

11-IL LEGISLATURA

**RAPPORT
TAL-KUMITAT MAGHŻUL**

DWAR

IL-PROKREAZZJONI MEDIKAMENT ASSISTITA

Settembru 2010

**KAMRA TAD-DEPUTATI
PARLAMENT TA' MALTA**

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1. Sommarju

1.1. Obbjettiv

Żewġ deċennji wara li twieldet l-ewwel tarbija bit-teknoloġija ta' riproduzzjoni assistita f'pajjiżna, dan is-settur irid jiġi regolat b'liġi biex barra li jkun jista' jiġi mgħarbel minn awtorità jkun jista' jiġi finanzjat mill-Istat u b'hekk isir aċċessibbli għal koppji infertili irrispettivament mid-dhul finanzjarju tagħhom.

1.2. Mandat tal-Kumitat Magħżul

Kif indikat fil-Mozzjoni 113, il-Kumitat Magħżul kien presedut mill-Onor. Jean Pierre Farrugia. Min-naħa tal-Gvern ġie maħtur l-Onor. Francis Agius, filwaqt li min-naħa tal-Oppożizzjoni ġie maħtur l-Onor. Michael Farrugia.

Dan il-Kumitat Magħżul ġie inkarigat jiffoka esklussivament fuq l-użu tal-Prokreazzjoni Medikament Assistita fir-rigward tal-oqsma kruċjali li kien baqa' indeċiż dwarhom il-Kumitat Permanenti dwar l-Affarijiet Soċjali fl-2005 meta tfasslu r-rakkomandazzjonijiet dwar l-użu tal-bijoteknoloġija. Għalhekk dawn ir-rakkomandazzjonijiet thallew fit-**test oriġinali** tagħhom f'dan ir-Rapport, ħlief għall-emendi li dwarhom hemm **qbil unanimu fost it-tliet membri parlamentari li pparteċipaw b'mod attiv fil-laqgħat kollha.**

Wara rapport marbut mal-prinċipji ta' moralità kif imressqa lill-Kumitat Permanenti dwar l-Affarijiet Soċjali mir-Rev. Prof. Emmanuel Agius f'Settembru 2009, kien intlaħaq qbil li diskussjoni iktar wiesgħa riedet tkompli fuq livell mediku u legali, dwar:

1.3. Deciżjonijiet tal-Kumitat Magħżul

1.3.1. Liema koppji ser ikunu eliġibbli għas-servizzi tal-prokreazzjoni medikament assistita

Qbilna li mit-teknoloġiji ta' riproduzzjoni medikament assistita m'għandhomx jiġu esklużi koppji eterosesswali stabbli ta' *child bearing age* fejn persuni mxew b'mod responsabbli lejn xulxin u lejn il-*welfare* ta' wliedhom. Minkejja li koppja stabbli mhix definita fil-liġi Maltija u bħalissa għadna fl-istadju bikri li l-Kumitat Permanenti dwar l-Affarijiet Soċjali għaddej b'konsultazzjoni pubblika sabiex persuni f'koabitazzjoni jkun jistgħu jingħataw ċertu drittijiet (xi koppji stabbli jista' ma jingħatalhomx dan l-istatus) aħna tal-fehma li dokumentazzjoni li turi li koppja tkun eżawriet il-possibiltajiet kollha mediċi biex tikkura l-infertilità hi prova biżżejjed ta' stabbiltà. Biex koppja tinstab eliġibbli tkun meħtieġa wkoll riċerka biex jiġi aċċertat li ġenituri jkun osservaw l-obbligi tagħhom skont l-artikoli 3B, 7, 131 u 149 tal-Kodiċi Ċivili.

1.3.2. L-iffriżar tal-embrijuni

Kien l-Uffiċċju tal-Avukat Ġenerali li hegġigna nixprunaw l-opinjoni medika. Stedinna erba' esperti li jaħdmu *hands on* f'dan il-qasam u kien hemm **kunsens shih**:

- *Prof. Mark Brincat, Kap tad-Dipartiment tal-Obstetrija u l-Ginekologija fl-Isptar Mater Dei*: “Jekk għandhom *frozen embryos* dak li jkun anke jekk ma rnexxiex għandu ftit ta' speranza. Hija *shattering* ħafna li tgħaddi mill-proċedura kollha u għandek 60%, 70% ċans li ma joħroġux *pregnant*.”
- *Dr. Paul Soler, Kap tan-Neonatal Intensive Care Unit fl-Isptar Mater Dei*: “Bl-avvanz li għamlet il-ginekologija fl-infertilità bħala *complication* ġew il-*multi-fetal gestations*. L-*early neonatal deaths* għal tqala b'tarbija waħda hija tlieta għal kull 1,000 live birth. Jekk ikun hemm tewmin titla' għal tmien darbiet iżjed u 'l fuq minn tewmin kważi 17-il darba iżjed...mill-istorja tal-baby u mill-interviews li jiena u l-kollegi tiegħi għamilna mal-koppji li kellhom it-trabi tagħhom fil-kura intensiva sibna li 50% tat-trabi prematuri li jmutu fl-SCBU jiġu minn ommijiet li jkunu rċevew xi forma ta' kura ta' *artificial reproductive technology*, inkluż l-IVF... Jien naħseb li l-freezing mil-lat mediku huwa vantaġġjuż immens.”

Evoluzzjoni:

- *Mrs. Simone Attard, Applied Systemic Theory, Family Therapy Counsellor*: “Wara l-laqgħa li fiha *Dr Luca Gianaroli* għamel preżentazzjoni ferm dettaljata rigward proċeduri ta' Riproduzzjoni u Prokreazzjoni Medikament Assistita f'himt ferm aħjar il-bżonn tal-‘Embryo Freezing’ u dan anke fid-dawl li *Dr Gianaroli* spjega fid-dettall kemm il-*freezing* tal-*ovum* mhuwiex daqshekk ta' suċċess daqs l-‘Embryo Freezing’. Nixtieq li l-Kumitat jaħdem iktar fuq il-kwistjoni dwar x'ser jiġri mill-*embryos* li jkunu ffrizati imma ma jintużawx mill-koppja għaliex bħalma spjega tant tajjeb *Dr Gianaroli* fuq mistoqsija ta' *Chairman* wieħed ma jistax jobbliha lill-koppja biex tuża l-*embryos* kollha li jkunu ffrizaw.... L-iktar li qiegħda hawn bażikament biex nenfasizza l-punt ta' kemm għandhom bżonn *counselling* u *support* il-koppji li jkunu għaddejnin minn dan il-proċess.”
- Innutajna l-istess bidla radikali fil-pożizzjoni tal-*Kummissarju għat-Tfal u tal-Kunsill Nazzjonali tat-Tfal* li qed “jissuġġerixxu li, dejjem biex ikun fil-*best interests* tat-tfal, jithallew li jiġu impjantati zewġ embrijuni biss fl-utru tal-mara, filwaqt li l-embrijuni l-oħrajn li ma jintużawx, jiġu ffrizati għall-użu fil-futur mill-istess koppja”.

Adozzjoni ta' embrijuni ffrizati:

Il-koppji li jkollhom embrijuni ffrizati jridu jiġu mħajra jagħmlu użu minnhom kollha imma fejn jirriżulta li għal xi raġuni jew oħra dan ma jkunx possibbli, l-embrijuni ffrizati jkunu jistgħu jiġu adottati minn koppji li jkollhom problema ta' sterilità. Irid jiġi enfasizzat li embrijuni maħżuna jkunu jridu jikkonformaw mad-Direttiva 2006/17/KE li stipula l-*standards* ta' kwalità u ta' sigurtà fir-rigward ta' gameti u li tippermetti

t-traċċabilità shiha tagħhom. L-Avukat Ġenerali qed jissuggerixxi emendi fil-Kodiċi Ċivili dwar l-Adozzjoni biex dan ikun jista' japplika wkoll għall-embrijuni.

Leġislazzjoni ta' diversi pajjiżi:

Filwaqt li pereżempju l-*counselling* hu inforzat, il-liġi ma torbotx kemm jinholqu *embryos* u kemm minnhom jiġu impjantati f'salt, iżda għandu jkun hemm **guidelines ċari** u f'każ li ma jiġux osservati jkunu jridu jingħataw raġunijiet bil-miktub.

1.3.3. Id-donazzjoni ta' gameti minn terzi persuni

Fic-ċirkostanzi dehrilna li abbażi tar-rakkomandazzjoni illi għandu jkun permess l-iffriżar tal-embrijuni, ikun għaqli nistennew kif se jirreaġixxu koppji sterili għall-opportunità ta' **adozzjoni ta' embrijuni** u għalissa tibqa' projbita d-donazzjoni ta' gameti minn terzi persuni.

1.4. Awtorità

Kien hemm ukoll qbil fost il-membri tal-Kumitat Magħżul li avviż legali għandu jipprovi li titwaqqaf Awtorità b'**kollaborazzjoni mal-ESHRE** (European Society of Human Reproduction and Embryology) u **mal-HFEA** (Human Fertilisation and Embryology Authority) tal-Ingilterra. Din l-Awtorità għandha tkun awtonoma b'dawn il-funzjonijiet ewlenin:

1. tohroġ liċenzja lil klinika li f'*spezzjonijiet regolari jkun gie aċċertat li qed tosserva kundizzjonijiet ta' **Standards of Best Practice**, li jkunu supplimentari għall-Att*
2. tiġbor l-informazzjoni mogħtija lilha b'mod aggregat regolarment mill-kliniċi awtorizzati
3. tiċċertifika l-*eligibbiltà* ta' koppja biex isir l-IVF.

1.5. Konkluzjoni

Wara li għarbilna l-fehma tal-esperti mediċi, inheggu l-Gvern iħabrek iressaq **Abbozz fil-Parlament** li jirrifletti dawn il-proposti. Ir-Rapport estensiv tal-Kumitat Magħżul għandu jservi ta' għajjnuna għal kull membru parlamentari li jixtieq jinforma ruħu aktar dwar is-sugġett sabiex **b'mod meqjus u hieles** iwassal għal liġi li tirregola l-prokreazzjoni medikament assistita f'Malta.

Għandu jixprunana kliem id-Direttur taċ-Ċentru Fidi u Ġustizzja:

“It is better to have a law which permits certain things I am against from a moral point of view rather than have no law at all.”

2. Diskussjoni fil-Kumitat Magħżul

2.1. Introduzzjoni

Kien fit-13 ta' Frar 2008 li l-Kumitat għall-Impjiegi u l-Affarijiet Soċjali fil-Parlament Ewropew stqarr li l-mizuri għat-tnejn tal-bidla demografika fl-Ewropa għandhom jinkludu dritt garantit għal trattament f'każ ta' infertilità. Skont ir-rapport imhejji minn Françoise Castex (PES, FR) "il-fatt li l-medja tar-rata ta' twelid fl-UE hija biss 1.5, mhux normali. Għalkemm l-għażla tal-maternità hija waħda privata hafna u għandha tiġi rispettata, ir-rata ta' twelid tista' tiġi influwenzata b'mod pożittiv permezz ta' ambjent materjali u psikoloġiku li jiffavorixxi l-familji u t-tfal".

Fl-ewwel laqgħa fit-3 ta' Frar 2010 ġie diskuss kif għandu jitmexxa x-xogħol ta' dan il-Kumitat Magħżul. L-Onor. Michael Farrugia ssoleva illi fil-Laqgħa Nru 46 tal-11 ta' Lulju 2005 tal-Kumitat Permanenti dwar l-Affarijiet Soċjali tal-X Legislatura l-Membri tal-Oppożizzjoni rrapreżentati fil-Kumitat ma pparteċipawx fl-approvazzjoni tar-Rakkomandazzjonijiet peress li kien qed jintalab aktar żmien għad-diskussjoni fil-gruppi parlamentari rispettivi. Wara li saret evalwazzjoni mill-Kumitat Permanenti dwar l-Affarijiet Soċjali tal-XI-il Legislatura minn Rev. Prof. Emmanuel Agius, Dekan tal-Fakultà tat-Teoloġija (Etika Filosofika u Teoloġija Morali) ġie deċiż li d-diskussjonijiet kellhom ikunu limitati skont kif definit fil-Mozzjoni Nru 113 tal-21 ta' Ottubru 2009, li tgħid li:

- "Il-Kumitat Permanenti dwar l-Affarijiet Soċjali fit-Tielet Rapport tiegħu ta' Settembru 2009 osserva li diskussjoni iktar wiesgħa trid tkompli fuq livell mediku u legali dwar:
 - (a) liema koppji jkunu eliġibbli għas-servizzi tal-prokreazzjoni assistita;
 - (b) il-kwestjoni jekk għandux jiġi permiss jew le l-iffriżar tal-embrijuni; u
 - (c) id-donazzjoni ta' *gametes* minn terzi persuni."
- Il-Kumitat Magħżul kien mitlub ukoll jeżamina u jagħrbel il-kwestjonijiet kollha konnessi ma' din il-materja u jelenka l-elementi bażiċi ta' legiżlazzjoni futura dwar il-prokreazzjoni medikament assistita.

Il-Kumitat talab:

- a) għar-rakkomandazzjonijiet mibgħuta lill-Gvern mill-Kumitat Konsultattiv tal-Bijoetika;
- b) lix-xhieda li dehru quddiem il-Kumitat Permanenti dwar l-Affarijiet Soċjali tal-X Legislatura jissottomettu xi bdil jew żviluppi fil-pożizzjoni li kienu pprezentaw matul il-laqgħat li nżammu matul l-2004 u l-2005; u
- c) permezz ta' stqarrija għall-istampa, lil kulmin kellu interess fis-sugġett biex jagħmel is-sottomissjonijiet tiegħu bil-miktub.

Fi tmiem id-diskussjonijiet il-Kumitat kellu jagħmel ir-rakkomandazzjonijiet finali tiegħu lill-Gvern li sussegwentement jipprezenta abbozz fil-Parlament.

2.2. Sottomissjonijiet bil-miktub

Minbarra l-fehma tal-Kumitat Konsultattiv tal-Bijoetika, waslulna erbatax-il sottomissjoni:

SOMMARJU TAL-KONSULTAZZJONIJIET DWAR TEMI SPECIFIĊI:

	Liema koppji ?	Iffriżar tal-embrijuni ?	Donazzjoni ta' gameti ?
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Konsultazzjonijiet bil-miktub lil dan il-Kumitat:			
Kumitat Konsultattiv tal-Bijoetika	KS	LE	LE
Dr Ray Busuttil	M	LE	? IVA
Dr Mario Saliba MD, MSc, MMCFD		IVA	LE
Prof Pierre Mallia	KS	LE	LE
Dr Michael Ascjak	KS	LE	LE
Dr Stephen Mamo			LE
Wanting And Waiting, Cana Movement	M	LE	LE
Fr Edgar Busuttil (Ċentru Fidi u Ġustizzja)	M	LE	LE
Ms Sonia Camilleri (ex-Kummissarju Tfal)	<u>M</u>	<u>LE</u>	LE
Kummissarju/Kunsill Nazzjonali tat-Tfal	<u>KS</u>	<u>IVA</u>	LE

Esperti mistiedna minn dan il-Kumitat:			
Prof. Mark Brincat	KS	IVA	IVA
Dr Paul Soler		IVA	
Dr Luca Gianaroli	KS	IVA	IVA
Ms Simone Attard 2005/April 2010	M	<u>LE /IVA</u>	LE

Esperti mqabnda mill-Kumitat tal-Affarijiet Soċjali fl-2005 li ma reġghux issottomew opinjoni meta kkomunika magħhom dan il-Kumitat :			
Prof. Alex E. Felice	M	IVA	IVA
Dr Josie Muscat	M	?IVA	LE
Dr Deborah Schembri Tabone	M	LE	LE
Dr Janet Mifsud (Kummissjoni Nazzjonali Promozzjoni Ugwaljanza)	M	LE	LE
Dr Andrè Camilleri (Kummissjoni Nazzjonali Familja)	M	LE	LE
Ms Doreen Susanne Micallef (Kunsill Nazzjonali Nisa)	KS*	LE	LE
Rev. Prof Peter Serracino	M	IVA	LE

Inglott			
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	Liema koppji ?	Iffriżar tal-embrijuni ?	Donazzjoni ta' gameti ?
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Espert imqabbd mill-Kumitat tal-Affarijiet Soċjali fl-2005 u fl-2009:			
Rev. Prof. Emmanuel Agius	M	LE	LE

KS = KOPPJI STABBLI;

KS* = KOPPJI STABBLI REGOLATI BIL-LIĠI TAL-KOABITAZZJONI;

M= MIŻŻEWĠIN

2.3. Diskussjoni wiesgha fuq livell mediku f' soċjetà pluralista

Dwar it-tema “il-bijoteknologija f' Malta u d-drittijiet tal-bniedem” Prof. Peter Serracino Inglott kien stqarr fil-Kumitat Permanenti dwar l-Affarijiet Soċjali fis-7 ta' Frar 2005:

“Jiena ma rridx nidhol fil-partijiet tekniċi bijoloġiċi u mediċi għax dak mhuwiex il-kompitu tiegħi. Jiena aċċettajt li nagħmel din il-prezentazzjoni għax jiena professur tal-filosofija u l-etika hija parti bażika mill-filosofija....

