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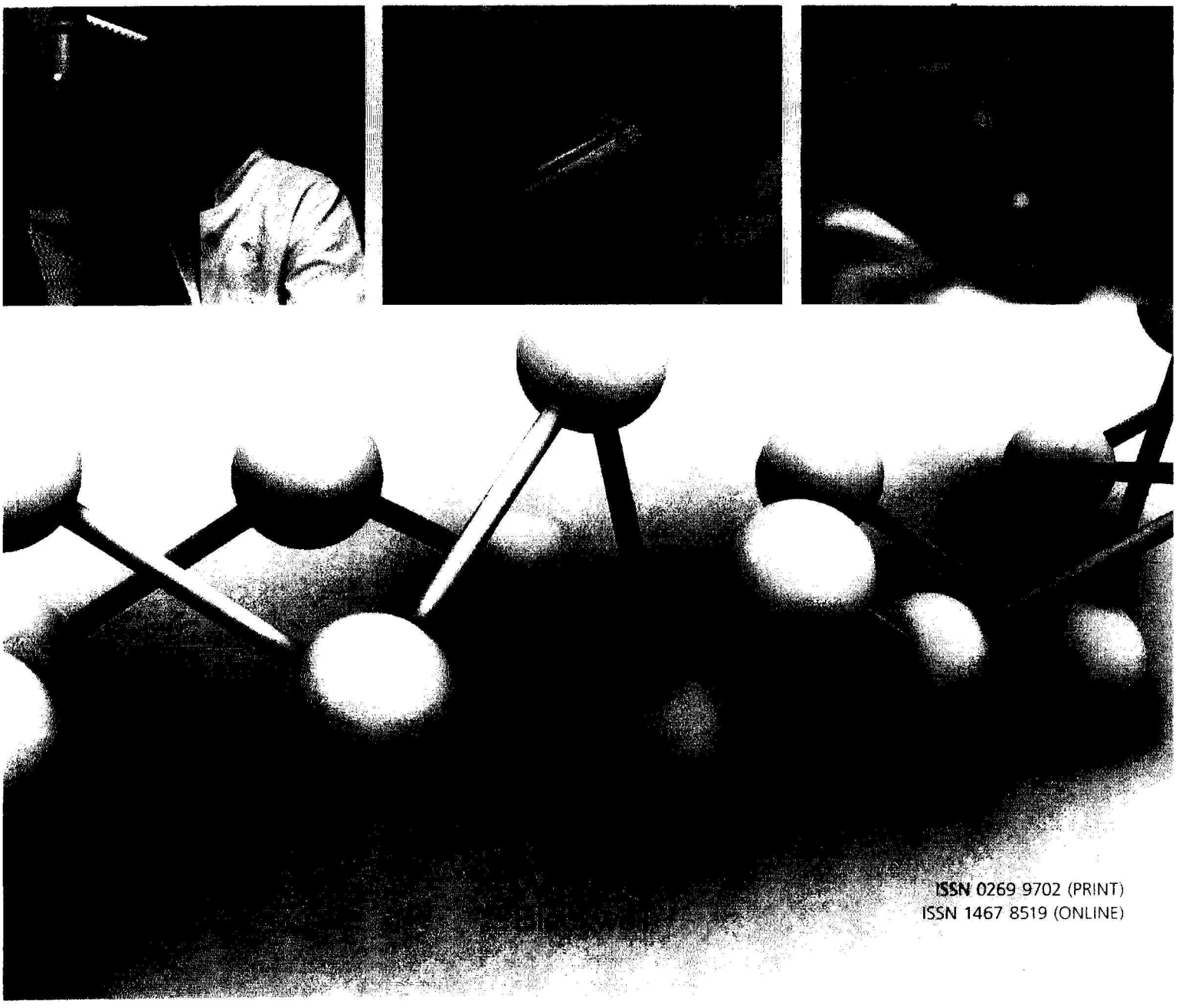

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NOT THE USUAL SUSPECTS: ADDRESSING LAYERS OF VULNERABILITY

FLORENCIA LUNA AND SHERYL VANDERPOEL

Keywords
layers of vulnerability, cord blood bank, Latin America, middle-class pregnant women, public health policies

