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Patients' views on the embryo storage time limits




Margarida Pereira ^{a,1}, Catarina Samorinha ^{a,b,1}, Elisabete Alves ^a,
Helena Machado ^c, Mariana Amorim ^a, Susana Silva ^{a,*}

^a EPIUnit-Institute of Public Health, University of Porto, Rua das Taipas 135, Porto, 4050-600 Portugal; ^b Department of Clinical Epidemiology, Predictive Medicine and Public Health, Alameda Professor Hernâni Monteiro, University of Porto Medical School, Porto 4200-319, Portugal; ^c Centre for Social Studies, University of Coimbra, Coimbra 3000-995, Portugal

* Corresponding author. E-mail address: susilva@ispup.up.pt (S Silva). ¹ MP and CS are equal first authors.



Susana Silva completed a PhD in Sociology, in 2008, and is a senior researcher at the Institute of Public Health – University of Porto, coordinating the Department of Health and Society. She has participated in national projects and international research networks, in the field of Social Studies of Science and Technology, Health and Society, in areas such as reproductive and genetic technologies (regulation, ethics, and social uses), relationships between users and health professionals, and social determinants of health, which resulted in (co)authorship of more than 100 scientific publications.

Abstract The establishment of the length of embryo storage has been based on socio-political criteria. There are different regulations, guidelines and health care policies worldwide. This mixed-methods study aimed to assess the opinion of patients about the embryo storage time limit, and the perception of the criteria underlying the establishment of the storage period offered to them. Between August 2011 and December 2012, 534 IVF patients from Portugal participated in a quantitative questionnaire and 34 couples were interviewed. Overall, 38% of participants preferred the duration of 4–5 years, 38% extended it beyond 5 years and 23% indicated 3 years. Having experienced at least one previous cycle was directly associated with agreeing with a duration of storage longer than 5 years, for both women and men. Having children was inversely associated with longer duration of storage, among women. One-third of the 34 interviewed couples stated that their knowledge concerning embryo storage was insufficient. Nevertheless, all the interviewees reported at least one possible reason for the legal establishment of the storage period offered to them, highlighting financial costs and decreased embryo quality. There are misconceptions and gaps in awareness of cryopreservation, which may shape patients' opinions. Accurate information regarding policy on storage of embryos is needed. 

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Introduction

Storage of embryos has been in widespread use for over 30 years, after successful achievement of the first pregnancy from frozen embryos in 1983 (Trounson and Mohr, 1983). Cryopreservation offers patients undergoing IVF extra chances to conceive without the need to go through a new stimulation cycle (Capalbo et al., 2011; Silva and Machado, 2011). A recent review demonstrated that frozen embryo transfers reduce the risk of ovarian hyperstimulation syndrome and improve health outcomes, not only in terms of achieving higher pregnancy rates, but also in terms of lower maternal and infant morbidity and mortality (Evans et al., 2014). However, embryo viability may be threatened either in the process of freezing or thawing (Ashrafi et al., 2011; Michelmann and Nayudu, 2006), by cross-contamination (Bielanski, 2012) or by osmotic shock, cryoprotectant toxicity and intracellular ice formation (Saragusty and Arav, 2011), respectively. Despite evidence showing that the storage period does not interfere with the quality of cryopreserved embryos (Marietta, 2011; Riggs et al., 2010), qualitative studies indicate that patients believe that the quality of the embryo diminishes throughout cryopreservation (Provoost et al., 2010, 2011c). Additionally, little is known about the impact of long-term storage on children's and parents' health and well-being (Marietta, 2011).

Storing an increasing number of embryos raises concerns surrounding disputes over ownership or disposition (Lyerly et al., 2011; Provoost et al., 2012), and poses problems and ethical questions to address for clinics (Ethics Committee of the American Society for Reproductive Medicine, 2013; Provoost et al., 2011b). These situations draw attention to the need to establish a storage limit for embryos, which until now has been based more on social and political criteria (Edwards and Beard, 1997; Englert and Revelard, 1997; Fasouliotis and Schenker, 2000; Reproductive Technology Council, 2010; Ron-El, 1997). There are different regulations, guidelines and health care policies among countries on this matter (Bielanski, 2012) which may influence cross-border reproductive care services (Brezina and Zhao, 2012; Deonandan, 2010; Provoost et al., 2011a). Embryo storage limit ranges from a period of 3 years in Portugal, 5 years in Denmark, Egypt or Norway to 10 years in Austria, Australia or Taiwan (Ory et al., 2013). It is possibly longer in some countries, such as the UK, where a maximum storage period of 55 years is provided (The Human Fertilization and Embryology [Statutory Storage Period for Embryos and Gametes] Regulations, 2009), and it is unlimited in Canada and Finland (Ory et al., 2013).