*Donum Vitae*¹ fiha l-ewwel erba' sezzjonijiet li jikkellmu fuq is-sustanza tal-ħaġa, imma mbagħad għandek il-ħames sezzjoni li tagħmel enfasi kbira fuq il-fatt li dak li huma qegħdin jiddikjaraw li mhuwiex morali, li għal Kattoliku huwa dnub, m'għandux ikun neċessarjament illegislat kontra. Dan huwa prinċipju magħruf hafna, tradizzjonali minn dejjem, li **mhuwx kull dnub għandu jkun delitt...**

...min qed jikkellem hawnhekk fuq il-moralità qed jikkellem fuq ċerti *assumptions* li huma ta' natura xjentifika u teknoloġika fejn min mhuwiex kompetenti faċilment jiżbalja. Għalhekk jiena ridt inkun kawt u ma nipprovax nippreskrivi kemm *embryos* tista' toħloq u kemm huwa l-ammont minimu li għandu jiġi impjantat għax **dawn iktar jistghu jiddeċiduhom in-nies b'kompetenza xjentifika milli nies b'kompetenza etika jew legiſlattiva, biex ngħid hekk....**

Fil-prezent l-isptar pubbiku qed iwassal il-proċess sal-mument tal-implantazzjoni. Jiġifieri l-biċċa l-kbira tal-ispiza qiegħed diġà jagħmilha. Jiġifieri r-raġuni għaliex qed jipprobiha mhijiex raġuni għax il-gvern ma jistax jaffordjaha, imma għax qed iqis li hija immorali. **X'mhuwiex ġust hu li jipprobiha għaliex iqisha immorali fl-isptarijiet tiegħu imma jhalliha ssir, għalkemm iqisha immorali, fl-isptarijiet privati. Din hija ingustizzja.**”

Konfortati minn dan il-kliem, aħna l-membri tal-Kumitat Magħżul dwar ir-Regolamentazzjoni tal-Prokreazzjoni Medikament Assistita, għalkemm il-koll tobbja, poġġejna l-opinjoni personali tagħna fil-ġenb u użajna l-esperjenza tagħna biex nistimulaw lix-xjenzati lokali u kontinentali li ilhom is-snin jaħdmu *hands on* f'dan il-qasam sabiex jesprimu rwieħhom professjonalment.

Kompla jixprunana niffukaw fuq livell mediku l-uffiċċju tal-Avukat Ġenerali li stqarr bla tlaqliq: **“Ir-regolamentazzjoni tal-prokreazzjoni medikament assistita tistrieħ hafna fuq l-opinjoni medika aktar milli fuq l-opinjoni legali. Fil-fatt hi aktar l-opinjoni medika li għandha tinforma l-opinjoni legali f'din il-materja milli l-kuntrarju.”**

¹ *Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation* maħruġa fit-22 ta' Frar 1987 mill Kongregazzjoni tad-Duttrina tal-Fidi - http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html

2.4. Laqgħat tal-Kumitat Magħżul

Fis-sitt xhur disponibbli minn Frar sa Lulju 2010 il-Kumitat Magħżul iltaqa' 11-il darba u t-tliet membri kienu preżenti għal kull laqgħa. Minbarra li ffoka dwar liema koppji għandhom ikunu eligibbli għas-servizzi tal-prokreazzjoni medikament assistita u f'liema ċirkostanzi jistgħu jkunu meħtieġa l-iffriżar tal-embrijuni u d-donazzjoni ta' gameti minn terzi persuni, il-Kumitat ra wkoll hemmx kunsens dwar ir-Rakkomandazzjonijiet approvati mill-Kumitat Permanenti dwar l-Affarijiet Soċjali fl-2005, esklussivament għal dak li jirrigwarda l-Użu tal-Prokreazzjoni Assistita.

Fil-fatt hemm kunsens unanimu fuq it-test originali kif emendat hawnhekk bl-ispjegazzjoni dettaljata wara kull artiklu li dwaru kien hemm diskussjoni.

7. Prokreazzjoni assistita

L-użu ta' din it-teknoloġija għandu jkun permissibbli bil-liġi taht ċerti kundizzjonijiet.

7.1 L-użu legittimu tat-teknoloġija: Din it-teknoloġija tkun legittimament użata meta:

- (A) Tirrispetta l-hajja umana u lill-persuna umana fl-istadju ta' dan il-proċess.
- (B) Tintuża biss għall-kundizzjonijiet tal-infertilità u l-prevenzjoni ta' ċerti problemi ta' mard futur.
- (C) Ma tintużax għal raġunijiet ta' selezzjoni ewġenika negattiva.
- (D) Ma tesponix lill-omm jew lill-wild għal riskji li mhumiex raġjonevoli.

7.2 Il-harsien tal-ulied

It-teknoloġija tal-Prokreazzjoni Assistita għandha qabel kollox tipproteġi d-dinjità u l-integrità tal-wild futur billi tassigura li:

- (A) Ma tagħmel xejn li jhedded stat ta' saħħa tajjeb għall-wild futur.
- (B) L-eventwali ġenituri għandhom ikunu **adulti** ta' *child bearing age*.
- (C) **It-twelid iseħħ fil-wens ta' koppja eterosesswali f'relazzjoni stabbli.**

Fil-laqgħa tad-9 ta' Frar dwar liema koppji eterosesswali għandhom ikunu eligibbli għall-prokreazzjoni medikament assistita kien hemm kunsens unanimu fil-Kumitat

Magħżul li wiehed m'għandux jeskludi lil min verament jixtieq ikollu tarbija, basta jkun hemm koppja li tkun verament responsabbli lejn xulxin u lejn il-welfare tat-tfal.

- Rajna xi tgħid il-*ligi Taljana* għax il-*ligi* tal-prokreazzjoni medikament assistita (*Legge 19 febbraio 2004, n. 40 "Norme in materia di procreazione medicalmente assistita"*) ippreċediet dik dwar id-drittijiet u d-dmirijiet ta' koppji stabbli (*Diritti e doveri delle persone stabilmente conviventi (DICO) - Disegno di legge 8 febbraio 2007*).

ART. 5.
(Requisiti soggettivi).

1. Fermo restando quanto stabilito dall'articolo 4, comma 1, possono accedere alle tecniche di procreazione medicalmente assistita coppie di maggiorenni di sesso diverso, coniugate o conviventi, in età potenzialmente fertile, entrambi viventi.

Dwar dan is-sugġett fis-sit tal-Unione di Centro insibu ittra miktuba f'Diċembru 2006 minn Rocco Buttiglione li ma sarx Kummissarju tal-UE f'Ottubru 2004 minhabba oġġezzjoni mill-Kumitat għal-Libertajiet Ċivili, il-Ġustizzja u l-Intern (LIBE) tal-Parlament Ewropew.

Sul tema d'attualità delle famiglie di fatto pubblichiamo una lettera che il presidente del Consiglio Nazionale, Rocco Buttiglione, ha inviato ai dirigenti del partito:

"...Il governo e la maggioranza intendono proporre un provvedimento sulle "coppie di fatto". Si tratta – essi dicono – di una questione di diritti. Noi osserviamo umilmente che non ogni desiderio o rivendicazione soggettiva costituisce un diritto. Ricorda proprio in questi giorni Benedetto XVI che ai diritti corrispondono i doveri.... Che diciamo delle coppie di fatto eterosessuali? È presto detto: le coppie di fatto eterosessuali per lo più dopo un certo numero di anni o si lasciano o si sposano. Se tuttavia persistono nel loro vincolo, hanno dei figli, li amano e li educano, svolgono la funzione sociale della famiglia e assolvono in tutto o in parte i doveri della famiglia, allora è giusto che abbiano anche i diritti della famiglia. In questi casi è però lecita la domanda: perché non si sposano? In realtà nella maggioranza dei casi alla fine si sposano. In ogni caso non si può accettare che alcuni pretendano di avere i diritti della famiglia senza adempiere ai corrispondenti doveri ed alla funzione sociale della famiglia..."²

- F'pajjizna l-Prim Awla tal-Qorti Ċivili fl-14 ta' Ottubru 2008 u l-Qorti Kostituzzjonali fl-Appell Ċivili Nru 28/2008/1 fit-3 ta' April 2009, fir-rigward tal-Liġi dwar l-Adozzjoni stqarret: "F'każ ta' persuni li jgħixu flimkien, ikun xieraq illi jkun hemm xi garanzija ta' stabilità tal-koppja qabel ma tiddaħhal persuna oħra fir-relazzjoni permezz ta' adozzjoni, biex jitnaqqas kemm jista' jkun - għalkemm qatt ma jista' jitneħħa għal kollox - il-biża' li koppja tinfired u l-wild adottat jgħaddi mit-trauma tal-firda ta' dawk li jħares lejhom bħala l-ġenituri tiegħu."
- Staqsejna lill-Uffiċċju tal-Avukat Ġenerali: Kif il-liġijiet ta' Malta jiddefinixxu 'koppja stabbli'? "Is-sottoskritt mhuwiex a konozzenza illi f'xi liġi Maltija tezisti xi definizzjoni ta' "koppja stabbli."

² <http://www.udc-italia.it/Dipartimenti/ContenutiStaitci.aspx?tipo=226&dip=21>

- Bħalissa l-Kumitat Permanenti tal-Affarijiet Soċjali qiegħed f'konsultazzjoni pubblika "sabiex persuni f'koabitazzjoni jkunu jistgħu jingħataw ċertu drittijiet".

Il-Kumitat tagħna fil-frattemp sħarreg dwar:

- **Aġenziji lokali pubbliċi** bħall-Korporazzjoni għall-Impjiegi u t-Taħriġ li jitolbu bħala evidenza ta' relazzjoni stabbli karti tal-identità u kontijiet fil-banek. Staqsejna lill-Uffiċċju tal-Avukat Ġenerali: Min għandu dritt bil-liġi jkun jaf persuna x'kontijiet għandha fil-banek, partikolarment meta dawn ikunu *joint accounts*? "Il-kontijiet fil-banek huma kuntratt bejn id-depożitant u l-bank biex il-bank iżomm u jhaddem il-flus tad-depożitant kontra pagament ta' imgħax. Dawn il-kontijiet huma l-proprjetà personali ta' sidhom u, salv il-liġijiet li jipprovdu għall-ħruġ ta' mandati ta' sekwestru jew xort'ohra mill-Qrati, għal-liġijiet li jipprovdu għall-investigazzjonijiet fiskali u kriminali u għal liġijiet ohra li jipprovdu għal poteri ta' interferenza minn xi awtorità pubblika f'dan il-qasam, hadd ma għandu dritt li jkun jaf dwar il-kontijiet bankarji ta' persuni ohra."

Fil-fatt kif spjega l-Onor. Michael Farrugia din it-tip ta' evidenza ftit tista' tiswa fil-prattika:

"Mela għandek koppja separata; il-fatt li inti separat għad fadallek ċerti obbligi. Mela jekk ir-raġel jaħdem u l-mara taħdem ukoll, hafna drabi kollox jimxi sew u m'għandekx problemi. Imma jekk il-mara ma taħdimx u r-raġel jaħdem, il-mara tista' titlob manteniment minghand ir-raġel. U viċversa, jista' jagħmel l-istess haġa r-raġel. Mela allura, pereżempju, ir-raġel ma jaqbillux - jekk is-sieħba tiegħu taħdem filwaqt li hu jidher li ma jaħdimx - jagħmel *joint account* mas-sieħba tiegħu għax inkella se jitlef il-manteniment li jieħu minghand il-mara tiegħu."

- Koppja infertili f'relazzjoni stabbli li jkollha dokumentazzjoni li flimkien eżawrew il-possibilitajiet kollha mediċi – dawn id-dokumenti huma prova li l-persuni speċifiċi jkunu ilhom flimkien mill-inqas f'relazzjoni ta' sentejn. Fil-fatt l-ESHRE (European Society of Human Reproduction and Embryology) tikkonferma li 92% ta' koppji li ma jużawx kontraċezzjoni u li jkollhom x'jaqsmu sesswalment b'mod regolari għandhom jikkonċepixxu fi żmien sentejn.
- Persuni separati legalment jew persuni mhux miżżewġa li huma ġa ġenituri għandhom responsabilitajiet li jibqgħu jingarru – fil-każ ta' tfal imnijsla u mwielda barra miż-żwieġ għandu jkun mistħarreg jekk il-missier ikunx għaraf lil uliedu u jkunx ikkontribwixxa għall-manteniment tagħhom. Għandu jsir l-istess fejn japplika għall-omm (*Mater semper certa est*). Għalhekk tkun meħtieġa riċerka fir-Registru Pubbliku u dwar rikorsi fil-qrati qabel ma koppja tinstab eliġibbli għall-prokreazzjoni assistita. Staqsejna lill-Uffiċċju tal-Avukat Ġenerali: X'inhuma l-obbligi legali ta' ġenituri, kemm jekk dawn ikunu miżżewġin u wara jisseparaw u kemm jekk dawn kellhom ulied barra ż-żwieġ?:

"Skont l-artikoli 3B u 7 tal-Kodiċi Ċivili il-ġenituri għandhom l-obbligu li jieħdu ħsieb, imantnu, jgħallmu u jedukaw lil uliedhom skont il-hila, xeħtiet naturali u l-aspirazzjonijiet tal-ulied. Dispożizzjonijiet ohra tal-Kodiċi Ċivili (Artikoli 131 sa 149 tal-Kodiċi Ċivili)

imbagħad jipprovdu f'aktar dettall dwar kif dawn l-obbligi jiġu implimentati. Id-deċizjonijiet tal-Qrati li jipprovdu għall-kustodja tat-tfal fejn il-ġenituri jkunu sseparaw jew ta' tfal imweldin barra ż-żwieġ jirregolaw dan l-obbligu fis-sitwazzjonijiet partikolari u fl-aħjar interess tal-minuri.”

(D) Id-donazzjoni ta' embrijuni lil koppji oħra li ma jkunux il-ġenituri ġenetiċi m'għandhiex tkun permessa.

(E) Embrijuni maħzuna li jkunu se jiġu b'xi mod distrutti jistgħu jiġu addottati minn koppji oħra bil-liġijiet relatati kollha japplikaw.

Iddiskutejna dwar dan fit-28 ta' Ġunju fejn rajna qabel xejn l-opinjoni tal-Avukat Ġenerali:

Fil-fehma tiegħi il-kliem tad-dispożizzjonijiet legali fil-Kodiċi Ċivili li jirregolaw l-adozzjoni ma jipprestawx ruħhom li jiġu interpretati li jestendu għall-adozzjoni ta' embrijuni. Biżżejjed jingħad li artikolu 116 tal-Kodiċi jipprovdi li:

116. (1) Hlief meta r-rikorrent jew wiehed mir-rikorrenti jkun l-omm jew il-missier tal-persuna li tkun se tiġi adottata, ma jingħatax digriet ta' adożzjoni jekk il-persuna li tkun se tiġi adottata ma kinitx kontinwament fil-kura u l-pussess tar-rikorrent għal mill-inqas tliet xhur konsekuttivi minnufih qabel id-data tad-digriet ta' adożzjoni,....