ABSTRACT

This paper challenges the traditional account of vulnerability in healthcare which conceptualizes vulnerability as a list of identifiable subpopulations. This list of usual suspects, focusing on groups from lower resource settings, is a narrow account of vulnerability. In this article we argue that in certain circumstances middle-class women can also be considered vulnerable. We draw on critical relational and layered accounts of vulnerability and explore this [illegible] cord blood (CB) banking. [illegible] In the first section we present different approaches to vulnerability and contrast categorical versus layered accounts. In the second section, we describe CB banking and present a case study of CB banking in Argentina. We examine the types of pressure that middle-class pregnant women feel when considering CB collection and storage. In section three, we use the CB banking case study to critique the categorical approach to vulnerability: the model is unable to account for the ways in which these women are vulnerable. A layered account of vulnerability identifies several ways in which middle-class women are vulnerable. Finally, we explore ways in which this layered approach to vulnerability can be used to overcome vulnerabilities.

NOT THE USUAL SUSPECTS: ADDRESSING LAYERS OF VULNERABILITY

In the categorical (or traditional) approach to vulnerability in medical and research ethics, those considered 'vulnerable' seem to be drawn up from a list of 'usual suspects': persons with mental or behavioral disorders, prisoners, residents of nursing homes, people receiving benefits or social assistance ,the unemployed, patients in emergency rooms, some ethnic and racial minority groups, homeless persons, nomads, refugees.[1] This paper challenges the traditional way of thinking about vulnerabilities, on the grounds that it is simultaneously too broad and too narrow. Too broad in that it labels entire sub-populations as vulnerable and too narrow in that it is blind to the inclusion of individuals from society who are from a more privileged background, such as middle-class women.[2] In contrast, we develop a layered account of vulnerability.[3] This paper shows the relevance and applicability of an approach of vulnerability that is more nuanced and respectful of complexity. In the second section, we describe CB banking and present a case study of CB banking in Argentina. We examine the types of pressure that middle-class pregnant women feel when considering CB collection and storage. In section three, we use the case study to critique the categorical approach to vulnerability: this model is unable to account for the ways in which these women are vulnerable. A layered account of vulnerability identifies several ways in which

[1] CIOMS-WHO 1993. International ethical guidelines for biomedical research involving human subject. CIOMS, Geneva. Guideline 10.

[2] The authors focus on women as targets of private CB banking strategies, but most of the arguments can be extended to the couple. Middle-class women are defined as: having had opportunity of secondary or tertiary education, having a good income meeting global standards that allow certain comforts.

[3] F. Luna. Elucidating the Concept of Vulnerability. Layers not Labels. *Int J Fem Approaches Bioeth* 2009; 1: 120–138.

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middle-class women are vulnerable. Finally, by utilizing the layered approach, this paper suggests how public health policies could be designed to overcome vulnerabilities.

PART I. REVISITING VULNERABILITY: THE LAYERED ACCOUNT

The concept of vulnerability is widely used in bioethics. In 'Elucidating the Concept of Vulnerability: Layers not Labels',[4] Luna analyzed the use of 'vulnerability' in international research ethics codes. Common to the majority of these codes is a sub-population approach to vulnerability: they have listed and identified groups requiring protection.

A serious shortcoming of most current conceptions of vulnerability[5] is a tendency to treat vulnerability as a 'label' affixed to a particular subpopulation.[6] There is an implicit assumption that there are necessary and sufficient conditions which populations must meet in order to be considered vulnerable.[7]

In targeting subpopulations, this labeling strategy accomplishes two things. First, it assumes a baseline standard, or a paradigmatic research subject: a mature, moderately well-educated, clear thinking, literate, self-supporting person. Second, it assumes the possibility of identifying vulnerabilities in subpopulations as variations to the paradigm. One problem of this categorical model of vulnerability is that a person or a group of persons can suffer different kinds of vulnerabilities; a complexity that is overlooked if whole groups of persons are merely defined as vulnerable. A consequence of the categorical model is a simplistic answer to a complicated problem. Vulnerability is understood as targeting a permanent and categorical condition, a label that is affixed to someone given certain characteristics that will persist throughout the person's existence. Thus, subpopulation analysis can lead to an overly rigid and fixed perspective.[8] Because of this, we suggest moving away from the categorical definition of vulnerability.