Knowledge about patients' views on embryo storage is necessary for the conceptualization of patient-centred policies and for ethics in clinical practice (Dancet et al., 2011). Although data on how patients' attitudes towards cryopreserved embryos influence embryo disposition is available, which highlights the importance of disseminating accurate information about cryopreservation throughout IVF treatments (Fuscaldo et al., 2007; Lyerly et al., 2004; Provoost et al., 2010), there are, to the best of our knowledge, no studies on patients' views regarding the embryo storage limit. This mixed-methods study contributes to fill this gap by assessing IVF patients' opinions about the storage limit for embryos and

exploring their perceptions of the criteria underlying the establishment of the storage period offered to them.

Materials and methods

This mixed-methods, observational and cross-sectional study was designed to be exploratory and hypothesis-generating since little is known about patients' views on embryo storage limit. It comprises a quantitative questionnaire and qualitative interviews with women and men undergoing IVF/intracytoplasmic sperm injection (ICSI) in one reproductive medicine centre in Porto, Portugal. This fertility centre is located in a public university hospital that performs IVF/ICSI homologous cycles. According to Portuguese law, these techniques are only available for heterosexual couples, married or living together for at least 2 years (Silva and Barros, 2012).

Between 17 August 2011 and 16 August 2012, all patients were consecutively and systematically invited to participate in both parts of the study, a total of 226 couples and 103 women. Among the patients invited, 97.8% of couples ($n = 221$) and 89.3% of women ($n = 92$) agreed to participate in the questionnaire, while 94.7% of couples ($n = 214$) and 88.3% of women ($n = 91$) agreed to participate in a qualitative interview. Participants were approached by the team in the hospital, about 15 days after embryo transfer.

Questionnaire: participants and data collection

Among the patients invited, 221 couples and 92 women participated in this part of the study. After exclusion of the participants who did not answer, did not know or presented missing values on the opinion regarding the embryo storage limit, 206 couples and 83 women were included in the quantitative analysis.

Self-reported data on demographic and socio-economic characteristics (age, educational level and household income), reproductive and obstetric history (reasons for using IVF/ICSI, duration of infertility, previous cycles and parental status), having cryopreserved embryos and opinion on embryo storage limit, were collected by two trained female interviewers using a structured questionnaire.

Reasons for using IVF/ICSI were reclassified as female, male or other (mixed, genetic or unknown). Parental status was defined by the existence of offspring, biological or adopted. The opinion question on the embryo storage limit included the following options: ≤ 3 years, 4–5 years and >5 years (sum of the categories 6–7 years, 8–9 years and ≥ 10 years).

Statistical analysis

Statistical analysis was performed using Stata 11.0 (College Station, TX, 2009), and statistical significance was defined as $P < 0.05$. Opinion about the embryo storage limit according to female and male participants' characteristics is presented as counts and proportions and was compared using the chi-squared test. Adjusted odds ratios (OR) and 95% confidence intervals (95% CI) were estimated by multinomial logistic regression models, stratified by gender, to assess the

association between demographic, socio-economic, reproductive and obstetric characteristics of the participants, and the opinion on the embryo storage limit.

Qualitative interviews: participants and data collection

Approximately 3 months after completing the questionnaire a sub-sample of those who agreed to participate in a qualitative interview was contacted by telephone or email, according to their preference, to confirm their availability to collaborate in the study. Between February and November 2012, 56 couples were invited to participate in the interview, and 34 accepted. Participants were purposively sampled to include pregnant and non-pregnant women, and couples willing to donate and not to donate embryos for research. In addition, a heterogeneity sampling was used for maximum variation of views and experiences, until thematic saturation was reached, thus recruitment continued until no new themes emerged from the interview data (Guest, 2006).