Fil-fehma tiegħi dan hu biżżejjed sabiex juri li l-liġi tal-adożzjoni ma kinitx intiza biex tapplika għall-adożzjoni ta' embrijuni. Sabiex ikun ċar li d-dispożizzjonijiet imsemmija jkunu jestendu wkoll għall-adożzjoni ta' embrijuni, darba jiġi deċiż li dan ikun desiderabbli, ikun irid isir aġġustament tad-dispożizzjonijiet imsemmija u ma hux eskluż li jkunu meħtieġa jiżdiedu xi dispożizzjonijiet biex speċifikament ikopru l-ħtiġijiet speċifiċi ta' adożzjonijiet ta' embrijuni.

F'din il-laqgħa gie enfasizzat li embrijuni maħzuna jkunu jridu jikkonformaw mad-Direttiva 2006/17/KE:

THE CHAIRMAN: Filwaqt li ma tistax tagħmilha tassattiva li l-*adoption of embryos* jrid isir minn Malta stess, għax nahseb li jkun hemm xi liġijiet li jkunu qegħdin jiġu *infringed* fejn jidhlu drittijiet ta' embrijuni, eċċ, nahseb li wiehed għandu jirrakkomanda li l-ewwel għandna nippruvaw nadottaw anke billi forsi l-gvern ikun jista' jgħin finanzjarjament. Jekk inti tadotta *embryo* minn Malta, il-gvern jgħinek finanzjarjament, mentri jekk inti tadotta *embryo* minn barra, il-gvern ma jgħinekx. Allura hemmhekk wiehed ikun jista' jiffacilita ...

ONOR. MICHAEL FARRUGIA: L-unika problema li se niffaccaw nahseb li tajjeb li nahsbu fuqha għax jista' jkun li nsibuha ma' wiċċna bhala wahda mill-mistoqsijiet, se tkun din: Jekk jiena nadotta persuna, jiena naf dik il-persuna kif inhi, jekk hijiex b'saħħitha, jekk hijiex marida, jekk għandhiex problemi ġenetiċi, eċċ. Jekk jiena se naddotta embrijun, se jsiru t-testijiet fuq l-embrijun qabel jiġi impjantat ...

ONOR. FRANCIS AGIUS: Jiena nara illi biex aħna nkunu konsistenti, bilfors irridu naraw li jkun hemm diskriminazzjoni pożittiva favur *embryos* Maltin li jiġu *adopted*. Għax aħna qegħdin nippruvaw insibu soluzzjoni għal dawn l-*embryos* ...

ONOR. MICHAEL FARRUGIA: Ma tista' żzomm lil hadd.

THE CHAIRMAN: Imma tista' tincentiva.

ONOR. MICHAEL FARRUGIA: Għax jekk jiena se mmur l-Ingilterra u se jgħiduli: Isma' ahna li se nipprovdh fuq l-NHS fejn se nagħtuk assigurazzjoni li dan l-embrijun għie ttestjat, huwa b'saħħtu u *ċ-chances* huma li se jkollok tarbija b'saħħitha. ...

THE CHAIRMAN: Inti tagħmel *gamete screening* f'każ li huma se jużaw l-*option* ta' *freezing of embryos*, halli jekk dawh l-*embryos* ma jużawhomx, wieħed ikun jista' jittrejsja li għejjin minn koppja fejn wieħed minnhom huwa *HIV positive*, pereżempju, jew għandu *muscular dystrophy* fil-familja. Għax jekk ma jsirx hekk, hadd ma jkun irid jadotta *embryos* u allura kulhadd se jmur għad-*donation of gametes*. Jiena tlaqt b'din il-premessa wara li smajt lilkom tesprimu lilkom infuskom b'dan il-mod.

*COMMISSION DIRECTIVE 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (Text with EEA relevance)*³

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(a) thereof,

Having regard to Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (1), and in particular points (b), (d), (e), (f), and (i) of Article 28 thereof,

Whereas:

(1) Directive 2004/23/EC lays down standards of quality and safety for the donation, procurement and testing of all human tissues and cells intended for human applications, and of manufactured products derived from human tissues and cells intended for human applications, so as to ensure a high level of human health protection.

(2) In order to prevent the transmission of diseases by human tissues and cells for human applications and to ensure an equivalent level of quality and safety, Directive 2004/23/EC calls for the establishment of specific technical requirements for each one of the steps in the human tissue and cell application process.

(3) The use of tissues and cells for application in the human body carries a risk of disease transmission and other potential adverse effects in recipients. That risk can be reduced by careful donor selection, testing of each donation and the application of procedures to procure tissues and cells in accordance with rules and processes established and updated according to the best available scientific advice. Therefore, all tissues and cells, including those used as starting material for the manufacture of medicinal products, to be used in the Community should meet the quality and safety requirements laid down in this Directive.

(4) Reproductive cells have, due to the specific nature of their application, specific quality and safety characteristics that are taken into account in this Directive.

(5) For the donation of reproductive cells between partners that have an intimate physical relationship, it is justified to require less stringent biological testing, given that in this case the risk for the recipient is considered less than for donation from third parties. In order to minimise the risk of cross-contamination, biological testing of the donor will be necessary only when the donated cells will be processed, cultured or stored.

³ Id-Direttiva shiha tinsab annessa ma' dan ir-rapport.

(6) *This Directive is based on international experience drawn upon through an extensive consultation, the Council of Europe's Guide to safety and quality assurance for organs, tissues and cells, the European Convention on Human Rights, the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4.IV.1997), with its additional protocols, and recommendations from the World Health Organisation. In particular, with regard to further additional biological testing for donors originating from high-incidence areas of specific diseases or whose sexual partners or parents originate from high-incidence areas, Member States will refer to existing international scientific evidence. The Directive is consistent with the fundamental principles set out in the European Charter of Fundamental Rights.*

(7) *The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2004/23/EC,*

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions

For the purposes of this Directive, the following definitions apply:

(a) 'reproductive cells' means all tissues and cells intended to be used for the purpose of assisted reproduction;

(b) 'partner donation' means the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship;

(c) 'direct use' means any procedure where cells are donated and used without any banking;

....

Article 3

Selection criteria for donors of tissues and cells

The competent authority or authorities shall ensure that donors comply with the selection criteria set out in:

(a) Annex I for donors of tissues and cells, except donors of reproductive cells;

(b) Annex III for donors of reproductive cells.

Article 4

Laboratory tests required for donors

1. The competent authority or authorities shall ensure that:

(a) donors of tissues and cells, except donors of reproductive cells, undergo the biological tests set out in point 1 of Annex II;

(b) the tests referred to in point (a) are carried out in compliance with the general requirements set out in point 2 of Annex II.

2. The competent authority or authorities shall ensure that:

(a) donors of reproductive cells undergo the biological tests set out in points 1, 2 and 3 of Annex III;

(b) the tests referred to in point (a) above are carried out in compliance with the general requirements set out in point 4 of Annex III.

...

ANNEX III

SELECTION CRITERIA AND LABORATORY TESTS REQUIRED FOR DONORS OF REPRODUCTIVE CELLS

AS REFERRED TO IN ARTICLE 3(b) AND ARTICLE 4(2)

1. Partner donation for direct use

Donor selection criteria and laboratory testing do not need to be applied in the case of partner donation of reproductive cells for direct use.

2. Partner donation (not direct use)

Reproductive cells that are processed and/or stored and reproductive cells that will result in the cryopreservation of embryos must meet the following criteria:

2.1. the clinician responsible for the donor must determine and document, based on the patient's medical history and therapeutic indications, the justification for the donation and its safety for the recipient and any child(ren) that might result;

2.2. the following biological tests must be carried out to assess the risk of cross-contamination:

- HIV 1 and 2 Anti-HIV-1,2***
- Hepatitis B HBsAg***
- Anti-HBc***
- Hepatitis C Anti-HCV-Ab***

In case of sperm processed for intrauterine insemination and not to be stored, if the tissue establishment can demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated processes, biological testing may not be required;

2.3. where HIV 1 and 2, hepatitis B or hepatitis C test results are positive or unavailable, or where the donor is known to be a source of infection risk, a system of separate storage must be devised;

2.4. HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;

2.5. in certain circumstances, additional testing may be required depending on the donor's travel and exposure history and the characteristics of the tissue or cells donated (e.g. Rh D, malaria, CMV, T. cruzi);

2.6. positive results will not necessarily prevent partner donation in accordance with national rules.

3. Donations other than by partners

The use of reproductive cells other than for partner donation must meet the following criteria:

3.1. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases (such as sexually transmitted infections), or health risks to themselves (e.g. superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor);

3.2. the donors must be negative for HIV 1 and 2, HCV, HBV and syphilis on a serum or plasma sample, tested in accordance with Annex II, point 1.1, and sperm donors must additionally be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT);

3.3. HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from

3.4. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, malaria, CMV, T. cruzi).

3.5. for autologous donors, Annex I, point 2.1.1 applies;

3.6. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information must be provided, in accordance with the requirements in force in Member States. Complete information on the associated risk and on

the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

4. General requirements to be met for determining biological markers

4.1. The tests must be carried out in accordance with Annex II, points 2.1 and 2.2.

4.2. Blood samples must be obtained at the time of donation.

4.3. Sperm donations other than by partners will be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

- **Interessanti d-divergenzi fil-Knisja Kattolika f' dan ir-rigward:**

Dignitas Personae⁴

"The proposal that these embryos could be put at the disposal of infertile couples as a treatment for infertility is not ethically acceptable for the same reasons which make artificial heterologous procreation illicit as well as any form of surrogate motherhood; this practice would also lead to other problems of a medical, psychological and legal nature.

It has also been proposed, solely in order to allow human beings to be born who are otherwise condemned to destruction, that there could be a form of "prenatal adoption". This proposal, praiseworthy with regard to the intention of respecting and defending human life, presents however various problems not dissimilar to those mentioned above."

In the United States, there is the Snowflake Baby Program, promoted by National Right to Life as an alternative to embryo destructive research on these embryos. Certainly, this was a well-intentioned movement. At the time, between "Donum Vitae" and "Dignitas Personae," Catholics could in good conscience, after weighing both sides of the debate, adopt a frozen embryo. Following the publication of Dignitas Personae this would no longer seem to be an option a Catholic can in good faith pursue.

ZENIT: What issue is left uncovered by these two documents?

[ZENIT is a non-profit international news agency comprising a team of professionals and volunteers who are convinced of the extraordinary richness of the Catholic Church's message, particularly its social doctrine. The ZENIT team sees this message as a light for understanding today's world.]

Scarnecchia: Certain cases of altruistic frozen embryo "rescue". Paragraph 19 states that, despite the noble intention of saving their lives, rescuing frozen embryos would not be much different than heterologous in vitro fertilization (combining the gametes of non-spouses) and surrogacy. My talk was about the situation of a mother who repents of the sin of in vitro fertilization and wants to take back or rescue her own frozen embryos. When I was asked to advise on this issue for a legal case, Evans v. UK, pending before the European Court of Human Rights back in 2006, my response was that the genetic mother could rescue her own frozen embryos, and not become a surrogate and, so, Catholic members of the European Parliament could advocate for this outcome in good faith. Let's not forget, that back in the early 90s, Dr. Jerome Lejeune testified in court that the genetic mother had a duty to take

⁴ *Instruction on Certain Bioethical Questions - mahruġa fit-8 ta' Settembru 2008 mill-Kongregazzjoni tad-Duttrina tal-Fidi - http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html*

reasonable steps to save her “tiny children” frozen in a “concentration can.” I believe the principle that underlies “Donum Vitae’s” objection to in vitro fertilization is the relational nature of the human person, and in particular the gift of self that spouses promise to each other and have a duty to fulfill.

[D. Brian Scarnecchia is the founding President of the International Solidarity & Human Rights Institute (ISHRI). He is the Chairman of the Department of Humanities and Catholic Social Thought and the Director of the Legal Studies and the Human Life Studies programs at the Franciscan University of Steubenville. He is a member of the expert committee of the Rome Forum of Catholic NGOs.]

- **Intervista f’L’espresso April 21, 2006**

Heterologous fertilization

MARINO - You have also referred to the distinction between homologous and heterologous fertilization. This is a quite controversial question. In fact, if a couple’s desire to create a family cannot be realized because of infertility problems or the presence of genetic diseases in one of the two potential parents, why not have recourse to the sperm or egg of a person outside the couple? Couldn’t this represent a solution for meeting this family’s desire? Does genetic patrimony still matter more?

Reflecting on this topic, my first assessment would be in favor of heterologous fertilization, if this is the only means for having a child and if becoming pregnant is important for the woman. But I have also faced those who maintain that it is not rare for heterologous fertilization to introduce an imbalance in the couple between the biological parent, who transmits part of his or her DNA to the child, and the other.

Some of the studies published in scientific journals and conducted in countries where heterologous fertilization is permitted have highlighted the fact that nuclear families can be created that are psychologically unbalanced in favor of the parent who has transmitted part of his or her genetic patrimony to the child, as if one parent were somehow more valuable than the other.

Another question concerns transparency: should the child conceived by heterologous fertilization be informed of this fact? And, if the answer is in the affirmative, is it right to follow a path that can create psychological traumas, even if this is done from the desire to have a child? Does outlawing the recourse to heterologous fertilization mean limiting citizens’ freedom, or should it be interpreted as a way of safeguarding future generations?

[Professor Ignazio Marino, a Catholic scientist and bioethicist of international fame, is the director of the transplant center at Jefferson Medical College in Philadelphia. Last April 10, he was elected to the Italian senate for the party of the Democrats of the Left.]

MARTINI – The objections of a psychological nature that you have recalled are some of the reasons that have prevented more than a few couples from proceeding along the way of heterologous fertilization, even if this can involve suffering on the part of some. From the ethical point of view, a related issue is the protection of the privileged relationship that is instituted between a man and a woman in marriage.

Nevertheless, my personal reflections also turn to the situations that are created with the various forms of adoption and foster care, where apart from the genetic patrimony it is possible to establish a real emotional and formative relationship with persons who are not parents in the physical sense of the word. I would, therefore, be prudent about expressing my views on the cases that you bring up, where it is not possible to resort to the sperm or egg of the couple itself. This is all the more true in cases in which the fate of embryos otherwise destined for destruction

must be decided, and in which the implantation of these in a woman's womb – even a single woman – would seem to be preferable to their pure and simple destruction.

It seems to me that we are in those gray areas of which I spoke earlier, in which the correct view probably stands on the side of those who reject heterologous fertilization, but in which it may not be opportune to demonstrate a certainty that is still waiting for confirmation and experimentation.

[Cardinal Carlo Maria Martini, 79, a Jesuit and a great specialist in Sacred Scripture, was archbishop of Milan from 1979 to 2002. He now lives in Jerusalem where he has resumed his biblical studies.]

The existing frozen embryos

MARINO – Your reply permits me to expand upon our reflection on the fate of existing embryos, even beyond what has been hypothesized above. When these are not to be used, what would be the ethical thing to do? At present no solution has been identified, except that of leaving the test tubes in the freezers. But is it ethically correct and acceptable to tolerate that thousands of human embryos should remain frozen in the infertility clinics, simply waiting to expire in the cold over the passing years? Could they not, for example, be destined for single women who want to become pregnant? Or for couples with problems linked to genetic illnesses who cannot have recourse to normal artificial fertilization to avoid the risk of transmitting a genetic defect?

MARTINI – It seems to me that here we are facing a conflict of values, which is more evident in the case of the single woman who wants to become pregnant, but which also exists, for the reasons I explained above, in the case of couples who for serious medical reasons cannot have recourse to normal artificial fertilization. Where there is a conflict of values, it seems to me more ethically meaningful to favor the solution that permits a life to flourish, rather than let it die. But I understand that not everyone is of this opinion. I would only like to avoid a clash on the basis of abstract and general principles where, instead, we are in a gray area that it is proper to enter free from dogmatic judgments.

Adoption for single persons

MARINO – Then there are other problems connected to the development of life, and in particular to the care that society should have for children who do not have a family. In these cases, there appears the possibility for the usefulness, the necessity almost, of adoption. In Italy today, adoption is not allowed for single persons, and more generally the legislation is very complex and makes every sort of adoption difficult. I ask myself whether, from the ethical point of view, it is better for a child who has been orphaned or abandoned by his parents to spend his life in an institution or on the street rather than having a family composed of a single parent? Are we sure that this is the right way to guarantee the best upbringing possible for this child?

