

Hybrid cord blood banking in a private-public-partnership: Women's perspectives

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Abstract

Background: The increasing demand for umbilical cord blood (UCB) used in stem cell transplantation led to the establishment of cord blood (CB) banks worldwide. These include public foreign donor banks and private family-directed donor banks. Recently, our department has introduced a third banking model within a private-public-partnership. This hybrid banking allows for storage of family-directed CB units, while also getting Human leukocyte antigen (HLA)-typed and included in the national stem cell donor registry. So if the need arises, the HLA-compatible CB unit can be released to an unrelated recipient as a foreign donor stem cell graft.

Objectives: The aim of this study was to evaluate women's perspectives on the different CB banking options as well as retrospective satisfaction with their decisions.

Methods: We performed a prospective survey study in postpartum women, using a validated questionnaire.

Results: A total of 157 women were included in this survey study; 68% of them decided to have their UCB stored or donated. Among those women, 25% of them opted for hybrid storage, 72% of respondents stored UCB publicly, and 3% decided for private family-directed storage.

Conclusions: Our study shows the potential of hybrid banking as an attractive UCB storage option, as an alternative to family-directed banking rather than a substitute for public donation. Hybrid storage potentially combines advantages of family-directed banking as well as unrelated CB donation expanding the number of registered CB units available for transplantation and giving every pregnant woman the possibility to store UCB.

KEYWORDS

hybrid umbilical cord blood banking, umbilical cord blood banking, umbilical cord blood stem cell transplantation

Abbreviations: CB, Cord blood; HLA, Human leucocyte antigen; UCB, Umbilical Cord Blood.

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1 | INTRODUCTION

Stem cells from umbilical cord blood (UCB) have been successfully used for transplantation in hematopoietic diseases for many years. UCB is a viable alternative to the transplantation of bone marrow or mobilized peripheral blood progenitor cells.^{1,2} It can be collected after birth from the umbilical cord and placenta without any risks for mother and baby. After harvesting, UCB can be stored for years, providing a readily available source of stem cells for subsequent transplantation. In comparison to adult-sourced stem cell grafts, UCB transplantation has a lower incidence of graft-versus-host disease due to lower immunogenicity. Currently, the use of CB transplants is being investigated for a wide range of other conditions such as diabetes, cerebral palsy or spinal cord injury, showing potential for extended clinical application in the near future.^{3,4}

Until recently, two options of CB banking have been available in Switzerland: A. Public donation for unrelated patients in need of a stem cell graft (HLA-type is registered in a public database) and B. Private family-directed banking, where CB stem cells are exclusively stored for one's own child or first-degree relatives like siblings or parents (no third-party donation possible). These two options differ significantly in their organization and financing. Public banking is organized by public institutions (Swisscord, a commission of the Swiss Red Cross Transfusion organization, and participating public hospitals), whereas private banking is run by private health technology companies. In the case of public donation (unrelated stem cell transplantation), the costs in Switzerland are covered by a money fund consisting of health insurance reimbursements for foreign donor stem cell transplantations. Therefore, there are no expenses for the parents. Private banks are raising a storage fee for private family-directed CB storage, which must be fully covered by the parents.

At present, there are approximately 4 million family-directed CB samples stored in private facilities worldwide, while about 800'000 CB samples are stored in public banks.⁵ However, public banks have released 30 times more units for transplantation than private banks.⁶ The major reason is the currently small likelihood of the donor himself or first-degree relative developing a disease, which can be treated with autologous stem cell transplantation. Furthermore, due to strict inclusion criteria regarding a high minimal nucleated cell count threshold in the CB, around 80% of CB collections for public donation are discarded prior to being cryopreserved and stored.⁶ This is in contrast to private storage, where stem cells nearly always get stored, as it is argued that the minimum cell count is significantly less relevant

in autologous transplantation or treatment of diseases, where tissue regeneration is the aim of transplantation. Only in rare cases, with very low cell count, the collected CB needs to be discarded in the private banking setting.

From a woman's point of view, discardment of her child's CB after collection and previously having passed the selection process for public CB donation, is frustrating. This, in turn, makes private family-directed storage more attractive.