In contrast, if vulnerability is viewed as layered and dynamic then there is no single feature that in and of itself defines vulnerability; no 'solid and unique vulnerability' exhausts a category; and, most importantly, no single feature can suffice to explain it entirely. Instead, there is a set of layers that render a person vulnerable.

The metaphor of a layer implies multiplicity and differences that can be gradually peeled away. Some layers may be related to problems regarding lack of autonomy, difficulties with voluntary informed consent, or cognitive impairment; others to social circumstances such as stigmatization, lack of respect for basic human rights, risk of exploitation, and others. Layers may interact and can exacerbate an unjust or exploitative situation.

For example, being a woman does not *per se* entail vulnerability. However, a woman living in a country that does not recognize or is intolerant of *reproductive rights* would acquire a layer of vulnerability. In turn, an educated and resourceful woman in that same country can overcome some of the consequences of the denial of reproductive rights; however, a *poor woman* in that country acquires another layer of vulnerability. Moreover, an *illiterate* poor woman in that situation acquires yet another layer. And, if this woman is an *immigrant*, *undocumented* or belongs to an *aboriginal community*, she will acquire increasing layers of vulnerabilities and would suffer proportionately under these overlapping layers.[9]

Therefore, to fully address subjects' vulnerability, more than one safeguard may be necessary. The concept of vulnerability operates as a fine grained tool for analysis, interpretation and evaluation of situations. Once we have identified the different layers of vulnerability that persons endure, we can consider various ways to avoid, minimize or appropriately address those layers. Conceiving of vulnerability in this way prompts multiple approaches to address them; and these in turn can inform policy development.

In this paper we present a case study, in order to show how a layered approach unveils vulnerabilities that are not typically accounted for under the categorical approach.

PART II

One area of recent but controversial interest in access to innovations for health is the collection, storage and use of placental CB, a process described as 'CB banking'. The first part of this section explains basic procedures and terminology associated with CB banking. The second part focuses on middle-class pregnant women in Argentina and their experience of CB banking. We use this case study to explore and compare the categorical and layered accounts of vulnerability.

A. CB banking

Placental CB is the blood collected from the umbilical vein in the cord after delivery of a baby. If the CB is not collected the placenta is usually discarded as medical

[4] Ibid.

[5] For exceptions to this trend, see W. Rogers, C. Mackenzie & S. Dodds. Introduction: Special Issue on Vulnerability. *Int J Fem Approaches Bioeth* 2012; 5(2): 1–10.

[6] C. Levine et al. The Limitations of 'Vulnerability' as a Protection for Human Research Participants. *Am J Bioet* 2004; 4(3): 44–49.

[7] Luna, *op.cit.* note 2, p. 128.

[8] Ibid: 123–124.

[9] Ibid.

waste. Generally, so long as trained personnel collect CB, the risks to mother and child during the CB collection process are minimal.

When CB is processed, the serum is separated and the nucleated cells are harvested. These include, among other cell types, stem cells, which can be used for cell transplantation. Private CB banks collect and store CB, for a fee, for exclusive use by the child and their family. Public CB banks, usually subsided by national health care systems, collect CB free of charge, as donations. Public CB banks, once accredited, join and include their collected CB units onto globally searchable transplantation lists. These lists are used by physicians and transplant programs around the world to find an appropriate match for any patient who may qualify for a CB transplant.

There are two types of CB transplants. In autologous transplants (or auto-transplant) the collected CB unit is used to treat the individual from whom it was originally collected; in the case of allogeneic transplants (or allo-transplant) the CB unit is used to treat another person who may be related or unrelated to the donor. Private CB banks offer a service which predominantly collects CB for autologous use. Public CB banks collect cord blood from donors for unrelated 'allogeneic' use. Both CB banks (private and public) may offer an allogeneic program which is often described as a 'directed' cord program, whereby the CB is collected for use by an ill sibling or relative.