Semi-structured interviews took place between March and December 2012. Interview duration ranged from 62 to 111 min, with an average of 81 min. All were taped, transcribed verbatim and checked for accuracy.

The interview guide covered the following issues: views, values and knowledge mobilized to give meaning to the status of embryos; expectations, uncertainties and responsibilities associated with embryo cryopreservation, including the perception of the criteria underlying the establishment of the storage period offered to them; awareness of the processes of evaluation and classification of embryo quality and viability; how couples made their decisions regarding embryo disposition and their views of the consent process; and their understanding and knowledge of embryo research. For the purposes of this paper, data relating to the core theme of embryo storage limit will be discussed by exploring the answers obtained from the following topic question: 'How long should the storage period for embryos last? Why?'

Content analysis

Content analysis of qualitative data was carried out according to the protocol established by Stemler (Stemler, 2001) and was performed using NVivo 10 (QSR International, USA, 2013). Emergent coding was independently conducted by the first and last authors aiming to identify, sentence by sentence, the criteria invoked by the interviewees to justify the storage period offered to them. The categories were then grouped into the following analytical themes: (i) 'scientific and technical reasons', which includes references to embryo quality and viability, women's reproductive age or efficiency of technology; (ii) 'financial reasons', which contains references to financial costs of cryopreservation; (iii) 'policy decisions', comprising answers related with fertility promotion policies; and (iv) 'socio-ethical issues', which encompass arguments such as social representation of the appropriate time between deliveries or for embryo disposition decision, and statements of ethics committees. Disagreements in abstractions were discussed and an almost perfect strength of agreement was

achieved. The findings are reported below with verbatim anonymized quotes from interview transcripts translated by the authors.

Ethical approval

Ethical approval was granted by Ethics Committee for Health of the Centro Hospitalar de S. João on 11 March 2009. All participants formalized their collaboration through a written informed consent according to the World Association's Declaration of Helsinki.

Results

Opinion about the embryo storage limit

More than 40% of the women who participated in the questionnaire stated that the embryo storage limit should be between 4 and 5 years, while 41.7% of men responded more than 5 years (Table 1). Both women and men who had experienced at least one previous cycle were more likely to agree with a storage limit above 5 years ($P = 0.001$ and $P = 0.043$, respectively). Women with higher education and monthly household income tended to extend the limit of embryo storage, whereas those who answered that embryos should not be cryopreserved for more than 3 years tended to have a lower educational degree. Also, women with a duration of infertility longer than 36 months, with no children and without cryopreserved embryos were more likely to extend the limit of storage. A length of storage above 5 years was more frequently chosen by men with a duration of infertility over 36 months and those who reported other reasons for using assisted reproduction techniques, apart from female and male causes.

After adjustment, having experienced at least one previous treatment cycle was directly associated with agreeing with a storage limit longer than 5 years, for both women and men (OR = 2.94; 95% CI 1.51–5.71 and OR = 2.44; 95% CI 1.17–5.08, respectively) (Table 2). Women with higher educational degrees more frequently preferred a storage limit above 5 years (OR = 1.90; 95% CI 0.97–3.74). Women with children preferred the shorter storage limit.

Perception of the reasons for limiting embryo storage

One-third of the interviewed couples stated that their knowledge concerning embryo cryopreservation was insufficient, in particular relating to embryo storage limit. Catherine and Andrew's dialogue shows that they did not know about the storage limit, asking questions about the nature of the limit – 'technical' or 'legal':

Catherine: 'I had no idea that there is a limit for it [embryo storage]. (. . .)'

Andrew: 'But is there a technical limit? Or a legal limit?'

Nevertheless, all the interviewees reported at least one possible reason for the establishment of the storage period

Table 1 Characteristics of the participants according to the opinion about the embryo storage time limits, by gender (*n* = 495).