Unfortunately, due to relatively high costs, organizational complexity, and high-quality standard prerequisites, public CB donation is currently only being offered at four public hospitals in Switzerland in the following cities: Aarau, Basel, Geneva, and Berne.

We introduced a third banking method at our hospital center, called hybrid banking, within a framework of a public-private partnership project. Hybrid banking combines elements of options A. (public banking) and B. (private banking) and includes family-directed CB collection. However, the HLA-type is determined in the family-directed samples in order to include it in the foreign-donor registry, making it accessible to unrelated patients worldwide, if quality standards are met. When an unrelated patient needs specific HLA-compatible stem cells stored according to the hybrid model, the parents may opt to release the CB unit for transplantation to the respective patient, waiving their original rights on the CB of their child. Initial costs for CB collection and storage are covered by the parents, similarly to private family-directed banking, yet the parents are being reimbursed when stem cells are released for transplantation in an HLA-compatible unrelated patient.

Applying the hybrid banking model is expected to come with several advantages: It increases the HLA-registry and thus the possibility of allogeneic donations. Hybrid banking allows parents to store CB of their child for family-directed transplantation, while still having the opportunity to release it as a benevolent donation. A further benefit is the high probability of the CB being stored. If the nucleated cell count is not sufficient for inclusion in the foreign donor CB registry, the CB is stored as a family-directed sample. Therefore, from a parent's perspective, hybrid banking combines the advantages of foreign donation as well as family-directed banking.

Extending the donor registry will not only enhance the ability of finding a match, but will also allow a better knowledge on the therapeutic potential of CB transplantations. Eventually, parents should be offered tailored CB storage options in the future. This would have the advantage, for example, of CB specifically being collected from identified at-risk individuals as a preventive measure at birth.

The Department of Obstetrics and Gynecology at the University Hospital of Berne is the first to introduce this form of hybrid banking in Switzerland. In addition to public and private storage, pregnant women have now been offered all three banking options and could thus decide according to their preferences.

1.1 | Objective

The aim of this study is to evaluate women's perspectives on the different CB banking options, especially on the newly established hybrid banking method, as well as to elucidate their motivations to opt for a respective banking model.

2 | METHODS

The study was designed as a prospective survey. A structured, previously validated questionnaire was handed out to postpartum women at the University Hospital of Berne. Women giving birth in the institution were asked if they wanted to participate in the evaluation study 2–3 days postpartum. After giving written informed consent, they were requested to fill in the form (time needed: 15 min). The questionnaires were preferably collected before being discharged from the clinic. If an outpatient birth was planned, a stamped envelope was distributed, and the women were asked to return the survey within the first two weeks postpartum. Women were included in this survey study from November 2021 until June 2022. Subsequently, an analysis of the questionnaires was performed.

The study was formally exempted from ethical approval by the cantonal ethical committee of the Canton of Berne.

2.1 | Study population

Participants were postpartum women hospitalized at the University Hospital of Berne. Sociodemographic factors such as age, nationality, and mode of delivery were obtained from their medical records. All participants were aged between 22 and 42 years with sufficient German language skills (as in sufficient knowledge of vocabulary in order to express themselves and to be able to extract and understand written information). Exclusion criteria were twin pregnancies, pregnancies with intrauterine growth restriction, and preterm births. According to the chosen banking method, the participants were divided into subgroups.

2.2 | Study questionnaire

This prospective study was conducted using a questionnaire containing closed as well as open questions. The standardized questionnaire was distributed to postpartum women at the University Hospital of Berne. The survey was only available in German, therefore sufficient German language skills were required for inclusion.

The survey was divided into three sections. The first section contained questions on whether the participants opted for UCB banking in general and if so, which model (public, private, or hybrid) they had decided for. Furthermore, the participants were able to state why they had chosen accordingly. For each given statement, participants could indicate whether it applied to them strongly, predominantly, rather not or not at all. In a free text field, the interviewees also had the opportunity to name other reasons not mentioned above.

