatist approach highlighted that key stakeholders involved in the collection of UCB are positive regarding the protection of maternal and neonatal health, whilst those conducting maternity practices are not opposed to facilitating the collection of 'quality' UCB. Therefore previous portrayals of midwives and obstetricians as opposed or objecting to UCB collection were challenged, and emerging areas of potential agreement between previously opposed stakeholders (Fins, Bacchetta, and Miller 1997) have been identified. For the UK government and policy makers, awareness of such areas could prove useful when attempting to shift debate forward in the drive for 'quality' UCB.

Midwives, obstetricians, and UCB bankers attempted to find a way for UCB to be collected without jeopardising maternal and neonatal health. This compromising aspect of the options, in particular the consideration of other stakeholders' needs or requirements, suggested midwives, obstetricians, and UCB bankers acknowledged the 'significance' of their place in the debates surrounding the collection of 'quality' UCB (Nachi 2004; Menkel-Meadow 2006). In effect, if midwives, obstetricians, and UCB bankers did not deem each other to be

influential in the debates, then there would be little motivation to compromise their own requirements in an attempt to meet others' demands.

By adopting a clinical pragmatist approach, this study has also brought hidden nuances arising from the debate surrounding the collection of 'quality' UCB to the fore, which highlight how policy and practice are influenced today. For example, participants challenged the evidence available on the importance of deferred cord clamping for neonates born in Western Societies. It was surprising therefore for participants to agree upon the option that facilitated some UCB being passed to the neonate. This option required the activities of those involved in UCB collection to be restricted and limited in some way. Equally, the alternative option of mixing management of the third stage of labour required a shift in maternity practices, and was therefore opposed mostly by those conducting maternity practices. This is telling because it suggests that those powerful in the debates are those conducting maternity practices (Steinkamp and Gordijn 2003; Arnsperger and Picavet 2004; Menkel-Meadow 2006). In contrast, UCB bankers have less influence within the debates, perhaps arising from the lower priority of UCB collection in the goals of patient care highlighted via the clinical pragmatist approach. The power imbalance between stakeholders found in this study supports previous commentary on UCB banking (Fisk and Atun 2008) which positioned midwives and obstetricians in influential positions in determining the future of UCB collection. As the drive for 'quality' UCB intensifies, so too does the need for the UK government and policy makers to engage with these powerful stakeholders.

But the balancing of power can shift between stakeholders, if understanding around particular practices shift in light of emerging evidence (Papilloud and Rol 2004; Hussenot 2010). Adopting a clinical pragmatist approach has flagged two aspects of the debates surrounding the acquisition of 'quality' UCB that have the potential to challenge current understanding and therefore shape power dynamics between stakeholders. Firstly, the

purpose of cord clamping was destabilised when participants challenged the 'evidence' for its application. Participants in this study questioned if the purpose of cord clamping was to protect the new mother's health – "stop women bleeding heavily;" facilitate the health of the neonate – "prevent babies from becoming over-transfused;" or relieve the blood disease sufferers – "enough blood for a clinical unit." Future findings from research being conducted by midwives and obstetricians regarding the implications of cord clamping on neonates (Mercer and Erickson-Owens 2014) will undoubtedly contribute to, and continue, the destabilisation of understanding surrounding the purpose and practice of cord clamping, which in turn has the potential to influence and undermine the present balance of power between stakeholders (Papilloud and Rol 2004; Hussenot 2010).

Secondly, underpinning participants' discussions of a 'quality' UCB sample was the assumption that clamping 'immediate' enabled a larger volume of blood to remain in the umbilical cord, which left more blood to be collected. Conversely, if cord clamping was deferred, it was assumed that there would be less blood in the umbilical cord for collection (Andersson et al. 2011; Burgess and Hilton 2012). Therefore, in practice, the collection of a 'quality' UCB sample was dictated by the timing of cord clamping, and the volume of blood collected determined a 'quality' UCB sample. However, participants in this study undermined this assumption when they discussed the option to restrict the volume of UCB collected, which they described as still permitting a 'quality' UCB sample to be achieved, without imposing upon the timing of when the cord is clamped.

The findings from this study suggest further research is needed to explore the meanings surrounding 'quality' UCB samples in stem cell treatments **and to include the voices of those involved in using UCB in treatments, which were not included in this study**. Such research has the potential to also undermine the existing balance of power between stakeholders if understanding regarding practices that determine a 'quality' UCB sample shift.

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