	Women				Men			
	Total	≤3 years	4–5 years	>5 years	Total	≤3 years	4–5 years	>5 years
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Overall	289 (58.4)	66 (22.8)	120 (41.5)	103 (35.6)	206 (41.6)	50 (24.3)	70 (34.0)	86 (41.7)
Age (years)								
≤35	189 (65.4)	43 (65.2)	79 (65.8)	67 (65.0)	111 (53.9)	26 (52.0)	42 (60.0)	43 (50.0)
>35	100 (34.6)	23 (34.8)	41 (34.2)	36 (35.0)	95 (46.1)	24 (48.0)	28 (40.0)	43 (50.0)
Educational level								
≤12 years	172 (59.5)	46 (69.7)	71 (59.2)	55 (53.4)	144 (69.9)	33 (66.0)	52 (74.3)	59 (68.6)
>12 years	117 (40.5)	20 (30.3)	49 (40.8)	48 (46.6)	62 (30.1)	17 (34.0)	18 (25.7)	27 (31.4)
Household income (€/month)								
≤1500	118 (40.8)	32 (48.5)	51 (42.5)	35 (34.0)	83 (40.3)	18 (36.0)	36 (51.4)	29 (33.7)
>1500	171 (59.2)	34 (51.5)	69 (57.5)	68 (66.0)	123 (59.7)	32 (64.0)	34 (48.6)	57 (66.3)
Reasons for using ART								
Female	77 (26.6)	17 (25.8)	33 (27.5)	27 (26.2)	65 (31.6)	16 (32.0)	24 (34.3)	25 (29.1)
Male	95 (32.9)	18 (27.3)	41 (34.2)	36 (35.0)	57 (27.7)	15 (30.0)	22 (31.4)	20 (23.3)
Other	117 (40.5)	31 (47.0)	46 (38.3)	40 (38.8)	84 (40.8)	19 (38.0)	24 (34.3)	41 (47.7)
Duration of infertility (months)								
≤24	54 (18.7)	13 (19.7)	28 (23.3)	13 (12.6)	38 (18.4)	11 (22.0)	13 (18.6)	14 (16.3)
25–36	57 (19.7)	13 (10.8)	23 (19.2)	21 (20.4)	42 (20.4)	11 (22.0)	15 (21.4)	16 (18.6)
>36	178 (61.6)	40 (38.8)	69 (57.5)	69 (67.0)	126 (61.2)	28 (56.0)	42 (60.0)	56 (65.1)
Previous cycles^a								
0	122 (42.2)	35 (53.0)	58 (48.3)	29 (28.2)	90 (43.7)	27 (54.0)	34 (48.6)	29 (33.7)
≥1	167 (57.8)	31 (47.0)	62 (51.7)	74 (71.8)	116 (56.3)	23 (46.0)	36 (51.4)	57 (66.3)
Parental status								
No children	256 (88.6)	54 (81.8)	109 (90.8)	93 (90.3)	183 (88.8)	42 (84.0)	66 (94.3)	75 (87.2)
Children	33 (11.4)	12 (18.2)	11 (9.2)	10 (9.7)	23 (11.2)	8 (16.0)	4 (5.7)	11 (12.8)
Cryopreserved embryos								
No	169 (58.5)	43 (65.2)	70 (58.3)	56 (54.4)	122 (59.2)	28 (56.0)	39 (55.7)	55 (64.0)
Yes	107 (37.0)	20 (30.3)	43 (35.8)	44 (42.7)	75 (36.4)	19 (38.0)	26 (37.1)	30 (34.9)
Don't know	13 (4.5)	3 (4.5)	7 (5.8)	3 (2.9)	9 (4.4)	3 (6.0)	5 (7.1)	1 (1.2)

ART = assisted reproduction techniques.

^a*P* = 0.001 for women and *P* = 0.043 for men.

offered to them. The vast majority highlighted financial costs. The expense involved in the maintenance of embryo storage facilities was one of the most frequently reported arguments:

Betty: 'I think (. . .) is not only [a matter of] facilities but also a question of money, which in Portugal may define a three year period as limit [for embryo storage], because there is no money to extend it.'

Interviewees also perceived the decrease in quality of embryos as a main reason for the storage limit. Harry's narrative, for example, illustrates the misconceptions and fears the patients have regarding the 'degradation' of embryos throughout cryostorage:

Harry: 'I have the idea that two years would be the period considered reasonable to maintain the quality of a cryopreserved embryo. (. . .) Right or wrong, I believe that from then on degradation [of embryo] could occur.'

The national policy on fertility promotion was mentioned by few participants as a possible reason for the storage limit

offered to them. Nielson distinguished national legal frameworks according to the fertility rates, concluding that countries with 'normal' fertility rates tended to shorten the storage limit:

Nielson: 'Some countries want to raise their fertility rates, while other countries discourage this, as happens in Portugal (. . .) because our fertility rates can be considered normal, can't they?'