The second part of the survey included general questions concerning satisfaction with the information brochure as well as with the decision taken. The participants were also asked whether they would consider CB banking again in case of further pregnancies.

The third part focused on how women learned about UCB donation/storage.

Furthermore, the respondents were asked about their professional occupations. Finally, they had the possibility to add their personal comments too.

2.3 | Information brochure

The information brochure (see appendix) distributed in advance provided information on indications for stem cell transplants as well as the advantages and disadvantages of umbilical cord blood stem cells compared to bone marrow or peripheral blood stem cells. The brochure further explained the three storage options available, described how stem cells are harvested from the umbilical cord and which prerequisites and quality requirements must be met. In addition, the expecting parents were educated about the costs, genetic tests carried out as well as their obligation to inform the bank in case of any relevant changes in their own or respective child's medical history.

3 | RESULTS

3.1 | Banking method of choice

In total 175 questionnaires were returned, of which 157 could be included in this study. Reasons for exclusion were a mainly missing or incompletely filled in informed

consent. More than two-thirds (68%, $n = 106$) of the women surveyed, opted for stem cell storage. 72% ($n = 76$) of them donated their CB to the public inventory, while 25% ($n = 27$) chose hybrid banking. Only a minority of 3% ($n = 3$) opted for private storage (Figure 1A,B).

3.2 | Sociodemographic factors

All participants were postpartum women. Mean age was comparable in all subgroups, only women who opted for hybrid banking were slightly older on average (Figure 2: 33.4 years vs. 34.6 years). Overall, the women were well educated (university graduates or degree holders from a higher technical college), around 65% ($n = 102$) were academics and 21% ($n = 33$) worked in the health care sector. Among the women who rejected CB donation or storage 60% ($n = 31$) held an academic degree, whereas 67% ($n = 71$) of the women opting for CB donation or storage (public, private, or hybrid) had completed a university degree or were alumni of a higher technical college. Among both groups, the proportion of women with a medical background was similar (rejection of CB donation 21.6% ($n = 11$) vs. donation/banking (hybrid, public, private) 20.8% ($n = 22$)). Mainly well-educated persons or people working in the medical field opted for hybrid banking. Public donation was chosen by a mixed population (from school-leaving certificate, apprenticeship certificate to university degree). The majority of women who chose to get their CB stored privately had an academic background (67%, $n = 2$).

Of the 157 women surveyed, 116 (74%) were of Swiss nationality (defined by citizenship), while 41 (26%) women were of other citizenship (mainly European, a minority consisted of respectively 9.8% of women from African countries and Russia). Among the Swiss women, 47% ($n = 54$) opted for public banking, 18% ($n = 21$) for hybrid banking and one participant decided to bank privately. Around 34% ($n = 40$) of the Swiss women declared they had neither donated nor stored CB. Among

the Non-Swiss respondents, more than half (55%, $n = 22$) opted for public banking and only 25% ($n = 10$) rejected storage or donation. A similar number of women (15%, $n = 6$) as their Swiss counterpart (18%, $n = 22$) opted for hybrid banking. Two Non-Swiss females chose private storage (Table I). Non-Swiss citizens were, in relation to the total number of persons in each subgroup, nearly equally distributed (29% in public donation vs. 22.2% in hybrid storage).

3.3 | Reasons for public banking

Almost all women (*applies strongly*, 97%, $n = 74$) who chose public donation stated altruistic thoughts as the main reason for their choice. About 80% (*applies strongly or predominantly*, $n = 60$) of women opted for public banking, as access to stem cells via the public registry is still possible, in case of personal need. Financial reasons seemed to have been of minor relevance, as less than 50% (*applies strongly or predominantly*, $n = 35$) cited freedom from costs as a reason for their decision (Figure 3). Other reasons for public donation mentioned in the free text field were that the donation can support research, as well as human lives potentially being saved without any disadvantages for the donor. Additionally, another