Private CB banks promise that the blood collected from a particular newborn can be used to treat that child's future illnesses throughout life. They rely heavily on future developments in regenerative medicine.

The rationale of public CB banks is to collect samples from many donors, for allogeneic use by national and international patients who may require them. Allo-transplantation is an established medical practice. In leukemias or other disease, allogeneic (rather than autologous) transplantation of cells is often considered medically preferable. Currently, patients are on long waiting lists, for stored, immunologically typed and matched CB units. Hence, publicly accessible CB banks provide a very important service addressing global health today, and will continue doing so in future.

Let us consider a case study. Variations of this case exist in many other countries. In Argentina, pregnant middle-class women attending private obstetric practices are offered the option to choose private CB banking at the time of delivery.[10] Many private obstetricians in Argentina advertise CB banking, a process not covered by health insurance plans. Prices for private CB collection vary between US$ 1500 to US$ 2000, with on-going annual storage fees between US$ 150 and US$ 200. This represents a significant out-of-pocket expense, even for middle-class families. Private CB banks aggressively market these services as biological life insurance for the newborn, claiming that the CB unit would be useful to cure a multitude of future diseases and illnesses.

Since 1996 Argentina has a National public CB bank and a Related Program for the Collection of CB. The latter enables families with medical conditions to store the CB of newborn siblings at no cost. However, services of the public bank are not publicized or widely known.

B. Layers of vulnerability

1. The information layer

a. The biological life insurance metaphor: A first concern is accuracy of the promise of a 'biological life insurance'.[11] The brochure of one of these Argentine private CB banks states:

> The future has arrived. More than 40 illnesses can already be treated with stem cells from umbilical cord . . . they possess an exact genetic compatibility with your son. In the future, if he needs it, it may help him or his siblings to combat numerous and serious illnesses [. . .].[12]

The brochure goes on to list cancers, metabolic, and a significant number of other diseases and disorders that could be treated with CB. Statistically, the chance of a person being diagnosed in future with one of these treatable conditions is very low. Yet, this CB bank marketing text sells a powerful image of a guaranteed passport for the newborn's future good health, and the promises of regenerative medicine.

In order to determine if this life insurance metaphor is appropriate and does not overly distort reality, it is important to investigate whether private CB banking will actually be as beneficial as implied. In order to achieve this, women have to ascertain the accuracy and reliability of the medical information provided.

b. The nature of the information: CB research is still, at this stage, characterized by uncertainty. Even though

[10] This practice was supposed to change in 2009 because a new regulation was issued. The INCUCAI Resolution 069/09 required that all samples previously collected and to be collected be included in the National Registry and available for donation. However this policy resulted in strong legal opposition by private banks which is yet unresolved. INCUCAI. Resolution 069/09. Available at: www.incucai.gov.ar/docs/resoluciones/resolucion_incucai_069_09.pdf [Accesed 23 Aug 2012].

[11] G. Annas. Waste and Longing. The Legal Status of Placental-Blood Banking. *NEngl J Med* 1999; 340: 1521–1524; Committee on Establishing a National Cord Blood Stem Cell Bank Program, E.A. Meyer. K. Hanna & K. Gebbie, eds. 2005. *Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program*. Available at: http://www.nap.edu/catalog/11269.html [Accesed 23 May 2012].

[12] Brochures of *Bioprocrearte* obtained at a gynecologist's office in December 2009. The emphasis is ours.

private CB banking may not yet live up to its expectation as a 'biological life insurance', it is not possible to categorically deny that private CB banking might provide future benefit.

Some doctors and researchers endorse the future possibilities for CB banking, recognizing CB as useful treatment for unforeseen diseases, disabilities or disorders. Others state that regenerative medicine claims are generating disproportionate and inflated expectations. Evidence of curative or preventive therapies is rare, and subsequent translation to patient care takes even longer.[13] As experts are divided into often extreme differing opinions, it is very difficult for a woman to be able to assess the purported benefits and costs of private CB banking.

c. **Information sources:** Obtaining accurate information which would verify the claims of private CB banking is difficult as this is a cutting-edge area of medicine dependent upon complex clinical research. The information that women receive may often be biased, excessive, or fail to mention alternatives such as donation to public CB banks. Some Argentine hematologists point out that publicity from private CB banks is misleading.[14] Globally-distributed information may often be unclear; and, there are contradictions and ambiguities within the information which complicate informed decision-making.