Angela invoked the appropriate time frame for making the decision regarding embryo disposition as the criteria for the storage limit offered to the couple:

Angela: 'I think that [the storage limit] is enough time for a couple to decide [embryo disposition].'

Philippe and Sarah's testimony shows how storage limits may be seen as similar to any process of freezing, in the sense that any 'frozen product' has an 'expiry date', after which it loses quality or might be 'weakened', and, thus, cannot be used:

Table 2 Adjusted odds ratios for the association between socio-demographic characteristics and obstetric history, and opinion about the embryo storage time limits, among women and men undergoing IVF/ICSI ($n = 495$).

	<i>Opinion about the embryo storage time limits^a</i>			
	<i>Women</i>		<i>Men</i>	
	<i>4-5 years</i>	<i>>5 years</i>	<i>4-5 years</i>	<i>>5 years</i>
	<i>Adjusted OR (95% CI)^b</i>	<i>Adjusted OR (95% CI)^b</i>	<i>Adjusted OR (95% CI)^b</i>	<i>Adjusted OR (95% CI)^b</i>
Age (years)				
≤35	1	1	1	1
>35	1.07 (0.55–2.05)	1.05 (0.53–2.09)	0.82 (0.38–1.80)	1.01 (0.48–2.14)
Educational level				
≤12 years	1	1	1	1
>12 years	1.64 (0.85–3.15)	1.90 (0.97–3.74)	0.70 (0.31–1.60)	0.80 (0.37–1.73)
Previous cycles				
0	1	1	1	1
≥1	1.24 (0.67–2.31)	2.94 (1.51–5.71)	1.43 (0.67–3.05)	2.44 (1.17–5.08)
Parental status				
No children	1	1	1	1
Children	0.40 (0.16–1.00)	0.35 (0.14–0.92)	0.34 (0.09–1.24)	0.69 (0.24–1.95)

95% CI = 95% confidence interval; OR = odds ratio.

^aReference class: ≤ 3 years; ^bAdjusted for all the variables in the table.

Philippe: 'It's almost like buying a frozen product. (. . .)'
 Sarah: 'It has a[n] [expiry] date; it has a[n] [expiry] date.'
 Philippe: '[After some time] you cannot keep it in the fridge, because it deteriorates.'

This 'expiry date' view tended to be used as an argument that sustains the idea that there is an evidence-based limit for embryo storage. Interviewees also talked about other criteria allegedly based on scientific knowledge, such as the 'efficiency of technology' and 'women's reproductive age'. Andrea considered that 'the embryo storage limit should be extended until the end of the woman's reproductive age', while Charles believed that legal frameworks are grounded on evidence assuring that embryos are 'in a good condition':

Charles: 'To be regulated in the law [embryo storage limit], it should be the period that medicine considers acceptable for maintaining embryos in a good condition.'

Assuming that an embryo in Portugal should be like an embryo wherever, Mathew highlighted how the establishment of different storage limits may reproduce social inequalities between countries:

Mathew: 'I also think that it [cryopreservation] is related with institutional funds and with its importance for assuring future generations in each country. (. . .) An embryo here [in Portugal] should be like an embryo in Germany (. . .) or wherever. . . They are embryos, [but] there could be differences in funding to keep them and to carry out [embryo] research.'

Aiming to mitigate some of these inequalities, Anthony proposed the publication of transnational legislation establishing a storage limit which includes alternatives for storage fees:

Anthony: 'I think that this issue [storage limit] should be ruled by a European Code (. . .). If we are talking about [financial] costs, an alternative should be offered to families after [public] funded treatments.'

The flexible stipulation of a storage limit, according to couple's reproductive trajectories (namely the 'appropriate time between deliveries', either because women's bodies need to 'normalize' or because it is the 'ideal gap between siblings'), was also invoked, as the dialogue between Harry and Annabelle illustrates:

Harry: 'The embryo storage limit is also related with the time that one must give for women's [bodies] to get back to normal, I suppose.'

Annabelle: '(. . .) even if we want more children, we always want some time [from one baby to another], like three years, for a baby to grow (. . .).'