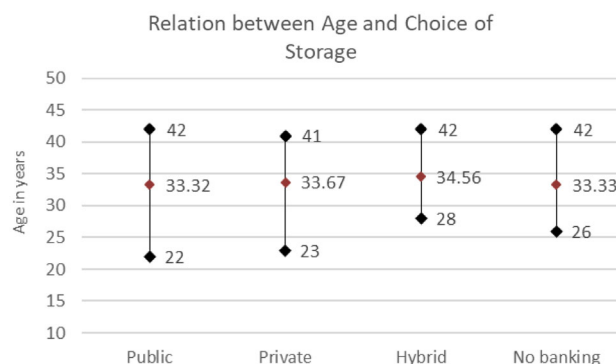
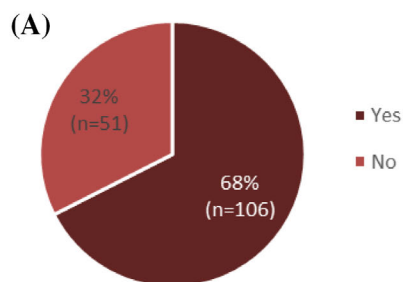


FIGURE 2 Relationship between age and banking method.

Participation in Umbilical Cord Blood Donation



Type of Donation

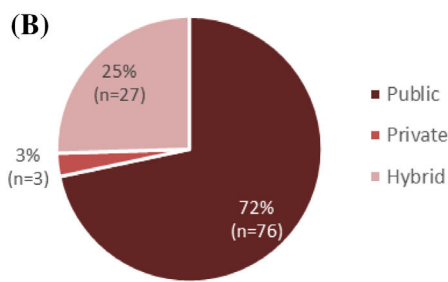
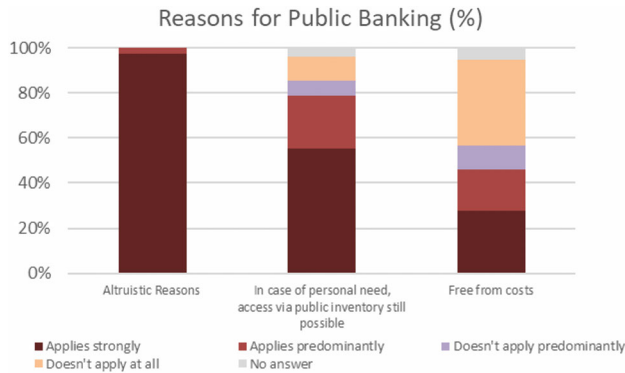


FIGURE 1 (A) Participation in UCB donation, (B) Type of Donation.

TABLE 1 Nationality and choice of banking method.

Nationality	Total: 157	Public	Hybrid	Private	No banking
Swiss	116 (100%)	54 (47%)	21 (18%)	1 (1%)	40 (34%)
Non-Swiss	40 (100%)	22 (55%)	6 (15%)	2 (5%)	10 (25%)
No answer	1 (100%)	0	0	0	1 (100%)

**FIGURE 3** Reasons for public banking.

interviewee stated that hybrid donation had been an alternative option, but she ultimately opted for public donation, as hybrid storage is not free of costs and storage fees are currently relatively high, compared to the potential risk of needing UCB.

3.4 | Reasons for hybrid banking

All women (*applies strongly* or *applies predominantly*, $n = 27$) who had opted for hybrid storage cited freedom of choice, and the possibility to donate later, as major reasons for their decision. Around 74% of patients stated that financial reasons played a very important (33%, $n = 9$) or rather important (41%, $n = 11$) role in the decision process. Furthermore, about 80% (*applies strongly* or *predominantly*, $n = 22$) of women agreed with the high probability of CB being stored as an additional motive (Figure 4).

3.5 | Reasons for private banking

Only 3% ($n = 3$) of women opted for private storage. One of the privately stored UCB units was used for direct CB donation (collected umbilical cord stem cells were donated directly to a family member, who suffers from a hematopoietic disease). The exclusive right over stem cells seems to play an important role in the decision-making for private storage, as well as the confidence that umbilical cord stem cell transplantation can be used to treat and possibly heal other diseases in the future (figure not shown).