Besides, if one of the parents loses a spouse, even after the birth of their first child, no one thinks that the child should not continue to live in his nuclear family, even if there is only one parent. Or again, the Church maintains that in the presence of a fetus, no matter what the circumstances, the woman must be invited to bring her pregnancy to term, even if the father is absent or is opposed to the pregnancy, thus making this a matter of supporting a mother who will, in practical terms, be single. So why not support adoption by single persons, once assurance has been made of the potential parent's motivation, financial means, and ability to assure a peaceful upbringing for the adopted child?

MARTINI – You are raising serious and reasonable questions on a complex topic, where I do not have sufficient experience. But I think that the point of departure is the condition that you voiced at the end. That is to say, what is necessary is to assure that those who care for adopted children have the proper motivations and also the means and capacity to assure a serene

upbringing for them. Who fulfills these conditions? In the first place, this certainly includes the family composed of a man and a woman with wisdom and maturity, and who can also provide a network of intrafamilial relationships to foster the child's growth from every point of view. Lacking this, it is clear that other persons, including singles, could provide some essential guarantees. So I would not limit myself to just one possibility, but I would leave it to the experts to determine what is in fact the best solution, here and now, for this child. The goal is to assure the most favorable conditions that are practically possible. So when there is the possibility of choosing, the best choice must be made.

(F) It-teknika tal-prokreazzjoni artifiċjali m'għandhiex tkun użata għal skopijiet ta' tqala bi prokura (*surrogate motherhood*).

(G) Fil-każ ta' fertilizzazzjoni *in vitro* (IVF) għandhom jiġu fertilizzati biss l-ammont minimu neċessarju ta' ova li huma meħtieġa sabiex il-proċess teknoloġiku jirriżulta f'suċċess.

(H) Dawk l-embrijuni kollha li ma jiġux impjantati fil-ġuf ta' dik il-mara mingħand min ġew meħuda l-ova immedjatament kif jintemm il-proċess ta' fertilizzazzjoni għandhom jiġu maħżuna f'kundizzjonijiet li ma jagħmlulhom l-ebda ħsara, biex dawn jiġu impjantati f'ġuf ommhom fi żmien raġonevoli. Il-ġenituri li jagħzlu li jahżnu l-embrijuni għandhom jinżammu responsabbli biex jagħmlu dak kollu fil-hila tagħhom biex dawn l-embrijuni jiġu eventwalment impjantati fil-ġuf tal-omm.

Fis-17 ta' Marzu lqajna lill-Prof. Mark Brincat (Kap tad-Dipartiment tal-Obstetrija u l-Ġinekologija fl-Isptar Mater Dei) li qal:

... jekk għandhom *frozen embryos* dak li jkun anke jekk ma rnexxiex għandu ffit ta' speranza. Hija *shattering* hafna li tgħaddi mill-proċedura kollha u għandek 60%, 70% ċans li ma johorgux *pregnant*.

THE CHAIRMAN: Ejja nghidu li l-pajjiż jagħzel li ma jkollux *freezing facilities* ta' *embryos*. Nagħtu każ wara li tipproduċi *embryo* il-mara jinqalghalha xi haġa u trid tistenna ċertu ammont ta' żmien sakemm tiġi biex timpjanta, dik hija xi haġa li tiġri spiss? Allura xorta jrid ikollok faċilitajiet ta' *freezing* għal dik l-eventwalità? F'dak il-każ bhala *costs*, bhala NHS u anke l-privat xorta jrid ikollok *proviso* u allura *might as well* ikollok, jew bhala *costs* tagħmel differenza?

PROF. MARK BRINCAT: Il-*pipelles* li jżommu l-*embryos* huma żgħar hafna jiġifieri tista' tistorja kwantitajiet enormi u għal żmien twil hafna, jekk trid. Kull m'għandek bżonn hu l-*liquid nitrogen* u xi hadd li joqgħod attent biex jimmantjeni l-livelli ta' *liquid nitrogen* jiġifieri l-*cost* huwa minimu hafna. Hawnhekk ċertament għandna *facilities over and above*, kwantitajiet enormi jekk irridu nużawhom. Issa sta għalina niddeċiedu fuq l-*istatus* ta' dawk l-*embryos*, u xi trid tagħmel bihom *at the end of the day*. Dik hija problema oħra. ...Għandna faċilitajiet adegwati hafna basta jkollna r-rizorsi biex immantnuhom. L-*equipment* u l-*consumables* qegħdin hawn. Ovvjament irridu nużaw l-attenzjoni f'ambitu ta' post responsabbli għalhekk *I'm very keen* li jkun hemm post responsabbli.

Nagħmel punt ieħor lura peress li semmejna l-*freezing of gametes*. Dik hija linja wahda: *embryo* hija l-iktar haġa reżiljenti u l-iktar faċli biex tpoġġi lura. Ir-rizultati tal-*frozen sperm* huma diżappuntanti hafna paragonati ma' *fresh sperm*. Però peress li għandek kwantità kbira ta' *sperm* meta tiffrizaha tista' taffordja 80% *loss rate*. Ikollok 20% li mbagħad tuża iżda mhux għall-*injections* kif konna

nagħmlu bil-*fresh sperm* fil-passat barra minn Malta, imma trid tagħmel IVF jew ICSI. Dan għaliex tant tlift sperma li biex tagħmel *donor sperm* biss wara li tkun iffriżajtha, jekk għandek *below a certain concentration* - u għadna ma nafux għaliex għandek bżonn ta' ċerta *concentration* - iċ-*chances* tiegħek huma baxxi hafna. Qed nitkellmu fuq-ICSI.

THE CHAIRMAN: *Frozen sperm* qed ngħidu Malta jew b'dawn l-*standards* tal-EU li konna qegħdin insemmu?

PROF. MARK BRINCAT: Dawn huma l-*standards* tal-UE, qed nitkellem fuq esperjenza internazzjonali. L-iktar haġa vulnerabbli hi li jkun hemm hafna aspettativi sa ċertu punt foloz li taw it-Taljani; *they were banking a lot* fuq il-fatt li se jkollhom hafna *frozen oocytes*. Ahna hadna hsieb li nixtru apparat biex niffriżaw *oocytes* hawnhekk imma *oocyte* hija ċellola waħda, allura tista' timmagine kemm hija iktar vulnerabbli jekk titlifha. Din hija problema serja hafna u għadha esperimentali. L-ewwel nett hafna drabi l-bajd li thalli barra huwa l-aġar bajd li jkollok, l-iktar vulnerabbli, u t-tieni nett mhux qed ngħid li hija impossibbli imma qiegħda *bottom of the heap* din il-bajda. L-iktar haġa vulnerabbli fl-iskala kollha ta' *gametes* hija l-bajda.

THE CHAIRMAN: Ejja ngħidu qegħdin inqas nies Malta; allura l-*costs* Malta jkunu iktar għaljin fil-privat? Qed ngħidu *economies of scale*.

PROF. MARK BRINCAT: Ahna noperaw bħal hafna pajjizi oħra; tajjeb kieku jkollna programm kontinwu għaddej però m'għandniex in-numri biex immexxu programm kontinwu. Li ahna nagħmlu f'gimghatejn, pajjizi oħrajn jagħmluhom kontinwament. Meta nitkellmu fuq problemi bit-trabi meta jitwiieldu, pajjizi oħrajn, bħal pereżempju Kings College ta' Londra għandhom 1,200 *cycles* fis-sena u jridu jaħsbu għalihom. Jekk taraw l-istatistika tal-HFEA dawn issibuhom. Oħrajn għandhom 600 fis-sena biex imantnu programm kontinwu u jiena nara li jekk ahna jkollna programm fuq l-NHS ikollna dawn in-numri, jiġifieri 600 jew 400 fis-sena. Nemmen li nitilgħu sa dawk il-livelli però *I don't want to preempt anything*. Ejja nkunu konservattivi u nitkellmu 200 għalissa, però naħseb li 'l quddiem forsi jitilgħu però ma rridx inbezza' n-nies u noqogħdu ngħidu fuq in-numri.

THE CHAIRMAN: Meta ngħidu 200 qed ngħidu 200 *cycle* fis-sena.

PROF. MARK BRINCAT: Iva, però hemm ċentri fejn b'dawk il-200 *cycle* għandhom programm kontinwu.

THE CHAIRMAN: Meta tgħid 200 *cycles* fis-sena tista' tispjegaha?

PROF. MARK BRINCAT: Ahna bħal hafna pajjizi oħrajn *we group* minhabba fil-*human resources*, ma tistax dak il-livell ta' koncentrament iżżommu kontinwu, hija diffiċli hafna. It-tieni nett hija kwestjoni ta' numri, sempliċement m'hawnx in-numri. Meta ngħidu *we group* hija xi haġa li ssir internazzjonalment meta jkollok numri żgħar. Xi ngħidu kieku kellna l-istess numri għaddejjin il-hin kollu kontinwament? Li jidhol johrog.

THE CHAIRMAN: 200 *cycles* jiġifieri 200 *couples*?

PROF. MARK BRINCAT: Mhux neċessarjament, għax jista' jkun hemm min jagħmel żewġ *cycles* f'sena. Bħalissa forsi jsiru xi 90 imma m'għandix il-figuri eżatti.

ONOR. FRANCIS AGIUS: Għandek indikazzjoni kemm jista' jkollok *outcome* minnhom dawn minhabba SCBU *facilities* u hekk? Jifilhu *if we gear up to 200 cycles*?

PROF. MARK BRINCAT: X'inhu l-għan tagħna? Li jkollna leġislazzjoni għall-aqwa *outcome* għall-pazjenti? Jew li nfasslu *outcome* skont ir-rizorsi li għandna fil-preżent? Jekk nagħmlu hekk nistgħu ma nagħmlu xejn... Irridu nżommu id f'id u n-nies iridu jżommu paripassu mal-avvanzi li għandna preżentement. Nistenna li kif *cardiologist* nafdah li jaf x'qed jagħmel, haddiehor jafda speċjalista fir-*reproductive medicine* li jaf x'qed jagħmel.

Fit-23 ta' Marzu smajna b'attenzjoni lil Dr Paul Soler (Kap tan-Neonatal Intensive Care Unit fl-Isptar Mater Dei) fejn stqarr:

...Bl-avvanz li għamlet il-ginekologija fl-infertilità bhala *complications* ġew il-*multi-fetal gestations*... L-*early neonatal deaths* għal tqala b'tarbija waħda hija tlieta għal kull 1,000 *live birth*. Jekk ikun hemm tewmin titla' għal tmien darbiet iżjed u '1 fuq minn tewmin kważi 17-il darba iżjed...

... mill-istorja tal-*baby* u mill-*interviews* li jiena u l-kollegi tiegħi għamilna mal-koppji li kellhom it-trabi tagħhom fil-kura intensiva – qed nirreferi għal sezzjoni D⁵ – sibna li 50% tat-trabi prematuri li jmutu fl-SCBU jġu minn ommijiet li jkunu rċewew xi forma ta' kura ta' *artificial reproductive technology*, inkluż l-IVF.

... L-Ingilterra hemm din il-facilità [ta' *freezing*]. Fl-Ingilterra il-proċess tal-infertilità huwa kollu regolat mill-HFEA. Dawn l-aħħar rakkomandazzjonijiet tagħhom huma ċari li fl-IVF jiġi *transferred one embryo*. *In certain cases two embryos but definitely not more than two. The rest have to be frozen*

... Ikollok sitwazzjoni fejn omm tigi biex twelled *triplets* u jispiċċaw tliet trabi f'*units* differenti l-Ingilterra għax m'għandhomx *cots*. Jiġifieri din hi r-realtà u tant kemm kienet krizi kbira li l-HFEA u r-Royal College of Paediatricians and Child Health, kellhom jiddiskutu din il-problema. Din l-esperjenza għaddejna minnha u qed nġaddu minnha. Fl-NICU għandna bejn wiehed u iehor 18-il *cot*. Jekk ikollok pereżempju żewġ ommijiet bi *triplets* u oħra bi *twins* u dawn iwelldu tmien trabi fi żmien ġimgħa u kollha prematuri, dawn se jidhulek tmien *admissions* f'kwestjoni ta' ġimgħa. Dan *over and above* ir-rata naturali ta' *prematures* u trabi morda. Allura Prattikament int għandek *depletion* tar-riżorsi tal-pajjiż.

... Il-pożizzjoni tal-maġġoranza assoluta tal-*paediatricians* f'Malta, li l-maġġoranza tagħhom kollha huma membri tal-Maltese Paediatric Association, ovyament huma konxji ta' dawn il-fatti tal-*higher order pregnancies* u r-riskju ta' mewt eċċ. U tant hu hekk illi f'Lulju tal-2005 waqt *extraordinary general meeting* tal-assoċjazzjoni kienet ittiehdet riżoluzzjoni unanima u jekk tagħtuni l-permess naqrahielkom u nagħtikom kopja tagħha. Din ir-riżoluzzjoni kienet saret fil-21 ta' Lulju, 2005...

THE CHAIRMAN: Imma allura l-Maltese Paediatric Association għaliex f'Lulju 2005 ma rakkomandatx il-*freezing*? Għaliex ma dahhilitx dan l-aspett, jiġifieri tirrakkomanda l-*freezing* biex ovyament wiehed jiffacilita l-affarijiet anke bhala legislazzjoni?

Dr. PAUL SOLER: Jien nahseb li l-*freezing* mil-lat mediku huwa vantaġġjuż immens.

Fis-6 ta' April kellna preżentazzjoni mill-Prof. Luca Gianaroli (Chairman tal-ESHRE).

ONOR. MICHAEL FARRUGIA: In a scenario of freezing of embryos would you still go for triple embryos?

PROF. BRINCAT: You can never completely eradicate the need for three embryos although you have got much more leeway.

...

THE CHAIRMAN: Maybe more specifically, how will the facility of freezing reduce the necessity to implant more than two embryos? And if I could refer to the document which one can find online

⁵ [Dokument Statistika fil-Qosor ipprezentat minn Dr Paul Soler waqt Laqgħa Nru 5.](#)

on the website of your organisation, which I must say is also provided in very good Maltese, I would like to read the conclusion which says;

“Attwalment politika ta’ trasferiment ta’ żewġ embrijuni hija komuni f’ħafna pajjiżi Ewropej. *Single embryo transfer* elettiv hija llum parti mill-politika għal trasferiment ta’ embriji b’legislazzjoni u/jew linji gwida, fehim volontarju f’ħames pajjiżi tal-Unjoni Ewropea.”⁶

...

DR LUCA GIANAROLI: when it was forbidden in Italy and when we started again to do freezing, it was a disaster because all our specialists, after five years of not freezing properly, had lost all or most of their skills...

... [freezing should] enable the embryologist to do his job routinely, not accidentally.

...

THE CHAIRMAN: ... Maybe we could specify more whether freezing would totally avoid the necessity to implant, for instance, three embryos. Would it be avoided in all cases?

DR LUCA GIANAROLI: Not totally, because sometimes you have couples whose reproductive performance is so low and so poor, that there is no reason not to transfer the three embryos if you have the opportunity. Let me give you an example. From women who are 42 or 43 years old, with a lot of effort, we are able to get three eggs, the three of them fertilised, that is you must be very lucky that this happens. Why should you transfer two embryos and leave one apart or freeze that knowing that 70% of those ovocytes are chromosomally abnormal and they will never implant. So I think that you must leave a certain degree of freedom to the professionals according to the indication of the patients.

THE CHAIRMAN: But cannot there be a protocol?

DR LUCA GIANAROLI: Yes, in fact in some countries we have protocols, for instance in Belgium. You know what they do in Belgium? They say: second attempt two embryos, third attempt up to three embryos. And over 40 years old, they can even go up to four embryos. So this is only based on the age, to me you can design a protocol, but again like in the evidence-based medicine, then there is a risk that you have a 40 year old woman that behaves like a 35 year old that has young ovaries and three embryos are too many, or maybe she already had one baby... in fact the protocols that we have are recommendations and they leave a degree of freedom and flexibility to the clinicians according to the patients’ problem.

...

ONOR. FRANCIS AGIUS: ... Am I reading that with the present state of technology, it is unethical not to have freezing facilities?