Thus a first layer of vulnerability is created by difficulties in obtaining accurate information.

2. *The present-future tension layer*

A problematic element of this scenario is that collection techniques for CB[15] are ahead of its potential use. If CB does have greater future potential than has been currently established, the pressing question is: what do women do in the meantime when the clinical field remains uncertain and divisive?

Widespread collection of donated CB units may seem like a responsible and precautionary public health strategy. But the significant cost of collection and storage need to be considered. Therefore, current public CB banks function on the assumption (or mandate) that they must prioritize collection and storage of material that is currently of a quality standard considered useful. They follow pre-specified standards of identification of donors and collection requirements for current clinical practice. Many collected CB samples are rejected for storage by public banks because they do not meet pre-qualification standards: presence of certain infectious diseases, minimum number of nucleated cells collected, and other screening criteria prior to and following CB processing. Thus, less than 40% of CB public donation units collected meet the requirements for storage.[16]

If current obstacles for auto transplants are solved, should public banks be discarding CB units deemed suboptimal now, which may prove useful in future? Would a woman feel a loss if this previously deemed 'suboptimal' CB unit might have proved useful in resolving a future medical problem of her newborn or related family members? This uncertainty renders the decision-making situation even more complex.

3. *The obstetrician's influence layer*

a. Conflict of interest: The obstetrician is often viewed as the 'natural' medical and scientific adviser because they are professionals who are committed to acting in the patients' best interest. But in Argentina, a conflict arises as obstetricians often receive a fee from private CB banks, either for collection or acting as a liaison.[17] CB banks may also pay the equivalent or more for CB collection than obstetricians receive for delivering a baby. These payments can introduce a potential conflicts-of-interest between the obstetrician's duty to provide their patients with objective advice and the obstetrician's own financial interest. These fees may influence and bias the information on CB banking that obstetricians provide to pregnant women and this may affect a woman's decision-making.

Furthermore, the financial incentives for obstetricians may inadvertently place another layer of vulnerability on middle-class women using their services, because the focus on CB collection may undermine the obstetrician's focus on the safety of the procedures during maternal delivery. The obstetrician might be clamping the cord too quickly after the birth of a child in order to increase the chance of collecting a larger volume of CB, or might inadvertently be distracted from the maternal delivery process by concentrating on CB collection, thus increasing maternal-child risks.

b. Medical 'idealization': Adding to the 'standard' power asymmetry between doctor and patient, an

[13] A.M. Mhashilkar & A. Atala. Advent and maturation of regenerative medicine. *Curr Stem Cell Res Ther.* 2012 Nov; 7(6): 430–445. Early optimism produced a productive initial burst of research activity followed by a slower, cautious approach as new technologies emerge to find solutions. P. Nightingale & P. Martin. The Myth of the Biotech Revolution. *Trends Biotechnol* 2004; 22: 564–569.

[14] G. Kusminsky. Criopreservación para uso propio de la sangre de cordón umbilical. *Medicina* 2006; 66(4): 367–371; A.E. Del Pozo. Bancos de células progenitoras hematopoyéticas de sangre de cordón umbilical y la placenta: análisis de las resoluciones sobre su habilitación y regulación. *PerspectivasBioéticas* 2009; 14(26–27): 57–63.

[15] CB cells can be stored indefinitely under proper conditions. J. Linden et al. Guidelines for Cord Blood Banking. *J Hematother* 1997; 6: 535–541.

[16] National Marrow Donor Program. Available at: http://www.marrow.org/HELP/Donate_Cord_Blood_Share_Life/Cord_Blood_Donation_FAQs/index.html [Accesed 23 May 2012].