3.6 | Reasons for rejection of CB banking

32% ($n = 51$) of all women interviewed, decided against CB banking in general. As a reason, 24% ($n = 12$, *applies strongly or predominantly*) of the non-donors indicated a lack of interest. Another 24% ($n = 12$) cited financial considerations as a motive. Ethical/ religious concerns seemed to hardly play a role in the decision process, as only one person stated accordingly. 18% ($n = 9$) mentioned a lack of information as a reason for their non-participation, which is perhaps related to the fact that not all participants had been provided with the information brochure in advance (Figure 5A). A large part of the women did not quote any of the four suggested answers above as a reason for rejection, as they gave no answer, but 41% ($n = 21$) of non-donors mentioned other reasons. A frequently mentioned motive was the wish for the umbilical cord to be pulsed out (19%, $n = 10$). Three women (6%) stated that they would have liked to donate but were unable due to a very rapid birth. Further reasons for rejection of CB storage mentioned in the open text field were uncertainty regarding safety or risks for the child and indecisiveness at the time of delivery (Figure 5B).

3.7 | Information on banking options

Participants received an information brochure on the three storage options prepartum. 62% ($n = 97$) of respondents stated that they were very satisfied with the information brochure distributed. 15% ($n = 24$) were mostly satisfied, while only 3% (*doesn't apply predominantly or at all*, $n = 5$) were not content. 13% ($n = 20$) of women indicated that they had not received a brochure (figure not shown).

The information leaflet served for 71% ($n = 112$) of the respondents as a basis for the decision-making process (figure not shown).

3.8 | Source of information

With 75% ($n = 117$), most respondents learned about UCB banking from their doctor/ midwife or clinic staff. Other sources mentioned were media and websites

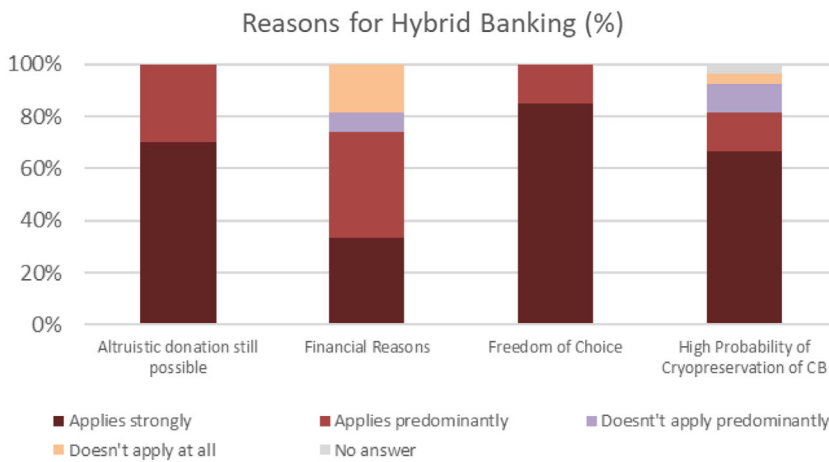


FIGURE 4 Reasons for hybrid banking.