DR LUCA GIANAROLI: I think it is not ethical because when you start to work the day after, you possibly have embryos that cannot be put back in the womb of the potential mother. So what are you going to do?

ONOR. MICHAEL FARRUGIA: I look at it as immoral and unethical not to have a freezing process because if something happens what do you do, do you flush the embryos? ...

...

⁶ [Trattament Kliniku Tajjeb f’Riproduzzjoni Assistita - Kitba ta’ pożizzjoni ta’ ESHRE, Ġunju 2008.](#)

THE CHAIRMAN: Ethically I believe that in our cultural background, it will always be difficult to go for selective single embryo transfer. Because automatically, as you say, the other embryos are inferior and probably would have died a natural death, but ethically it is very difficult to assume. So to select an embryo and not select the others remains a problem.

DR LUCA GIANAROLI: Yes but sometimes you are confronted with the clinical practice that pushes you to make a selection. There are patients that cannot afford to have twins because otherwise their risk in their pregnancy is too high. I am talking about paraplegic women, I am talking about women with heart problems, I am talking about dystrophia patients. These patients cannot afford to have twins. For them it is life threatening, so you have to go for single transfer. And once again you need to have your clinicians able to switch and work for the best treatment. ...we need to be assisted by a helpful law, a law that does not oblige us to make mistakes.

...

THE CHAIRMAN: ... Can one legislate to make it compulsory to have one's embryos used throughout the gestational age of the lady?...

DR LUCA GIANAROLI: ... What you can do, like other countries including UK, is that you give a term, so that if patients ask you, the centres have to keep a record, we do this also in Italy and in Switzerland, we look after them every year and we trace them to check if they want their embryos back, but it cannot be compulsory.

To avoid that there is an economical interest, for instance in Italy, but we apply it also in other countries, we do not ask for money for freezing embryos, so embryos are kept at the cost of the single centre, and this is also helpful to avoid patients making a choice influenced by economic considerations. After a certain number of years - in Switzerland, in the UK and in Belgium it is five years - patients are allowed either to get their embryos back, or to allow them to be used for research or in some countries, they can also be donated to other couples.

...

THE CHAIRMAN: Frozen embryos are not as effective as fresh embryos.

DR LUCA GIANAROLI: That is the reason why if you transfer only one embryo and then you freeze and thaw all the others, you cannot expect, unless you go in very small number of young women with blocked tubes, what we call the simple case, otherwise ... So that is the reason why in the majority of our patients you have to be flexible and transfer two embryos, maybe sometimes three. Embryo freezing is a need for the reasons that we have said, but it is not the aim of the treatment. Once again, the aim of the treatment is a pregnant woman. If you freeze embryos and you keep them frozen, you do not get what the patient wants and what the clinicians want. So it is a need but it is not the final goal.

THE CHAIRMAN: But we have been reassured by paediatricians that congenital abnormalities do not increase with frozen embryos.

DR LUCA GIANAROLI: No, this for sure because now there are hundred thousand babies born by frozen embryos.

Dwar dan interessanti artiklu li deher f' 'The Guardian fit-13 ta' Ġunju 2010⁷:

⁷ The Guardian, 13 ta' Ġunju 2010 - *Doctors should warn of IVF defect risk, says report* - <http://www.guardian.co.uk/lifeandstyle/2010/jun/13/ivf-malformation-risk-doctors-warn>

Doctors should warn couples attempting to have children through fertilisation treatment that there is a small risk that the child will suffer some sort of malformation, geneticists said today.

Scientists in France looked at the records for over 15,000 children born as a result of treatment in 33 fertility centres and found that more than 4% of them had some sort of major congenital malformation.

Reporting their findings at the European Society of Human Genetics, however, they say this is lower than the 11% previously found in smaller studies, but because their study is the largest to look at the issue so far, the French team believes the lower figure is more likely to be accurate.

"We found a major congenital malformation in 4.24% of the children," said Dr Geraldine Viot, a clinical geneticist at the Maternité Port Royal hospital in Paris, "compared with the 2-3% that we had expected from previous published studies of the general population. This higher rate was due in part to an excess of heart diseases and malformations of the urogenital system. This was much more common in boys. Among the minor malformations, we found a five times higher rate of angioma, benign tumours made up of small blood vessels on or near the surface of the skin. These occurred more than twice as frequently in girls than boys."

The scientists decided there were probably multiple factors at work. The parents of malformed children were not older on average than others who went through fertility treatment, for example. "We need more research in order to understand the relationship between embryo culture media, timing of embryo transfer, the effects of ovarian stimulation, the use of ICSI, where sperm is injected directly into the egg, freezing of gametes and embryos and these disorders," said Dr Viot.

But the malformations are "a public health issue" that needs to be addressed, the scientists believe. "It is important that all doctors and also politicians are informed about this. We also need to follow up all children born after ART and to put much more effort into trying to understand which of the procedures involved is implicated in this problem," said Viot.

Mil-lat legali, fil-laqgħat tat-18 ta' Mejj u tat-8 ta' Ġunju rajna kif il-ligi Taljana tal-prokreezzjoni medikament assistita (Legge 19 febbraio 2004, n. 40 "Norme in materia di procreazione medicalmente assistita") għet ikkontestata b'suċċess fil-Qorti Kostituzzjonali Taljana.

ART. 14.

(Limiti all'applicazione delle tecniche sugli embrioni).

1. È vietata la crioconservazione e la soppressione di embrioni, fermo restando quanto previsto dalla legge 22 maggio 1978, n. 194.

2. Le tecniche di produzione degli embrioni, tenuto conto dell'evoluzione tecnico-scientifica e di quanto previsto dall'articolo 7, comma 3, non devono creare un numero di embrioni superiore a quello strettamente necessario ad un unico e contemporaneo impianto, comunque non superiore a tre.

3. Qualora il trasferimento nell'utero degli embrioni non risulti possibile per grave e documentata causa di forza maggiore relativa allo stato di salute della donna non prevedibile al momento della fecondazione è consentita la crioconservazione degli embrioni stessi fino alla data del trasferimento, da realizzare non appena possibile.

4. Ai fini della presente legge sulla procreazione medicalmente assistita è vietata la riduzione embrionaria di gravidanze plurime, salvo nei casi previsti dalla legge 22 maggio 1978, n. 194.

Costituzione:

Art 3:

Tutti i cittadini hanno pari dignità sociale e sono eguali davanti alla legge, senza distinzione di sesso, di razza, di lingua, di religione, di opinioni politiche, di condizioni personali e sociali.

È compito della Repubblica rimuovere gli ostacoli di ordine economico e sociale, che, limitando di fatto la libertà e l'eguaglianza dei cittadini, impediscono il pieno sviluppo della persona umana e l'effettiva partecipazione di tutti i lavoratori all'organizzazione politica, economica e sociale del Paese.

Art 32:

La Repubblica tutela la salute come fondamentale diritto dell'individuo e interesse della collettività, e garantisce cure gratuite agli indigenti.

Nessuno può essere obbligato a un determinato trattamento sanitario se non per disposizione di legge. La legge non può in nessun caso violare i limiti imposti dal rispetto della persona umana.

SENTENZA N. 151 ANNO 2009 - LA CORTE COSTITUZIONALE

Le possibilità di successo variano, infatti, in relazione sia alle caratteristiche degli embrioni, sia alle condizioni soggettive delle donne che si sottopongono alla procedura di procreazione medicalmente assistita, sia, infine, all'età delle stesse, il cui progressivo avanzare riduce gradualmente le probabilità di una gravidanza.

Il limite legislativo in esame finisce, quindi, per un verso, per favorire – rendendo necessario il ricorso alla reiterazione di detti cicli di stimolazione ovarica, ove il primo impianto non dia luogo ad alcun esito – l'aumento dei rischi di insorgenza di patologie che a tale iperstimolazione sono collegate; per altro verso, determina, in quelle ipotesi in cui maggiori siano le possibilità di attecchimento, un pregiudizio di diverso tipo alla salute della donna e del feto, in presenza di gravidanze plurime, avuto riguardo al divieto di riduzione embrionaria selettiva di tali gravidanze di cui all'art. 14, comma 4, salvo il ricorso all'aborto. Ciò in quanto la previsione legislativa non riconosce al medico la possibilità di una valutazione, sulla base delle più aggiornate e accreditate conoscenze tecnico-scientifiche, del singolo caso sottoposto al trattamento, con conseguente individuazione, di volta in volta, del limite numerico di embrioni da impiantare, ritenuto idoneo ad assicurare un serio tentativo di procreazione assistita, riducendo al minimo ipotizzabile il rischio per la salute della donna e del feto.

Al riguardo, va segnalato che la giurisprudenza costituzionale ha ripetutamente posto l'accento sui limiti che alla discrezionalità legislativa pongono le acquisizioni scientifiche e sperimentali, che sono in continua evoluzione e sulle quali si fonda l'arte medica: sicché, in materia di pratica terapeutica, la regola di fondo deve essere la autonomia e la responsabilità del medico, che, con il consenso del paziente, opera le necessarie scelte professionali (sentenze n. 338 del 2003 e n. 282 del 2002).

La previsione della creazione di un numero di embrioni non superiore a tre, in assenza di ogni considerazione delle condizioni soggettive della donna che di volta in volta si sottopone alla procedura di procreazione medicalmente assistita, si pone, in definitiva, in contrasto con l'art.

3 Cost., riguardato sotto il duplice profilo del principio di ragionevolezza e di quello di uguaglianza, in quanto il legislatore riserva il medesimo trattamento a situazioni dissimili; nonché con l'art. 32 Cost., per il pregiudizio alla salute della donna – ed eventualmente, come si è visto, del feto – ad esso connesso.

Deve, pertanto, dichiararsi la illegittimità costituzionale dell'art. 14, comma 2, della legge n. 40 del 2004 limitatamente alle parole «ad un unico e contemporaneo impianto, comunque non superiore a tre».

L'intervento demolitorio mantiene, così, salvo il principio secondo cui le tecniche di produzione non devono creare un numero di embrioni superiore a quello strettamente necessario, secondo accertamenti demandati, nella fattispecie concreta, al medico, ma esclude la previsione dell'obbligo di un unico e contemporaneo impianto e del numero massimo di embrioni da impiantare, con ciò eliminando sia la irragionevolezza di un trattamento identico di fattispecie diverse, sia la necessità, per la donna, di sottoporsi eventualmente ad altra stimolazione ovarica, con possibile lesione del suo diritto alla salute.

Le raggiunte conclusioni, che introducono una deroga al principio generale di divieto di crioconservazione di cui al comma 1 dell'art. 14, quale logica conseguenza della caducazione, nei limiti indicati, del comma 2 – che determina la necessità del ricorso alla tecnica di congelamento con riguardo agli embrioni prodotti ma non impiantati per scelta medica – comportano, altresì, la declaratoria di incostituzionalità del comma 3, nella parte in cui non prevede che il trasferimento degli embrioni, da realizzare non appena possibile, come previsto in tale norma, debba essere effettuato senza pregiudizio della salute della donna.

Il-Kumitat Magħżul, wara li ra d-deċiżjoni tal-Qorti Kostituzzjonali Taljana, wasal għall-konkluzjoni li għalkemm il-liġi ma tistax torbot kemm *embryos* tista' toħloq u kemm huwa l-ammont massimu li jista' jiġi impjantat f'salt, minn żmien għal żmien għandu jkun hemm linji gwida. Skont studju riċenti Kanadiż, l-ammont massimu li jista' jiġi impjantat f'salt jiġi determinat minn:

- l-istorja tal-mara;
- l-eżitu ta' *cycles* preċedenti; u
- in-numru u l-kwalità ta' *embryos* disponibbli.

PubMed - *Int J Gynaecol Obstet.* 2008 Aug;102(2):203-16.

Guidelines for the number of embryos to transfer following in vitro fertilization No. 182, September 2006

Abstract

OBJECTIVE: To review the effect of the number of embryos transferred on the outcome of in vitro fertilization (IVF), to provide guidelines on the number of embryos to transfer in IVF-embryo transfer (ET) in order to optimize healthy live births and minimize multiple pregnancies.

OPTIONS: Rates of live birth, clinical pregnancy, and multiple pregnancy or birth by number of embryos transferred are compared.

RECOMMENDATIONS: The recommendations made in this guideline were derived mainly from studies of cleavage stage embryos-those cultured for two or three days.

1. Individual IVF-ET programs should evaluate their own data to identify patient-specific, embryo-specific, and cycle-specific determinants of implantation and live birth in order to develop embryo transfer policies that minimize the occurrence of multifetal gestation while maintaining acceptable overall pregnancy and live birth rates (III-B).
2. In general, consideration should be given to the transfer of fewer blastocyst stage embryos than cleavage stage embryos, particularly in women with excellent prognoses and high-quality blastocysts (I-A). **SUMMARY STATEMENT:** The following recommendations are generally intended for cleavage stage embryos transferred on day two or three. Because blastocyst stage embryos have higher implantation rates than cleavage stage embryos, fewer blastocyst stage embryos may need to be transferred (II).
3. In women under the age of 35 years, no more than two embryos should be transferred in a fresh IVF-ET cycle (II-2A).
4. In women under the age of 35 years with excellent prognoses, the transfer of a single embryo should be considered. Women with excellent prognoses include those undergoing their first or second IVF-ET cycle or one immediately following a successful IVF-ET cycle, with at least two high-quality embryos available for transfer (I-A).
5. In women aged 35 to 37 years, no more than three embryos should be transferred in a fresh IVF-ET cycle. In those with high-quality embryos and favorable prognoses, consideration should be given to the transfer of one or two embryos in the first or second cycle (II-2A).
6. In women aged 38 to 39 years, no more than three embryos should be transferred in a fresh IVF-ET cycle (III-B). In those with high-quality embryos and favorable prognoses, consideration should be given to the transfer of two embryos in the first or second cycle (III-B).
7. In women over the age of 39 years, no more than four embryos should be transferred in a fresh IVF-ET cycle (III-B). In those older women with high-quality embryos in excess of the number to be transferred, consideration should be given to the transfer of three embryos in the first IVF-ET cycle (III-B).
8. In exceptional cases when women with poor prognoses have had multiple failed fresh IVF-ET cycles, consideration may be given to the transfer of more embryos than recommended above in subsequent fresh IVF-ET cycles (III-C).
9. In donor-recipient cycles, the age of the oocyte/embryo donor should be used when determining the number of embryos to transfer (II-2B).
10. In women with obstetrical or medical contraindication to multifetal gestation, fewer embryos should be transferred to minimize the chance of multifetal gestation. In such cases, pre-treatment consultation with a maternal-fetal medicine specialist should be pursued (III-C). Whenever reasonable, consideration should be given to the transfer of a single embryo (II-3B).
11. Couples should be adequately counseled regarding the obstetrical, perinatal, and neonatal risks of multifetal gestation to facilitate informed decision making regarding the number of embryos to transfer (II-3B). Emphasis on healthy singleton live birth as the measure of success in IVF-ET may be beneficial in promoting a reduction in the number of embryos transferred (III-C).
12. A strategy for public funding of IVF-ET must be developed for the effective implementation of guidelines limiting the number of embryos transferred. In the context of this strategy, total health care costs would be lower as a result of reductions in the incidence of multifetal pregnancies and births (III-C).
13. Efforts should be made to limit iatrogenic multiple pregnancies resulting from non-IVF-ET ovarian stimulation through the development of suitable guidelines for cycle cancellation and the removal of financial barriers to IVF-ET (III-B).

VALIDATION: This guideline was reviewed by the Reproductive Endocrinology and Infertility Committee and the Maternal-Fetal Medicine Committee and approved by the Executive and

Council of the Society of Obstetricians and Gynaecologists of Canada and the Board of the Canadian Fertility and Andrology Society.