[17] Del Pozo, *op.cit.* note 12, p. 59.

additional layer of vulnerability is related to difficulties pregnant patients face in interpreting the exact role of their obstetrician. In many societies, and certainly in Argentina, the relationship that a woman establishes with her obstetrician is very strong, can be 'idealized', and is often based upon complete trust. As the financial relationship between the CB bank and the obstetrician may not be clearly disclosed, the woman may believe that her obstetrician's recommendations for CB banking represent best practice and the highest standard of care.

There is a risk of exploiting middle-class women by inducing them to decide on private CB banking based upon the obstetrician's stature.

4. Time-sensitive opportunity layer

There are timing obstacles because CB must be collected immediately after birth. Even though six to nine months of the antenatal period may appear to be enough time for women to decide, this may actually not be true because the options available are neither obvious nor straightforward. The CB collection time point cannot be altered, which creates time-sensitive pressures.[18] Ideally, these women should be able to make such a medical decision when a sufficient evidence-base has developed but, currently, this is not an option.

5. The ideal mother model layer

Another issue is the extent to which motherhood is entrenched and idealized. This is certainly is the case in Argentina and Latin America, but also in many other countries. Mothers are openly judged for their behavior; their actions are valued only when their decisions and behaviors conform to societal expectations. For example, devotion to children is often expected of mothers, even if it requires great sacrifice. Embedded within the ideal is the woman's guilt about not doing 'the right thing', or what good 'modern' mothers should do. Following this rationale, if there is a 'biological life insurance' for the future child, women may believe that efforts should be made to obtain it. Private CB banking may be perceived as the expected ideal. This represents a further layer of vulnerability based on social and psychological expectations.

6. The cost of the procedure layer

The decision to CB bank privately is quite expensive, even for a middle-class woman. The public CB bank provides 'directed' private CB banking for free, but only if there is an ill sibling or a clear medical indication. Women without a publicly defined family need, who do decide to CB bank privately, will strive to obtain funds, exacting a heavy financial burden.

As demonstrated, if a layered approach to vulnerability is followed, middle-class pregnant women considering CB banking can be vulnerable.

PART III

First, we will use the CB banking case study to compare the categorical and layered accounts of vulnerability. Second we will suggest public policy reform options that seek to mitigate the effects of the identified layers of vulnerability.

A. Vulnerability and women

Following a 'categorical fixed label' model, middle-class pregnant women would not have been deemed a vulnerable sub-population. Not all pregnant women are vulnerable merely because they are women and because they are pregnant. Further, due to the relevance of poverty in the attribution of vulnerability, middle-class women do not easily fit within established analyses of vulnerability. Vulnerability is absent because these women are not deprived, are resourceful and can defend themselves.

However, in this specific case of CB banking, when using a layered approach vulnerabilities are revealed in middle-class pregnant women, despite their relative socio-economic advantage. The layers of vulnerability include: the multiple difficulties in acquiring neutral clinically-relevant information; the pressure to be ideal mothers; the dual role of, and conflicts of interests facing, their obstetricians; the strain of providing the best start for their child by acquiring 'biological life insurance'; and the burden of the CB procedure and storage costs. These factors would render most pregnant women in this situation vulnerable; and thus subject to potential risk, possible manipulation and exploitation.

Interestingly, given the structural and socio-economic differences between poor and middle-class women,[19] in this particular case, poor women are not rendered vulnerable as they are not targets of private CB banks' recruitment efforts. The National Public CB Bank enables poorer women to donate cord blood. It is true that there

[18] We recognize there might be similar situations in clinical care where there are short time periods to decide about treatment options. The idea here is to identify all potential sources of vulnerability in order to consider whether anything can be done to mitigate the effects of these types of vulnerability on the women involved.

[19] We do not deny the difficult and unjust situation that poor women generally face and how this can impact on their pregnancies and future babies. However, poverty, as such, does not seem to be operating in the particular situation we are analyzing. Other problems might exist that have not yet been published or known, such as the sale of CB by poor or economically-disadvantaged mothers or parents.

is no guarantee that they will be able to recover their newborn's CB unit if required. However if, as many experts say, CB units are not a good source for auto-transplantation, but rather best for allo- transplantation; poor women do have the possibility of ensuring that their babies have a potential compatible allogeneic publicly stored CB unit.[20] In addition, if there is a health problem in the family and a child is ill, through the 'Related Program for the Collection of CB' the public CB bank allows pregnant women to store, at no cost, for siblings. All the transplantation procedures and medical treatments are done for free within the public hospitals and health system. Thus, the current Argentinean situation seems to have found a CB banking solution to protect the interests of poor pregnant women, who would have been traditionally labeled as vulnerable.