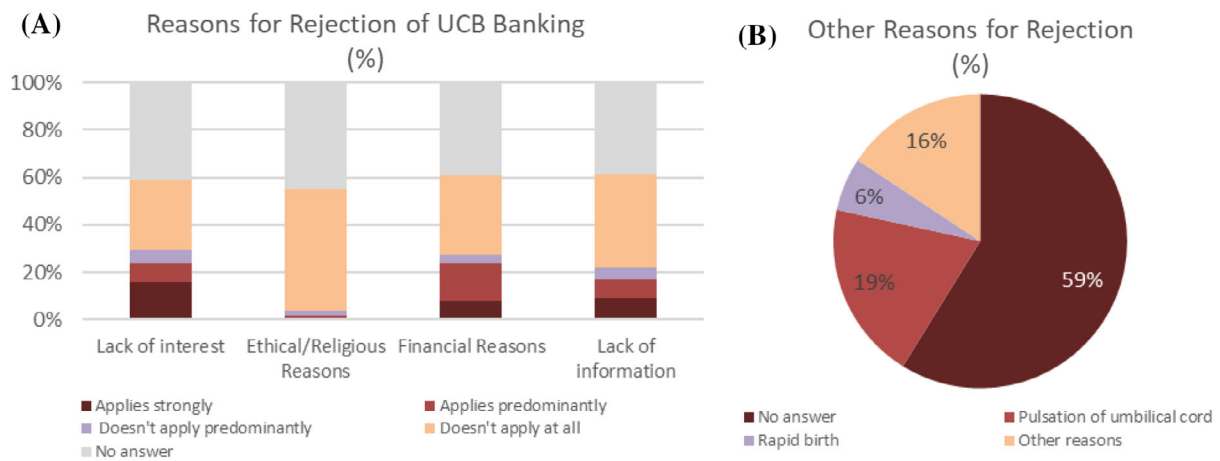


FIGURE 5 (A) Reasons for rejection of CB banking in general, (B) Other reasons for rejection.

($n = 20$, 13%), family/friends ($n = 14$, 9%) or antenatal classes ($n = 6$, 4%) (figure not shown).

3.9 | Satisfaction with decision/storage

Overall, 94% ($n = 100$) out of the 106 women who opted for UCB banking or donation were mostly or completely satisfied with their decision. 5% ($n = 5$) of the participants did not answer this question, while only 1% ($n = 1$) was not satisfied at all (figure not shown).

Among the women who chose public banking, 87% ($n = 66$) were very content and 7% ($n = 5$) were mostly satisfied with their decision.

Satisfaction was thus similarly high to hybrid storage, as 78% ($n = 21$) of women reported being very satisfied and 18% ($n = 5$) were mostly satisfied with hybrid banking. No woman was dissatisfied or very dissatisfied, which means that overall contentment was very high (Figure 6A).

However, some of the interviewees stated that the organization and collection process had been rather complicated. The amount of paperwork had also been criticized, as forms both from the University Hospital of Bern as well as from the private collecting center Swiss Stem Cell Biotech (SSCB) needed to be filled in.

Satisfaction with their decision among women who did not store nor donate CB (32%, $n = 51$) was significantly lower. Nearly 50% ($n = 25$) of them stated that they were completely satisfied with their decision, while around 14% ($n = 7$) were rather dissatisfied or dissatisfied (Figure 6B).

One reasonable explanation for this might be the inability of storage resulting from external circumstances (e.g., very rapid birth, infections). Six of the women interviewed were not able to choose hybrid banking due to a secondary diagnosis, shortly detected before birth (e.g., COVID-infection).

As seen in Figure 6C, 93 out of 106 women (88%, applies strongly and predominantly) who chose CB