SPONSOR: *Society of Obstetricians and Gynaecologists of Canada. The quality of evidence reported in this document has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam .*

HISTORY	Determinants of implantation			Maximum no. embryo/s transferred	
				embryo-specific	cycle-specific
<i>patient-specific</i>				cleavage stage	blastocyst transfer
				on day two or three	on day five or six
women under the age of 35 years				2	1
women under the age of 35 years	with excellent prognoses			1	1
women aged 35 to 37 years				3	1 or 2
women aged 35 to 37 years		with high-quality embryos and favourable prognoses	in the first or second cycle	1 or 2	1
women aged 38 to 39 years				3	1 or 2
women aged 38 to 39 years		with high-quality embryos and favourable prognoses	in the first or second cycle	2	1
women over the age of 39 years				4	1 or 2
women over the age of 39 years		with high-quality embryos in excess of the number to be transferred	in the first IVF-ET cycle	3	1 or 2
			multiple failed fresh IVF-ET cycles	more than above	1 or 2

Ta' min jenfasizza kif qed tahdem l-Awtorità fl-Ingilterra (HFEA):

*“Directions require centres to have a documented strategy to **minimise multiple births**. Its purpose is to reduce the annual rate of multiple births resulting from treatments at the centre. The centre must document regular audits that:*

- a) assess progress in reducing its multiple birth rate, and*
- b) help evaluate the effectiveness of its strategy.*

If more than one embryo is transferred to a patient who fulfilled the SET criteria outlined in the centre's strategy, this should be recorded in the patient's medical records, with:

a) an explanation of why the patient did not have SET, and

b) evidence that the risks of a multiple pregnancy were fully discussed with the patient before the procedure.

The centre must keep a summary log of all cases where more than one embryo was transferred to a patient who met the SET criteria outlined in the centre's strategy."

Il-Kumitat studja kif il-liġi f' diversi pajjiżi tirregola l-iffriżar tal-embrijuni:

- il-Liġi fir-Renju Unit kif emendata fl-2008⁸:

14 Conditions of storage licences

(4) The statutory storage period in respect of embryos is such period not exceeding ten years as the licence may specify.

(5) Regulations may provide that subsection (4) above shall have effect as if for ten years there were substituted:

(a) such shorter period, or

(b) in such circumstances as may be specified in the regulations, such longer period, as may be specified in the regulations.

- il-Liġi f' New Zealand⁹:

10. Human in vitro embryos and human in vitro gametes not to be stored for more than 10 years

(1) No person may keep a human in vitro gamete or a human in vitro embryo (being an embryo whose development has been suspended) that has been stored for more than—

(a) a period of 10 years; or

(b) if the ethics committee has, before the expiry of that period of 10 years, approved a longer period in respect of the gamete or embryo, the longer period approved by the ethics committee.

(2) Every person commits an offence who contravenes this section and is liable on summary conviction to a fine not exceeding \$20,000.

- il-Liġi fl-Istat ta' Victoria kif emendata fl-2005¹⁰:

21B. Meaning of excess ART embryo

(1) In this Part -

"excess ART embryo" means a human embryo that -

(a) was created, by assisted reproductive technology, for use in the assisted reproductive technology treatment of a woman; and

(b) is excess to the needs of -

(i) the woman for whom it was created; and

(ii) her spouse (if any) at the time the embryo was created.

(2) For the purposes of paragraph (b) of the definition of "excess ART embryo", a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if -

⁸ [Human Fertilisation and Embryology Act 1990](#)

⁹ [Human Assisted Reproductive Technology Act 2004](#)

¹⁰ [Infertility Treatment Act 1995](#)

- (a) each such person has given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or
- (b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time.

21C. Offence - use of excess ART embryo

(1) A person commits an offence if the person intentionally uses an excess ART embryo, unless -

- (a) the use by the person is authorised by a licence; or
 - (b) the use by the person is an exempt use within the meaning of sub-section (3).
- (2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 5 years.
- (3) A use of an excess ART embryo by a person is an exempt use for the purposes of sub-section (1) if -
- (a) the use consists only of -
 - (i) storage of the excess ART embryo; or
 - (ii) removal of the excess ART embryo from storage; or
 - (iii) transport of the excess ART embryo; or
 - (b) the use consists only of observation of the excess ART embryo; or
 - (c) the use consists only of allowing the excess ART embryo to succumb; or
 - (d) the use is carried out by an accredited ART centre, and -
 - (i) the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created where the suitability of the embryo is determined only on the basis of its biological fitness for implantation; and
 - (ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created; or
 - (e) the use is carried out by an accredited ART centre and is for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created; or
 - (f) the use is of a kind prescribed by the regulations for the purposes of this paragraph.

(4) Despite section 130(1) of the Magistrates' Court Act 1989, a defendant does not bear a burden of presenting or pointing to evidence in accordance with that section in relation to any matter in subsection (1) or (3) of this section.

(5) In sub-section (3) -

"diagnostic investigation", in relation to an excess ART embryo, means any procedure undertaken on embryos for the sole purpose of diagnostic investigations for the direct benefit of the woman for whom it was created;

"observation", in relation to an excess ART embryo, includes taking a photograph of the embryo, or taking a recording of the embryo from which a visual image can be produced.

21D. Offence - use of embryo that is not an excess ART embryo

(1) A person commits an offence if -

- (a) the person intentionally uses, outside the body of a woman, a human embryo that is not an excess ART embryo; and
- (b) the use is not for a purpose relating to the assisted reproductive technology treatment of a woman carried out by an accredited ART centre, and the person knows or is reckless as to that fact.

(2) An offence against sub-section (1) is an indictable offence punishable by imprisonment for a term not exceeding 5 years.

52. Storing embryos

(1) A person must not cause or permit an embryo to be placed or remain in storage.

Penalty: 240 penalty units or 2 years imprisonment or both.

(2) Sub-section (1) does not apply if -

- (a) it is intended to transfer the embryo to the body of a woman in a treatment procedure in accordance with this Act; and
 - (b) the persons who have produced the gametes from which the embryo has been formed have consented to its storage for the purpose of later transfer.
- (3) A consent under sub-section (2)(b) -
- (a) must be in writing; and
 - (b) must be lodged as soon as practicable after the consent has been given with the person storing the embryo.
- (4) A person must not cause or permit an embryo to which sub-section (2) applies to remain in storage -
- (a) if a person who has consented to storage has specified a period of less than 5 years, after that period; or
 - (b) in any other case, after -
 - (i) 5 years; or
 - (ii) any longer period approved by the Authority.
- Penalty: 240 penalty units or 2 years imprisonment or both.
- (5) The Authority may approve in writing a longer period for storage of an embryo if it considers that there are reasonable grounds for doing so in the particular case.
- (6) An approval under sub-section (5) may be subject to conditions.

56. Import or export of gametes and embryos

- (1) A person must not -
- (a) bring a gamete or embryo into Victoria outside the human body; or
 - (b) take a gamete or embryo from Victoria outside the human body.
- Penalty: 240 penalty units or 2 years imprisonment or both.
- (2) Sub-section (1) does not apply if the gamete or embryo is brought into or taken from Victoria in accordance with the written approval of the Authority.
- (3) The Authority's approval under sub-section (2) may apply to a particular case or class of cases and may be subject to conditions imposed by the Authority.
- (4) If a person has approval under sub-section (2) to bring a gamete or embryo into Victoria the Authority may exempt a person in relation to -
- (a) the gamete or embryo; or
 - (b) the donor of the gamete or embryo - from compliance with sections 14(3) and (4), 15(2) and (4), 16, 17, 18, 19, 36, 37(3), 52(1)(b) and (3) and 55, Division 1 of Part 7 and any other prescribed provision of the Act or the regulations, if the Authority is satisfied that -
 - (c) similar procedures have taken place outside Victoria; and
 - (d) there are special circumstances which warrant the exemption.
- (5) If a person has approval under sub-section (2) to take a gamete or embryo from Victoria the Authority may exempt a person in relation to the gamete or embryo from compliance with sections 52(2) and (3), 53, 89 and 90 and any other prescribed provision of the Act or the regulations, if the Authority is satisfied that -
- (a) the gamete or embryo will be used in a manner which is consistent with this Act; and
 - (b) there are special circumstances which warrant the exemption.
- (6) An exemption granted under this section must be made in writing, and may relate to the whole or a part of a provision, and may be subject to conditions.
- (7) A person granted an approval or exemption under this section must comply with any condition imposed by the Authority under this section.

Penalty: 240 penalty units or 2 years imprisonment or both.

7.3 Il-Ħarsien tal-Ġenituri

(A) Is-servizz ta' prokreazzjoni assistita għandu jingħata biss wara kunsens infurmat minn dawk li qed jipparteċipaw f'dawn il-proċeduri.

(B) Is-servizz ta' Prokreazzjoni Assistita għandu jinkludi *counselling* għall-ġenituri minn professjonisti kompetenti qabel, waqt u wara l-proċess.

Fis-26 ta' April wara li sottomettiet darbtejn bil-miktub, fuq talba tagħha stess saret preżentazzjoni minn Mrs Simone Attard, *Family Therapy Counsellor*. Minhabba s-sensittività tas-sugġett din il-laqgħa qed tiġi riprodotta b'mod estensiv.

MRS SIMONE ATTARD: Preżentament jiena naħdem voluntiera mal-Moviment ta' Kana bħala *family therapy counsellor* fis-settur tal-infertilità. Tista' tgħid li dan is-settur missejtu minn kull naħa, għax apparti milli għandi *post-graduate degree* fil-*family therapy*, jiena rajt ukoll in-naħa l-oħra tal-munita għax kont ukoll pazjenta għall-infertilità. Illum il-gurnata għandi tifel ta' hames snin, jiġifieri *I went through the whole process* u naf x'ifisser.

L-iktar li qiegħda hawn bażikament biex nenfasizza l-punt ta' kemm għandhom bżonn *counselling* u *support* il-koppji li jkunu għaddejnin minn dan il-proċess. Bhalma tafu, anke fejn hemm l-aktar *success rate*, li *the most you can say* huwa ta' 30%, għandek 70% *of a failure rate*. Allura *you have to be there to support them* għax dawn se jgħaddu minn zmien diffiċli, kemm qabel jibdeu *it-treatment*, waqt *it-treatment* u anke wara *t-treatment*. *Every failure is like a bereavement stage*. Jiġifieri kull meta jkun hemm *failure*, dak li jkun ikollu jgħaddi mill-istess proċess li jgħaddi minnu waqt *bereavement*. U jekk se jkun hemm *repeated cycles*, trid tara kemm in-nies huma lesti li jgħaddu minn dawn il-*failures* kollha, wieħed wara l-ieħor; għaldaqstant *we have to be with them through the whole process*.

Bhalma qal tajjeb Dr Luca Gianaroli l-aħħar darba, jekk se jsir il-proċess ta' *freezing*, dawn se jgħaddu minn aktar affarijiet għax inti m'intix se tagħmel *one cycle of IVF*, imma *you are going for another cycle, and another cycle and another cycle*. Allura *we have to assist them through the whole process and through all their failures*, jekk se jkun hemm *failures*. Minn meta ssir l-*implantation* sakemm wieħed ikun jaf jekk huwiex *pregnant* jew le, *there is a two-week wait*. F'dawk il-ġimgħatejn dawn il-persuni se jgħaddu mill-emozzjonijiet kollha, *so they have to be cushioned*. U hemm hafna dettalji oħra dwar meta inti tista' tgħinjom, fil-proċess tal-bidu, jekk inti se tagħmel *certain criteria*, min se japplika għall-IVF u min le, jiġifieri *you have to be with them through the whole process*. Perezempju jekk dak li jkun se jgħaddi mill-proċess tal-IVF, jaf minn xiex se jgħaddi?

...

...preżentament fl-istruttura tad-Dipartiment tas-Saħħa ma jeżistix dan is-*support* mhux biss għal min jgħaddi minn *artificial insemination* imma anke għal koppji li jkunu għaddejnin minn *ectopic pregnancy*, fejn hemm *loss* ukoll, kif ukoll għal koppji li jkollhom *early miscarriage*, perezempju. Fejn ikollok *an advanced pregnancy* and *you have a still birth or a neonatal death*, hemm is-*support* tas-SANDS (Stillbirths and Neonatal Deaths Society – Malta), li jgħinuk imma mhux fil-bidu. Biss ukoll SANDS hija NGO *within* Kana, jiġifieri mhijiex proprjament fl-istruttura tal-*health*, li toffri s-servizz tagħha fl-isptar.

F'dawn il-każijiet l-istess, mhuwiex id-Dipartiment tas-Saħħa li joffri dan is-servizz imma *a separate* NGO li hija l-WAW – *Wanting and Waiting Infertility Support Group*...

...

Min-naħa tad-dipartiment dan is-servizz mhuwiex offrut. Jiġifieri koppji bi problemi ta' infertilità qed imorru fl-NGO bħalissa biex ifittxu l-ġhajjnuna. Hafna minnhom meta tghidilhom li s-servizz għal koppji bla tfal fejn jingħata proċess ta' *assisted reproduction* joffrih il-Moviment ta' Kana, jiskantaw. Imma dan huwa l-uniku servizz offrut, fejn il-koppji l-ewwel ikollhom *one to one sessions* u mbagħad min ikun irid jingħaqad mas-*support group*, jista' jagħmel hekk. Imbagħad hemm il-*counselling section* fin-naħa ta' Kana li *it is more open* u tara kull tip ta' *counselling* li hemm bżonn. Biss dawn il-koppji żgur għandhom bżonn is-*support* li bħalissa mhuwiex offrut.

Jiena rajt kif taħdem is-sistema ġewwa l-Hewitt Centre ta' Liverpool Women's Hospital fejn għandhom sezzjoni li hija *within the reproduction unit* imma hija speċifikament awtonoma mill-*medical section*, fejn il-koppji jistgħu jgħaddu hemmhekk u jiehdu l-*counselling* li għandhom bżonn matul il-proċess kollu. Xi haġa oħra li forsi tajjeb li wiehed isemmi hi li min jaħdem f'dan is-settur fil-Liverpool's Women's Hospital, irid ikun *accredited* mill-British Infertility Counselling Association. Ovvjament f'Malta ma tantx hawn *counselling staff* speċjalizzat fl-infertilità, biss barra biex tkun tista' taħdem fil-*clinics* u fil-Hewitt Centre ta' Liverpool Women's Hospital fejn kont tlajt jien, irid ikollok *accreditation* mill-British Infertility Counselling Association. Jekk għad m'għandekx, *you have to apply and within two years you have to get that accreditation*. Għax mhux kull *psychologist* jew kull *counsellor* jista' jaħdem f'dan is-settur.

...

THE CHAIRMAN: Jiena xtaqt forsi nagħmlu l-liġi Taljana *available* lill-esperta. Jiena se naqra l-liġi bit-Taljan u bazikament nixtieqek tghidilna jekk kif inhi tagħmilx sens biżżejjed.

...

ART. 6.
(*Consenso informato*).

1. *Per le finalità indicate dal comma 3, prima del ricorso ed in ogni fase di applicazione delle tecniche di procreazione medicalmente assistita il medico informa in maniera dettagliata i soggetti di cui all'articolo 5 sui metodi, sui problemi bioetici e sui possibili effetti collaterali sanitari e psicologici conseguenti all'applicazione delle tecniche stesse, sulle probabilità di successo e sui rischi dalle stesse derivanti, nonché sulle relative conseguenze giuridiche per la donna, per l'uomo e per il nascituro. Alla coppia deve essere prospettata la possibilità di ricorrere a procedure di adozione o di affidamento ai sensi della legge 4 maggio 1983, n. 184, e successive modificazioni, come alternativa alla procreazione medicalmente assistita. Le informazioni di cui al presente comma e quelle concernenti il grado di invasività delle tecniche nei confronti della donna e dell'uomo devono essere fornite per ciascuna delle tecniche applicate e in modo tale da garantire il formarsi di una volontà consapevole e consapevolmente espressa.*

2. *Alla coppia devono essere prospettati con chiarezza i costi economici dell'intera procedura qualora si tratti di strutture private autorizzate.*

3. *La volontà di entrambi i soggetti di accedere alle tecniche di procreazione medicalmente assistita è espressa per iscritto congiuntamente al medico responsabile della struttura, secondo modalità definite con decreto dei Ministri della giustizia e della salute, adottato ai sensi dell'articolo 17, comma 3, della legge 23 agosto 1988, n. 400, entro tre mesi dalla data di entrata in vigore della presente legge. Tra la manifestazione della volontà e l'applicazione della tecnica deve intercorrere un termine non inferiore a sette giorni. La volontà può essere revocata*

da ciascuno dei soggetti indicati dal presente comma fino al momento della fecondazione dell'ovulo.