B. Vulnerability and policy design

The typical response to vulnerability is to introduce safeguards to try and protect those identified as vulnerable to harm or exploitation. From a public policy perspective, designing policies which are sensitive to the needs of those affected often requires fine-grained distinctions. When vulnerability is perceived in a layered way, we can focus on specific responses to each layer.

1. We have shown that layers of vulnerability can result from the barrier to *accessing accurate information*. The establishment of a Commission of Experts capable of providing neutral and accessible information for all forms of banking could address this issue. This Commission could be linked to international evidence-based health data sources, such as those provided by the World Health Organization (WHO). Alternatively, an information hotline, without commercial ties or conflicts-of-interest, could serve as a reliable public information source. Neutral information would help women differentiate between actual indications for CB product use (evidence-based clinical data) and promises of future use.

We also suggest that brochures, Internet sites or other promotions written by private as well as public banks include links to the Commission of Experts, and/or include hotline numbers. Material produced by private CB banks would have to indicate that there are also public CB banking options. This would ensure a less commercial view and increase knowledge about the public CB bank.

2. Informed consent processes should be conducted thoroughly, with information sheets that adhere to specific guidelines and include authoritative, evidence-based information about the benefit of CB banking. The informed consent process should attempt to minimize the *ideal mother layer* by ensuring that it is clear that 'mothers' have choices, and by avoiding misleading and emotive language.

3. Another layer of vulnerability relates to the *obstetrician dual role*. To avoid conflicts-of-interest, we should introduce limits on fees obstetricians (or clinic staff) receive for CB collections.[21] Further, public and private hospitals need to develop competency-based training for para-medical staff (phlebodomists) and require collection of CB units after the delivery of a child. This would address the possibility of diverting obstetric attention from the woman and child during the delivery.

In order to address the potential *medical idealization layer*, information sheets for women should be transparent about the obstetrician's involvement in the CB banking process. The pregnant woman should receive all relevant information about the role of the obstetrician and other staff in the collection process, including any payments they receive. This will ensure transparency without placing the pregnant women in the difficult situation of confronting or questioning her obstetrician.

4. Some layers of vulnerability may not be able to be eliminated or assuaged; however there may be ways to mitigate their effects. For example, with regard to the *procedure cost layer*, middle-class women could be made more aware of the public CB donation options. This would require public education campaigns regarding the benefits and values of public CB banking. Many middle-class pregnant women rely substantially on private health services and thus they miss advertising campaigns within the public system.

Awareness of the existence of a public CB bank will not solve the problem of cost of private banking. However it provides some women with an alternative option and allows women to consider a CB banking model based on non-commercial values such as altruism. Knowing that the public CB bank is an accessible and well-managed option for a range of cases where the usefulness of CB has already been demonstrated may be a source of relief to pregnant women. Also if there is already a treatable medical condition involving a sibling, the public CB bank will collect the CB of the next child for no cost. Secondly, a policy endorsing CB public banks helps to balance the information that private CB banks supply as there will be increased support and information about the value and importance of public CB banking activities and international outreach. Thirdly, it sends a positive message to the public as it implies an integral and powerful strategy in support of public health systems, which endorses solidarity and altruism.

[20] If future uses prove a benefit for autologous CB transplants, these women and their children/families might be then rendered vulnerable if they do not have a future possibility available.

[21] We acknowledge that this recommendation is not as radical as directly forbidding all fees and therefore might not eliminate all conflicts of interest; but it might help to minimize conflicts of interest and still allow a fee for a role the obstetrician does perform.

The policies suggested above can be relatively easy to implement; however, in order to avoid the *present-future tension layer*, we speculate and propose a specific design structure for CB banking.