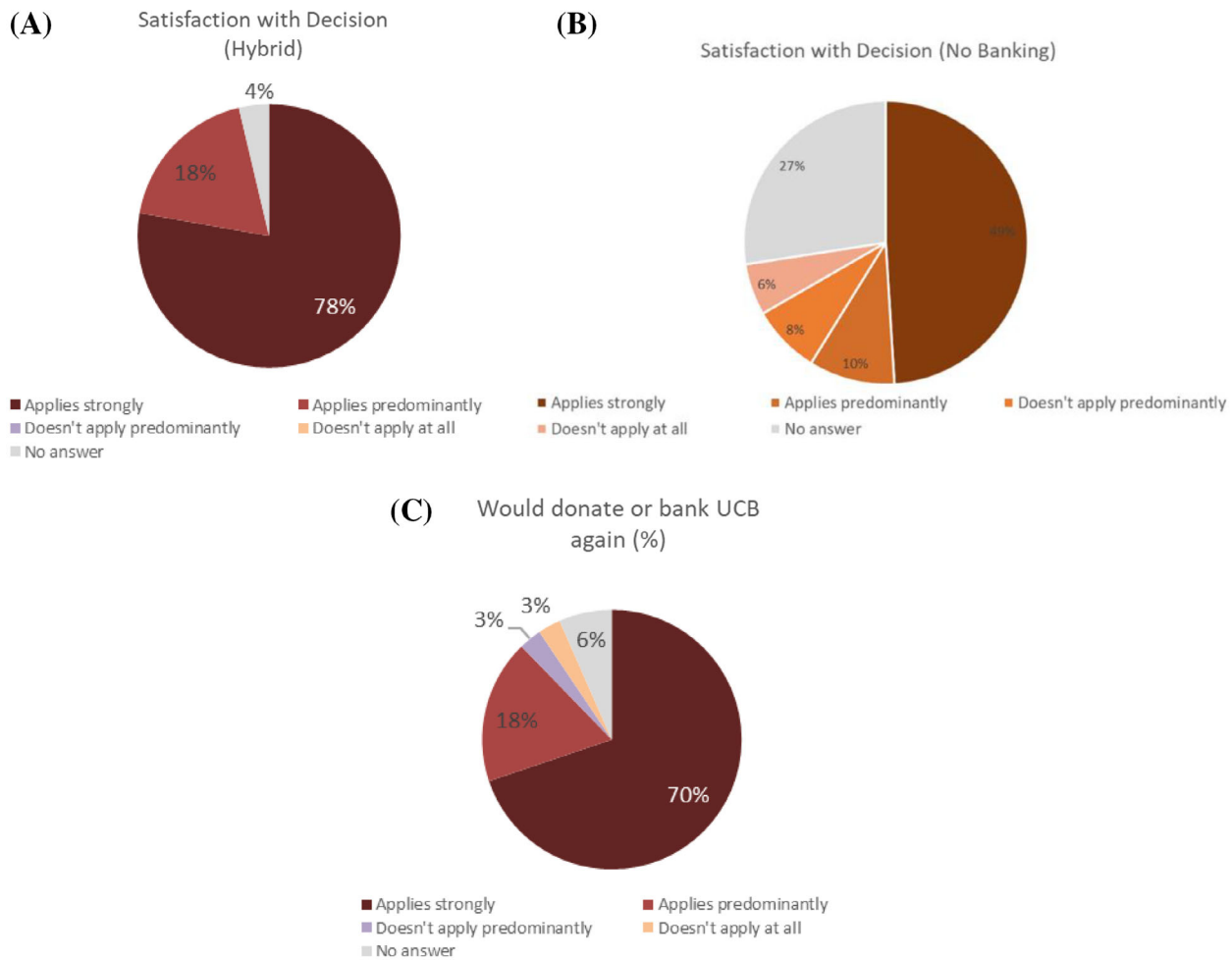


FIGURE 6 (A) Satisfaction with decision for hybrid banking, (B) Satisfaction with decision for no donation or banking, (C) Likelihood of donating or storing UCB again.

collection, would likely opt to do so again. However, it remains unclear whether they would select the same banking model or not.

4 | DISCUSSION

To the best of our knowledge, our study is the first to address the perspectives of women towards hybrid CB banking as an available option of CB collection and storage at birth.

Prior to this survey, a systematic literature review was performed, which showed great potential for hybrid CB banking as an alternative to the pre-existing banking methods.⁷ No study however addressed the women's perspectives on an available hybrid banking model.

A total of 175 questionnaires were completed during the data collection period from November 2021 to June 2022. Of these, 18 could not be evaluated as they were incompletely filled out. The number of collected

questionnaires was seen in the context of the survey solely being available in German, as well as the exclusion of twin pregnancies, pregnancies with intrauterine growth restriction, and preterm births. Furthermore, women who did not meet the prerequisites of public CB donation (absence of genetical defects, absence of systemic infection etc.) were also excluded from the study.

To avoid possible bias, age, nationality, and educational background were assessed. No significant differences were identified among the subgroups (private, public, hybrid, or no banking) regarding age and profession. Over two-thirds of the participants were of Swiss nationality. It has been observed that Non-Swiss women opted slightly more often for public donation, while Swiss women more frequently decided against donation, or storage in general. Approximately the same proportion of Swiss and Non-Swiss females opted for hybrid storage.

More than 90% of women were satisfied with their choice to store, or donate UCB.