4. Fatti salvi i requisiti previsti dalla presente legge, il medico responsabile della struttura può decidere di non procedere alla procreazione medicalmente assistita, esclusivamente per motivi di ordine medico-sanitario. In tale caso deve fornire alla coppia motivazione scritta di tale decisione.

5. Ai richiedenti, al momento di accedere alle tecniche di procreazione medicalmente assistita, devono essere esplicitate con chiarezza e mediante sottoscrizione le conseguenze giuridiche di cui all'articolo 8 e all'articolo 9 della presente legge.

...

MRS SIMONE ATTARD: Li forsi nżid ma' dan huwa illi iktar milli jkun il-*medico*, ikun xi hadd indipendenti mill-*medical staff*. Tajjeb li jkun indipendenti għax jisma' lill-koppja *without judging*, fl-istess hin ikun jista' wkoll ... Għax ovjament it-tabib qiegħed hemm biex joffri s-servizz mediku, imma inti jrid ikollok xi hadd li jista' jifhem l-emozzjonijiet li tkun għaddejja minnhom il-koppja dak il-hin. U miegħu tista' tiddiskuti wkoll is-*success*, il-*failure rate* u l-*implications* tat-*treatment*...

Il-*medico* jrid jinforma min-naħa tiegħu, iżda jrid jingħata *counselling* tul il-proċess kollu, jiġifieri qabel il-proċess, waqt il-proċess ...

...

Pereżempju għandek dawk it-*two-week waits*, minn meta jsir it-*transfer* għal sakemm inti eventwalment tkun taf intix *pregnant* jew le, hemmhekk huwa żmien ta' hafna emozzjonijiet, fejn inti tista' tmur fil-*unit* u ...

...

Jiena hawnhekk nista' naqralek il-*counselling* li jiġi offrut fil-Liverpool Women's Hospital, fl-Ingilterra. Dan jgħidlek hekk: ...

"You may find it helpful to talk to an individual who is independent from the medical staff, from the unit, who has the knowledge of the dilemmas, can listen and not judge, independent from the medical staff on the unit."

...

Fil-bidu ma tridx tagħmilha li *they have to be infertility counsellors* għax ovjament f'Malta m'hawnx daqstant. ... Infatti bħalissa għaddej ukoll proċess biex *counselling staff* within Kana li li joffri hafna s-servizz imma m'għandux *degree*, qegħdin jiġu biex ikollhom il-*warrant of counselling*, jiġifieri f'dan is-sens ukoll *grandparented*.

....

ONOR. FRANCIS AGIUS: Fil-liġi trid iddahħal l-element ta' *multidisciplinarity* and it has not to be only medical. Qed naqblu.

...

ONOR. MICHAEL FARRUGIA: Skuzani, se nkun daqsxejn impertinenti. Jiena ma nara xejn hażin illi l-NGOs jagħtu s-*support*. Jiena personalment nemmen illi bhala gvern għandu jara l-NGOs

eżistenti li diġà hawn fil-pajjiż u minflok nirduppjaw hafna servizzi, fejn wiehed jista' juża l-NGOs, mela le, wiehed jużahom imma l-unika problema li għandi hija din.

Li kieku inti għadek il-Presidenta tal-WAW u allura fi hdan il-Moviment ta' Kana, kif thossok li kieku jkollok liġi li tagħti l-opportunità li jkun hemm *freezing of embryos*? Kif thossok li kieku jkollok liġi li tagħti l-opportunità li jkun hemm *donation of gametes from third persons*? Kif thossok li kieku jkollok liġi li tagħti l-opportunità mhux lill-koppji miżżewġin biss, imma anke lil dawk il-koppji fejn id-definizzjoni ta' "stabbli" tkun aktar wiesgħa?

...

ONOR. FRANCIS AGIUS:... Inti qiegħda taħdem f'organizzazzjoni li hija tal-Knisja prattikament. Fix-xogħol tiegħek, kemm sibt metodi ta' konflitt? Għax dan huwa suġġett jahraq mil-lat etiku hafna. Kemm sibt diffikultà fuq livell professjonali u personali, jiġifieri fis-sens ta' xogħol jew indhil, jekk tista' tikkummenta fuqha, speċi safejn tista' tasal jew ma tasalx? Għalina huwa rilevanti hafna.

...

THE CHAIRMAN: ... Jiena rajt ir-rapporti tiegħek, sew l-ewwel wiehed kif ukoll it-tieni wiehed. Fuq it-tliet *issues* li qed nirrestringu għall-mument id-diskussjoni dwarhom, dwar il-kwestjoni ta' koppja li ma tkunx neċessarjament miżżewġa, din qed tgħidha inti personali jew f'isem din l-għaqda?

MS SIMONE ATTARD: Personali.

THE CHAIRMAN: Inti insistejt li l-koppja tkun miżżewġa. Rigward jekk jiġux iffrizati l-embrijuni jew le, wara li smajt lil Dr Gianaroli, ovvjament bil-*provisos* li għamilt li issa naqrahom, inti donnok qed tibda tapprezza li l-iffriżar tal-embrijuni jista' jgħin biex wiehed inaqqas id-diffikultà ta' *multiple pregnancies* minhabba l-impjantazzjoni ta' aktar minn żewġ embrijuni fl-istess hin.

Inti għidt li inti kontra li jkun hemm *donation of gametes*.

...

Ovvjament aħna hawnhekk marbutin anke bil-Kostituzzjoni ta' pajjiżna li kif qal il-President tar-Repubblika fiż-żjara tal-Papa, wara kollox aħna għandna wkoll din ir-responsabbiltà li nissalvagwardjaw l-aspett kulturali u reliġjuż tal-Knisja Kattolika f'pajjiżna. Imma wiehed irid japprezza wkoll li meta jilleġisla, ma jilleġisla biss għal min hu Kattoliku iżda jilleġisla wkoll għal min jista' ma jkunx Kattoliku. Allura d-domanda li se nagħmel hija din: Meta jiġu persuni għandkom għall-parir u ma jiffittjawx fil-parametri ta' kif thares lejha l-Knisja Kattolika, x'jagħmel il-Moviment ta' Kana? Jekk ma jkunx miżżewġin, pereżempju, u mhux talli jkunu totalment infertili imma addirittura sterili, minhabba mard anke forsi ġenetiku, allura ż-żerriegħa tagħhom assolutament ma tistax tintuża għax dan il-mard ġenetiku jiġi fit-tfal tagħhom. F'dawn il-kazijiet, l-għaqda tagħkom qiegħda mill-ewwel tagħtihom parir ta' adożzjoni jew tgħinjom xorta biex forsi jesperimentaw jew ikollhom informazzjoni dwar metodi li l-Knisja *a priori* ma taqbilx magħhom?...

MRS SIMONE ATTARD: Bazikament se nwieġeb it-tliet mistoqsijiet f'daqqa. Bħalma diġà spjegajt qabel, se nitkellem min-naħa ta' *counselling*. Jiena kelli koppji li marru barra minn Malta biex jagħmlu trattament fejn ir-raġel kien sterili, bħalma semma l-Onor. Farrugia, u kienu se jużaw *donor sperm*. Aħna ngħinuhom fil-proċess xorta, *because you still have to help them to go through the process*, tfhemhom ...

THE CHAIRMAN: Qabel ma sar il-*fertilisation*?

MRS SIMONE ATTARD: *They came before specifically for counselling.*

THE CHAIRMAN: Dak huwa punt kruċjali hux hekk?

MRS SIMONE ATTARD: Dawn ma ġewx fi grupp imma ġew *for one to one counselling*, għax Kana toffri kemm *is-support* tal-grupp tal-*infertility* u toffri wkoll il-*counselling* generali. Dawn ġew *for one to one counselling*, rajthom jiena kumbinazzjoni, għennihom jifhmu l-proċess li se jgħaddu minnu u x'konsegwenzi jista' jkun hemm anke wara. Għax peress li kienet se ssir l-Ingilterra fejn hemm id-*donor*, *on attaining 18 you can know who is the father*. Allura ahna fehennihom li kien se jkun hemm dan il-proċess. Staqsejniehom jekk min-naħa tagħhom rawx *the legal side of it and we helped them go through the process*.

THE CHAIRMAN: Meta ahna tkellimna f'dan il-Kumitat, il-verità ... Issa x'naħsbu ahna t-tlieta mhuwiex neċessarjament dak li se jiġi leġislat, għax dan fl-aħħar mill-aħħar huwa parlament ta' 69 ruħ li se jivvota. Imma fil-verità kien hemm kunsens madwar din il-mejda, li wiehed m'għandux jeskludi lil min verament jixtieq ikollu tarbija, basta jkun hemm verament koppja li tkun responsabbli lejn xulxin u lejn il-*welfare* tat-tfal.

Jekk nista' anke nikkwota – biex anke nipprova mmur lil hinn mill-Knisja Kattolika Maltija – minn dak li ġie ppublikat fil-gazzetta tal-bierah: “*Restoring Faith in Politics – General Elections 2010*” ippublikat mill-*Catholic Union*, fejn bażikament ingħad x'qalu l-knejjes Kattoliċi ġol-Ingilterra. Hemm kapitlu dwar “*The value of Human Life*” li filwaqt li jittratta l-abort u l-ewtanażja, imkien ma jidhöl fl-*artificial fertilisation*. Jiġifieri neħodha li ma tantx qiegħda tagħmel *queries* il-Human Fertilisation and Embryology Authority. Kieku naħseb li bħalma qed isaqsu b'mod qawwi, speċjalment dwar l-ewtanażja, kienu jidhlu anke fil-qasam tal-*fertilisation*. Allura din neħodha li l-HFEA hija pjuttost aċċettata mill-Knisja Kattolika - mhux biss minn knejjes oħrajn issa - ġol-Ingilterra?...

THE VALUE OF HUMAN LIFE

“The first duty of every government is to protect human life. It is contradictory to seek to promote human solidarity, welfare and the common good while failing to protect human life. The Catechism of the Catholic Church has this to say on the subject: “no one can under any circumstance claim for himself the right directly to destroy an innocent human being”. Abortion and euthanasia, whether by act or omission, threaten the life of the vulnerable. The Catechism of the Catholic Church has this to say on the subject: “Those whose lives are diminished or weakened deserve special respect. Sick or handicapped persons should be helped to lead lives as normal as possible”

The right to life is universally recognised as the primary fundamental right. It is reflected in all major charters of human rights and legal codes. Article 2 of the European Convention on Human Rights and Fundamental Freedoms protects the right to life and is accordingly the first substantial human right of the Convention. It states: “Everyone’s right to life shall be protected by law. No one shall be intentionally deprived of his life save in the execution of a sentence of a court following his conviction for a crime for which the penalty is provided by law”.

Without the protection of the right to life, other rights disappear. With an ageing population, and a greater use of medical resources by the elderly and infirm, has come an unhealthy debate about restricting such resources and about economic arguments for shortening the lives of the terminally or chronically ill. This has gone hand-in-hand with a spate of reports about the abuse and mistreatment of the elderly and infirm in our hospitals and caring institutions. This is a bleak prospect for us all since none of us can escape the inevitable fact of ageing. Once the unique and fundamental value of human life is compromised in one part of the spectrum it is compromised in all parts. Voters ought closely to examine the record of each party on these issues and satisfy themselves which party or parties have best protected human life.”

...

MS SIMONE ATTARD: ... jista' jigi offrut li mhux bilfors kulmin jagħmel trattament ta' IVF, irid jagħmel il-*freezing*. Dik thalliha f'idejn il-koppja jekk tkunx tixtieq tiffriża jew le. L-Ingilterra hemm ċerta spartarjiet li jagħtuk iċ-ċans li *according to your religion*, ...

...

ma tridx torbot lil kulhadd meta se jsir il-*freezing*, f'liema stadju jsir, eċċ. Naf li dan se jiftaħ aktar oċean shiħ għax f'liema każ se tapplika l-*freezing* tal-*blastocyst* u mhux aktar il-*freezing* tal-*embryo* fi *stages* aktar 'il quddiem! Forsi s-suggeriment tiegħi hu li fil-ligi tgħid li jista' jsir il-*freezing*, jigiġifieri *it is not specific at the blastocyst*, jew *at stage 4* jew *5*, jigiġifieri fejn isir thallih miftuh għall-prattikant flimkien mal-klijent. ... Għax f'Malta ma jeżistux biss *Christians* u *Catholics*...

ONOR. FRANCIS AGIUS: L-importanti li ma jkunx illegali kemm għat-tabib kif ukoll għall-individwu.

THE CHAIRMAN: L-ESHRE qalet li ma tistax, imma fl-opinjoni tiegħek, wiehed jista' jinforza l-fatt li koppja xorta jkollha t-ftal billi tuża l-*frozen embryos* f'każ li ma jkunx hemm mard, fiżiku jew mentali?

MRS SIMONE ATTARD: Fil-każ fejn għandek koppja li diġà kellhom *twins* u *twins* u għad għandhom *frozen embryos* ...

THE CHAIRMAN: Imma *twins* u *twins* huma *unlikely* hafna. Jekk inti kellek tliet *embryos* u poġġejt tnejn, ahna qed ngħidu li se jkun hemm massimu. Jekk ikun hemm *freezing of embryos*, ahna qed ngħidu li se jkun hemm ċertu numru limitat ta' *embryos* li se jiġu ffrizati. Etikament jiena ma nħossnix komdu li wiehed jiffriża kemm irid. Jigiġifieri ngħidu li wiehed jipproduċi ċertu ammont minimu li huwa possibbli, ovvjament skont l-età u skont kif qalet l-ESHRE xorta. Wiehed irid japprezza wkoll il-mod kif jaħsbuha n-nies kliniċi wkoll, ... Jiena ngħid li għandna, anke permezz tal-esperti, niddeterminaw in-numru. Nifhem li mhux iktar minn tnejn jiġu impjantati, issa hawn min qed jgħid, anke l-ginekologi li kienu hawnhekk, li wiehed għandu jhalliha libera li jiġu impjantati anke tlieta. Imma jiena qed ngħid li *at the end of the day*, kieku wiehed jara, mingħajr ma jorbot b'ligi imma b'ċertu regolamenti, li ma jiġux impjantati aktar minn tnejn minħabba *multiple pregnancy*. Imma mbagħad kemm hallejt warajk? Jigiġifieri jrid ikun hemm restrizzjoni fuq in-numru wkoll?

MRS SIMONE ATTARD: Tinsiex li jkollok koppji li jkollhom *secondary infertility* li jidhlu għall-IVF, jigiġifieri dawn diġà kellhom l-ewwel tarbija bi problemi ta' xejn u ma kellhomx bżonn ta' trattament.... imma jekk dawn għamlu *freezing* u mbagħad użawhom u kellhom *twins*... Jiena ltqajt anke ma' koppja li *on the first cycle they got pregnant with twins* u ma xtaqux li jkollhom familja ikbar. Jigiġifieri inti ma tistax tinfurzahom...

...

THE CHAIRMAN: ... La intom qed taslu anke biex tippruvaw tgħinu lil min kellu diġà tfal u għandu *secondary infertility*, għaliex għandna mbagħad inkunu daqshekk stretti ma' min addirittura qatt ma kellu tfal u għadda minn ċerti esperjenzi f'ħajtu u m'għandux allura jingħata *donation of gametes*?

ONOR. FRANCIS AGIUS: ... Jiena qed nara żewġ mistoqsijiet ta' dilemma u xtaqtek, inti bħala *counsellor* u bħala *counsellor* li taħdem fi hdan il-Knisja Kattolika Maltija. X'jiġri mill-embrijuni ffrizati? Dik hija waħda mid-dilemmi. U l-oħra hija illi kif qegħdin ngħidu, koppja li jew minħabba r-raġel jew minħabba l-mara, assolutament ma jistax ikollhom tfal, *at least*, mit-tnejn li huma - jista' jkun li bijologikament ikun wiehed minn dawn it-tnejn. Jigiġifieri dwar *donation of gametes*, kif toħroġ minnha din id-dilemma?

MRS SIMONE ATTARD: Bhalma spjegajt qabel, kellna kazijiet fejn ahna ghennihom *to go through the process* li juzaw *donor*, jigifieri ahna m'ahniex qed nghidulhom biex ma jaghmluhiex.

ONOR. FRANCIS AGIUS: Allura x'inhi l-pożizzjoni? Jigifieri l-Knisja qed tghid "iva"...