Discussion

This mixed-methods study reveals several aspects that can be useful in implementing patient-centred policies on embryo storage. It may help in developing patient information and understanding around storage periods and the reasons for limitations, in a context where the views of the patients apply across legal and political boundaries. The qualitative finding that the majority of the interviewed couples believed that financial costs and decreased embryo quality were the main reasons for the establishment of the storage limit draws attention to patients' educational and informational needs. Quantitative data suggest that having experienced at least one previous cycle influence the option for an extended storage

limit, while the shortest period was more often preferred by female participants with children. These features support the need of flexibility and sensitivity in enacting guidelines to regulate applications to extend embryo storage, taking into account reproductive trajectories and life conditions of patients. Knowledge about patients' perspectives and misconceptions helps in providing timely, consensual and relevant information to IVF patients. In this sense, these results challenge current clinical practices worldwide, including countries who currently have storage limits for embryos in storage.

In Portugal, the cost of embryo cryopreservation in private reproductive medicine centres is about €600 per 3 years, and there is no information about financial costs in the case of public storage facilities. In fact, financial costs of a storage facility depend upon the size of the facility and the number of embryos stored (ECASRM, 2013). Additionally, evidence shows that duration of embryo storage does not interfere with the quality of cryopreserved embryos (Marietta, 2011; Riggs et al., 2010), but patients' perception about diminishing embryo quality throughout storage has also been reported previously, grounded on similar metaphors associated with food freezing processes (Provoost et al., 2010, 2011c). What this study adds to the literature is the idea that the 'expiry date' view might be triggered by storage limits, in the sense that patients could construct a parallelism between storage limit and embryos' expiry date, calling attention to the policy and organisational aspects that influence patients' experiences (van Empel et al., 2011).

In a context where participants reported lack of knowledge about cryopreservation and embryo storage, the election of evidence-based criteria for justifying the establishment of the storage limit (namely financial costs and decreased embryo quality) might reveal the search for certainty and objectivity by which patients reinforce trust and hope in medicine and technology (Silva and Machado, 2010; Thompson, 2005). Furthermore, using food metaphors and financial reasoning might represent a way by which patients understand and make sense of highly specialized technologies and medical jargon conveyed by empirical knowledge and country's economic situation (Silva and Machado, 2011; Webster, 2007).

In this scenario, patient-related factors tended to be undervalued as criteria for limiting storage. This may explain the low number of interviewees mentioning the appropriate time frame for making the final decision regarding embryo disposition as a criteria for the storage limit. Conversely, the extension of the storage limit was prompted by personal experiences of previous cycles and not having children. These findings suggest that the opinion on the embryo storage limit might be influenced by the perception of the probability of using cryopreserved embryos for their own treatment – would-be parents could see reasons to hold on to their cryopreserved embryos as long as possible for maximizing the probability of achieving a pregnancy (Thompson, 2005), while women with children could feel more pressure to use cryopreserved embryos in a shorter period of time, in line with the belief in the existence of an age range for women to conceive (Campbell, 2011).

A limitation of this study is that data were collected at a single reproductive centre, which limits the generalizability of the results. Furthermore, answer options regarding the opinion about storage limit may have an effect on the answers of the participants, in the sense that they may presume that

it is more usual to have longer storage periods and that 3 years is about a set minimum.

In conclusion, this mixed-methods study shows how reproductive trajectories influence IVF patients' appraisal of embryo storage time limits and indicates misconceptions and gaps in awareness of cryopreservation among IVF patients. Findings suggest that the patients ought to be informed of the facts regarding cryopreservation of embryos, grounded on a practical ethical reasoning about embryo storage. This study also contributes to informing decision-making by all the participants in the health care system, including policy-makers. Although it does not aim to significantly influence current storage limits, this study calls attention to a critical discussion around the need of developing practice guidelines on embryo storage limits. However, future research is needed on patients' preferences regarding timing and volume of information about embryo storage.

The provision of accurate information regarding policy on embryo storage and the development of consensual guidelines regarding storage limit may contribute to raise awareness about cryopreservation, both among patients and among health professionals. Taking into account the consistent tendency to follow the international recommendations in the field of reproductive medicine, the development of guidelines could attenuate differences between countries (Brezina and Zhao, 2012), by standardizing the initial storage period and providing clear guidance on when it is lawful to extend storage beyond such a period (RTC, 2010).

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