With 75% the main source of information regarding UCB banking were doctors/ midwives, or clinic staff. The integrative review by Peperdy et al.¹² had led to the same conclusion. Other authors^{13,14} furthermore underlined the importance of raising more awareness among medical professionals in order to be able to provide correct and differentiated pieces of information to expecting parents, directing them to reliable sources and increasing their knowledge regarding UCB donation or storage.

Another significant conclusion of this study is that hybrid banking has been chosen by one-quarter of women who opted for CB storage, whereas private banking has been chosen only by very few participants (3%).

Our results clearly suggest that (1) hybrid CB banking is generally an attractive novel option from the perspective of women and (2) hybrid CB banking obviously has the potential to replace private banking in those parents who opt for family-directed CB storage of their child, rather than public foreign-donor CB storage.

Furthermore, the results from our study show a similar outcome to a previously completed survey by our group (Wagner et al.⁸) conducted between 2008 and 2009. This previous study showed a clear preference for hybrid banking, with 49% of all participants opting for the public-private partnership, if such option was made available. We assume that the reason why fewer women in our present survey opted for hybrid banking, is due to the actual concrete costs compared to the study of Wagner et al., which examined mainly the theoretical advocacy, where hybrid banking was not yet available to women in real life. Furthermore, the lower percentage can be also seen in context with the different study populations (here no differences were made between individuals with or without children, questionnaires were distributed postnatally, exclusion of women with pregnancy pathologies and with insufficient German skills).

In our survey, a total of 72% of women opting to store the CB of their child, chose to donate the CB to the public registry. This shows a high altruistic motivation of the respondents and may eventually also be due to the currently still limited indications for autologous stem cell transplants in regenerative medicine. A further explanation might be the lack of costs for parents when choosing this option.

Considering the worldwide situation, it is observed that significantly more stem cells are stored privately than donated to a public inventory.⁵ Given the ongoing and promising studies in the field of regenerative medicine, it is likely that CB transplants will be used to a greater extent in the future. Research reveals future potential for clinical use in the treatment of diseases such as diabetes, cerebrovascular disease, or Parkinson's disease.^{1,9-11}

Finally, another important aspect is the small number of obstetric departments where public CB donation is

possible. Public storage facilities are associated with relatively high costs and require a good infrastructure as much as well-trained staff. For that reason, CB collection for public donation is only possible at four selected clinics in four different cities in Switzerland. This also means inequity for women, depending on their region of residence as well as on the obstetrical clinic, where they plan to give birth. This is in contrast to private family-directed CB storage, which is available in all obstetrics departments. Our model of hybrid banking in a combined private-public partnership has the potential to improve this inequality: The collection and storage infrastructures could be combined to establish a model in which all pregnant women have full freedom of choice between public donation, private family-directed storage, and hybrid banking.

5 | CONCLUSION

Our study provides novel important insight into women's perspectives on a recently introduced hybrid CB banking model. With over two-thirds of women storing CB, the general acceptance of CB banking was quite high. One-quarter of these women opted for hybrid storage, being very satisfied with their decision overall. It shows a strong altruistic mindset of women regarding the CB of their child. In view of the potential increase of indications for autologous stem cell transplantation in the future, the proportion of public donors is likely to decrease while the family-directed storage might become more attractive. Hybrid banking has the potential to significantly expand the number of registered CB units available for transplantation. Furthermore, CB collection and storage facilities of private and public institutions could be combined, with processes being aligned, providing the accessibility to CB banking for all pregnant women.

From an ethical standpoint, it seems mandatory to not only consider the perspective of patients in need of a stem cell graft but also the perspective of pregnant women. Pregnant women (and their children) are not simply stem cell donors but must be given a real informed choice. Therefore, medical staff needs to be trained well and procedures should be optimized. In addition, all patients should be given the same possibilities to bank UCB, irrespective of their place of residence. Our study shows great potential to achieve this goal with hybrid CB banking.

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CONFLICT OF INTEREST STATEMENT

The authors have disclosed no conflicts of interest.

DATA AVAILABILITY STATEMENT

All data generated or analyzed during this study are included in this published article and its supplementary information files. The distributed information brochures and the validated questionnaire can be found attached as supplementary material.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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