5. Regarding the present-future informational challenge, we acknowledge that currently the allogeneic use of CB is a proven effective medical intervention and thus public CB banking should be endorsed and improved. However, public CB banks cannot afford to store all CB units donated. They need to choose samples which follow strict requirements and standards in order to maintain accreditation within global CB matching programs. Given the uncertainty of clinical future uses of CB (based on hopes for new possibilities in regenerative medicine), a temporary answer for policy development is to allow private CB banking but ensure private banks are strongly regulated and accredited under a harmonized set of standards.

Our design implies a compromise position for private as well as public CB banks. It could help diminish vulnerabilities for all pregnant women, relative to the current system. This design would require a strongly harmonized set of procedures. We propose a unique and centralized national processing centre(s) for CB collection, combined with national laboratory(ies) for processing (and infectious disease testing), which would lead to cryo-preservation of most CB units meeting a minimal international standard (even those whose amounts/quantity of CB that may be low for current transplantation standards). The processing centre(s) would be separate, but accessible both to public and, at a fee, to private CB banking facilities. Women would have several options if they agree to collect CB:

a) decide to donate to the public bank, without cost and if ever the family needs a CB unit they would be internationally prioritized;
b) if their own CB unit does not meet the higher standards for public CB banking two options could be available:
   b.1) discard the CB unit (at no cost); or
   b.2) redirect the sample for private CB banking at full cost; or
c) women could simply choose private CB banking. This requires full payment to the centralized processing centre for collection, a tax or fee to support public banking and transport costs to a private CB banking facility.

On this model, once the CB unit is cryo-preserved, months could be given for the informed decision-making process through which the women/parent(s) could opt for either public or private CB banking. This process avoids the time-sensitivity opportunity layer, while also allowing for a more neutral informed consent process. At a national level, biased publicity could be prevented. Instead there could be provision of balanced evidence-based education on the values and clinical benefit of CB banking. There will be no pressures to take a final decision during the antenatal period or at delivery. This design eliminates involvement of obstetricians during the decision-making process and also eliminates the layers of vulnerability relating to their role and influence. This public-private model is not without precedent and could also include incentives, for example, through special levied taxes associated with option c. For example, women who choose option (c) may pay more than the others, as a way of supporting the whole system. Implementation research and cost-effectiveness studies would be required to determine best practice and evaluate how partial financing through the private banks, coupled with recovery from global matching, could ensure sustainability of a quality public CB bank. Such an innovative policy could remain in place until regenerative medicine's potential use for CB becomes more clear.

In this layered model of vulnerability, protection of vulnerable people does not necessarily imply forbidding an activity or oscillating between extremes on policy, as often happens in response to the categorical analysis of vulnerability. Unless it could be categorically asserted that no use or benefits will follow private CB banking, it seems an overly strong policy to ban private CB banking of those units that would otherwise be discarded. Perhaps for some, prohibition represents a simple, effective solution. However, prohibition may not eliminate CB banking, but may instead enhance unregulated private cross-border CB banking opportunities, making this practice more expensive and available only to the well off. 'All or nothing' answers are less than satisfactory, and often result in denying a right to access services, and autonomous decision-making. By contrast, when the layered model of vulnerability is used, policies can be designed that respect and protect all persons involved, in a nuanced and diversified way.

CONCLUSION

This case study demonstrates a different approach to vulnerability. Vulnerability is usually related to the poor, to persons without resources. By challenging traditional ways of thinking about vulnerability, we have shown that others – and not the 'usual suspects'– can be rendered vulnerable and susceptible to policy decision-making. In this paper we show that in certain circumstances middle-class women can be also vulnerable.

There is complexity when applying a layered analysis of vulnerability; but we feel is more useful and constructive than an analysis which labels whole groups or subpopulations as vulnerable. Deconstructing vulnerability with the application of this layered strategy can

assist policy makers, by providing a nuanced way of approaching policy design. Furthermore, as these layers of vulnerability change with time, policies also can be adapted to address those changes. Hence, this conceptualization of vulnerability can be developed into a dynamic tool for policy design.

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Disclaimer

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