MRS SIMONE ATTARD: *Imma this is the only NGO* li tezisti, anzi niringrazzjaw lil Kana li tatna *l-premises* ...

...

Jien nixtieq nikkonkludi billi nghid li dan huwa servizz li suppost jinghata mill-Istat u anke fil-klinici privati.

...

Illum qeghdin noffru dan is-servizz li mhuwiex qed joffri l-Istat u nahseb li ma nsibu l-ebda diffikulta li *l-istaff* li hemm jahdem fl-NGO, jekk jigi mitlub, li jahdem fl-isptar ikun jista' jaghmel hekk.

Il-Kumitat studja kif il-ligi f'diversi pajjiżi tinforza *l-counselling*:

- Il-Ligi fir-Renju Unit kif emendata fl-2008 tipprovdi b'dan il-mod:

13 Conditions of licences for treatment

(6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.

- Hekk ukoll dik tal-Istat ta' Victoria kif emendata fl-2005:

11. Counselling

(1) Before a woman consents to undergo a treatment procedure, she and her husband must have received counselling (including counselling in relation to the prescribed matters) from a counsellor who has been approved under Part 8 to give counselling to women undergoing treatment procedures and their husbands.

(2) Before a woman undergoes a treatment procedure, the doctor in charge of that woman's case must take all reasonable steps to ensure that a counsellor who has been approved under Part 8 to give counselling to women undergoing treatment procedures and their husbands is available to give further counselling to the woman and her husband after the procedure is carried out.

(C) L-omm ghandha tinghata l-aħjar trattament possibbli biex tiġi mharsa saħħitha.

(D) Il-ħażna ta' gameti għal użu personali għandha tkun permissibbli biss f'dawk il-każi fejn hemm riskju ta' infertilità jew xi periklu li jista' jkun ta' dannu għall-kapaċità ta' prokreezzjoni. Meta l-persuna li minghandha ttiehdu l-gameti tmut, bl-ebda mod ma tinstab jew tirtira l-kunsens tagħha, il-gameti li ġew maħżuna m'għandhomx jintużaw għall-prokreezzjoni artifiċjali.

(E) Għalissa d-donazzjoni ta' gameti minn terzi persuni m'għandhiex tkun legalment aċċettata lanqas f'ċirkostanzi li fihom:

- i. Hemm sterilità irreversibbli ppruvata fil-koppja.
- ii. Hemm riskju serju ta' malformazzjoni jew abnormalità oħra fit-tarbija futura.
- iii. Kull mezz ieħor ġie kkunsidrat bħala mhux adegwat
- iv. Hemm il-kunsens mill-koppja.
- v. Ikun possibbli *donor screening* adegwat għal raġunijiet ta' mard skont Direttiva 2006/17/KE.
- vi. Ma jsir l-ebda pagament għal din id-donazzjoni.
- vii. In-numru ta' tfal li jitwiieldu minn donatur ikun limitat.
- viii. Tarbija li titwieled b'riżultat ta' inseminazzjoni artifiċjali minn donatur, tkun tista', f'età approprijata, ikollha aċċess għal informazzjoni dwar l-identità tad-donatur.
- ix. Ma jkun hemm l-ebda obligazzjoni legali (inkluż obligazzjoni ta' manteniment) b'riżultat li wiehed huwa donatur ta' gameti.
- x. Ma jkunx hemm dritt ta' titlu ta' paternità min-naħa tad-donatur

Fil-laqgħa tat-**28 ta' Ġunju** l-Kumitat Magħżul unanimament iddeċieda li din l-għażla tiġi posposta sakemm jiġu fis-seħħ miżuri oħra permezz tal-liġi. Fost l-oħrajn ikun għaqli nistennew kif se jirreaġixxu koppji sterili għall-opportunità ta' adozzjoni ta' embrijuni.

ONOR. MICHAEL FARRUGIA: Jiena kont nagħti ċ-ċans il-kwestjoni tal-IVF halli nara kif tkun qiegħda tiżviluppa, nara l-*freezing of embryos* u ndaħhal il-kwestjoni tal-*adoption of frozen embryos* li ma jkunux se jiġu utilizzati mill-ġenituri proprja ta' dawk l-*embryos*. Jekk imbagħad naraw li l-*adoption* normali of *embryos* ma jkunx biżżejjed, immorru biex nikkonsidraw il-kwestjoni tal-*gametes*. Issa din jien qiegħed inpoġġiha għad-diskussjoni.

THE CHAIRMAN: Mela l-pożizzjoni tal-Onor. Michael Farrugia hija waħda ċara u hija pożizzjoni li fl-aħħar mill-aħħar naħseb li tagħmel hafna sens. Issa nistaqsi lilek Onor. Aguis. X'taħseb?

ONOR. FRANCIS AGIUS: Jiena fuq din l-istess linja wkoll, anke jekk taqra x'intqal, issa jkollna nidhlu bilfors xi ffit jew wisq fuq l-aspett morali, fuq dak li qal Marino "my first assessment would be in favor of heterologous fertilization, if this is the only means for having a child and if becoming pregnant is important for the woman. But I have also faced those who maintain that it is not rare for heterologous fertilization to introduce an imbalance in the couple between the biological parent, who

transmits part of his or her DNA to the child, and the other” ...hekk mhux se jkun hemm *imbalance* għax il-*genetic material* mhux ġej minn parti jew ohra tal-koppja, la mill-missier u lanqas mill-omm. Jiġifieri nahseb li wiehed għandu jipprova jagħti ċans. Kif qed naraha jien huwa li l akbar problema li hemm bil-*freezing* huwa x'se jsir mill embryos.

ONOR. MICHAEL FARRUGIA: Jekk se noffru ħafna options hemm ċans li nispiċċaw bihom fil-*fridge*.

THE CHAIRMAN: Hekk hu. Ahna qed ngħidu li se nimxu b'mod li kemm jista' jkun wiehed iħeġġeg li l-*embryos* li jibqgħu ffrizati jkunu disponibbli għall-adoption, allura koppji sterili jkollhom din il-fakultà li ahna qed ngħidu li għandha tiġi użata aktar.

F'laqgħat preċedenti fis-**17 ta' Marzu** ma' Prof. Mark Brincat u fis-**6 ta' April** ma' Dr Luca Gianaroli kienet saret diskussjoni dwar proposta taċ-Chairman li biha, biex ma ssirx diskriminazzjoni kontra każijiet ta' sterilità, filwaqt li fit-territorju tagħna d-donazzjoni ta' gameti tibqa' ma sseħħ, pajjiżna jirreferihom barra, bl-isterilità tkun elenkata fil-lista tal-*health care package of services* u fis-*supra-regional care programmes and treatment measures* offrut mill-Istat. Dan diġà hu l-mod kif jaħdem id-Dipartiment tas-Saħħa f'każijiet ta' ħtieġa ta' ħażna ta' gameti tal-koppja stess qabel ma ssir kura kirurgika u/jew radjo/kemoterapewtika li tista' tnaffar b'mod irriversibbli il-kapaċità riproduttiva tal-pazjent.

Dwar dan ukoll intalbet l-opinjoni tal-Avukat Ġenerali li wieġeb:

“In kwantu għat-tieni domanda d-deċiżjoni jekk id-donazzjoni ta' gameti għandhiex tkun regolata f'liġi Maltija hi waħda ta' *policy* u jeħtieġ li tittiehed fil-kuntest aktar wiesa' ta' kwalunkwe tali donazzjoni, issir barra minn Malta jew f' Malta, issir a spejjeż tal-Gvern jew a spejjeż tal-privat. Fil-każ li d-donazzjoni tkun ser issir barra minn Malta, naturalment, ikun diffiċli li l-liġi Maltija tirregola xi haġa li tkun ser issir barra mill-ġurisdizzjoni ta' Malta; dan ċertament jiġġenera problemi ta' infurzar. Dan ma jfissirx, iżda, li ma jkun hemmx aspetti li xorta jkunu jistgħu jiġu regolati b'liġi Maltija bħal, pereżempju, li persuna li tkun ibbenefikat minn donazzjoni ta' gameti barra minn Malta tkun meħtieġa li tirregistra dik id-donazzjoni f'Malta u li tagħti certi dettalji ta' dik id-donazzjoni. F'dan il-każ, iżda, wiehed ikun irid jara x'konsegwenzi għandu jkun hemm jekk persuna tonqos milli tagħmel tali registrazzjoni u tkun trid issir evalwazzjoni fuq il-prospetti ta' infurzar ta' tali konsegwenzi. Wiehed jista' wkoll jidherli fl-eventwalità ta' twelid f' Malta b'effett ta' donazzjoni ta' gameti li tkun saret barra minn Malta, jkun meħtieġ li l-liġi Maltija tirregola l-effetti ta' dik id-donazzjoni bħal, pereżempju, fuq il-paternità u/jew maternità legittima u legalment rikonossuta tal-wild.

X'tip ta' regolamentazzjoni legali tkun meħtieġa tkun tiddependi mir-riżultat tar-riflessjonijiet tal-Kumitat u tad-deċiżjonijiet tiegħu fir-rigward.”

Kwestjonarju tal-Bioethics Steering Committee fil-Kunsill tal-Ewropa (CDBI) fl-2005 juri kif id-donazzjoni ta' gameti hi provduta b'mod shiħ f'sbatax-il pajjiż membru fl-UE u b'mod parzjali f'erba' ohra fosthom l-Awstrija fejn fl-1 ta' April 2010 il-Qorti Ewropea tad Drittijiet tal-Bniedem qatgħet il każ *S. H. and others v. Austria (Application no. 57813/00)* b'dan il-mod:

“THE FACTS

- 7. The applicants were born in 1966, 1962, 1971 and 1971 respectively and live in L. and R.*
- 8. The first applicant is married to the second applicant and the third applicant to the fourth applicant.*
- 9. The first applicant suffers from fallopian-tube-related infertility (eileiterbedingter Sterilität). The second applicant, her husband, is also infertile.*
- 10. The third applicant suffers from gonadism (Gonadendysgenese), which means that she does not produce ova at all. Thus she is completely infertile but has a fully developed uterus. The fourth applicant, her husband, in contrast to the second applicant, can produce sperm fit for procreation.*

The Court’s assessment

- 85...There has been a violation of Article 14 of the Convention taken in conjunction with Article 8 as regards the third and fourth applicants.*
- 94. The Court therefore finds that the difference in treatment between the first and second applicants who, for fulfilling their wish for a child could only resort to sperm donation for in vitro fertilisation and a couple which lawfully may make use of sperm donation for in vivo fertilisation, had no objective and reasonable justification and was disproportionate. Accordingly, there has been a violation of Article 14 of the Convention taken in conjunction with Article 8 as regards the first and second applicants.”*

The European Convention on Human Rights

ARTICLE 8

- 1. Everyone has the right to respect for his private and family life, his home and his correspondence.*
- 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.*

ARTICLE 14

The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.

It-tabella annessa turi kemm stat jipprovdi għajnuna f’kazi ta’ infertilità u hemmx legislazzjoni għal gamete u embryo donation kif ukoll għar-riċerka u f’liema ċirkostanzi:

Country	Donation			Research		
	NHS	Sperm	Oocyte	Embryo	Human embryonic stem cell research	Allowed by EU programmes
Austria	70%	Yes	No	No	No	
Belgium	Partial	Yes	Yes	Yes	Yes - therapeutic cloning allowed	No
Bulgaria						
Cyprus	Partial	Yes				
Czech Republic	Partial	Yes	Yes	Yes		
Denmark	Partial	Yes	Yes	Yes	Yes - only from supernumerary embryos	Yes
Estonia	Partial	Yes	Yes	Yes	Yes - only from supernumerary embryos	Yes
Finland	YES	Yes	Yes	Yes	Yes - only from supernumerary embryos	Yes
France	Partial	Yes	Yes	Yes	Yes - only from supernumerary embryos	Yes
Germany	50%	Yes	No	Yes	Yes - imported - embryos < 1/1/2002	Yes
Greece	Partial	Yes	Yes	Yes	Yes - only from supernumerary embryos	Yes
Hungary					Yes - only from supernumerary embryos	Yes
Ireland						
Italy		No	No	No	Yes - imported	Yes
Latvia	NO	Yes	Yes	Yes	Yes - only from supernumerary embryos	Yes
Lithuania	NO	Yes	Yes	No	No	
Luxembourg	Partial	Yes	Yes	Yes		
Malta	Partial					
Netherlands	Partial	Yes	Yes	Yes	Yes - only from supernumerary embryos	Yes
Poland	NO	Yes	Yes	Yes	No	
Portugal	YES	Yes	Yes	No		
Romania						
Slovakia	Partial	Yes	Yes	Yes		

Country	Donation			Research		
	NHS	Sperm	Oocyte	Embryo	Human embryonic stem cell research	Allowed by EU programmes
Slovenia	Partial	Yes*	Yes*	No	Yes - only from supernumerary embryos	Yes
Spain	YES	Yes	Yes	Yes	Yes - only from supernumerary embryos	Yes
Sweden	Partial	Yes	Yes	No	Yes - therapeutic cloning allowed	No
United Kingdom	Partial	Yes	Yes	Yes	Yes - therapeutic cloning allowed	No
Victoria		Yes	Yes		Yes - only from supernumerary embryos	
New Zealand		Yes	Yes			
Canada	Ontario only	Yes	Yes	Yes	Yes - only from supernumerary embryos	
USA		Yes	Yes	Yes	Yes - embryos < 9/8/2001	
		*either/or				

7.4 Il-Harsien tas-Socjeta':

- A. Intervent li jipprova jbidel il-*human germ cell line* ma huwiex acċettabli.
- B. Embrijun uman ma ghandux jitpoġġa fl-utru ta' speċi oħra u viċi versa.
- C. Il-fużjoni ta' gameta umana ma' dik ta' speċi oħra għandha tkun projbita.

Fl-aħħar laqgħa fil-5 ta' **Lulju** il-Kumitat deherlu li fiċ-ċirkostanzi, dwar il-Proċedura għal Regolamentazzjoni u dwar Kunsiderazzjonijiet Oħra jikkummenta biss dwar Punti 8.2, 8.3, 8.4, 8.5, 8.6 u 9.1.

8 Proċedura għal Regolamentazzjoni:

8.2 Id-Dipartiment tas-Saħħa jew Awtorità delegata minnu għandu jkollu rwol regolatorju, bi dritt u obbligu li jsegwi, jispezzjona u jevalwa l-livelli ta' proċeduri ppattikati fil-qasam tal-bijoteknoloġija. Huwa għandu jassigura li l-linji ta' gwida li johorġu mil-liġi jew minn regolamenti oħra ta' proċedura jiġu rispettati.

Kif spjegat fl-introduzzjoni, meta staqsejna lill-Uffiċċju tal-Avukat Ġenerali: "X'inhuma r-rwoli li għandu jkollha awtorità li tirregola s-servizzi ta' prokreazzjoni medikament assistita?" Dr Peter Grech, Deputat Avukat Ġenerali wieġeb li "is-sottoskritt jinhtieg illi jkollu aktar informazzjoni sabiex ikun jista' jwieġeb għal din id-domanda fuq dan is-sugġett kumpless. X'għandhom ikunu r-rwoli in kwestjoni jiddependi ferm fuq ix-xejra

li tiehu r-regolamentazzjoni tal-prokreezzjoni medikament assistita li fiha nnifisha tistrieħ hafna fuq l-opinjoni medika aktar milli fuq l-opinjoni legali. Fil-fatt hi aktar l-opinjoni medika li għandha tinforma l-opinjoni legali f'din il-materja milli l-kuntrarju”.

Kien hemm kunsens fost il-membri tal-Kumitat Magħżul li avviz legali għandu jipprovdi li titwaqqaf awtorità awtonoma li:

1. tiċcertifika *a priori* li koppja tkun eligibbli skont il-ligi sabiex issir l-IVF
2. ikollha r-rwol li tagħti l-liċenzji lill-kliniċi skont kundizzjonijiet ta' *Standards of Best Practice*, li jkunu supplimentari għall-Att

Rajna x'tgħid l-opinjoni medika – jidher ċar li jkun aħjar nutilizzaw l-ESHRE li fi hdanha għandha “*EIM data collection consortium which collects data from 1,000 clinics from around Europe on more than half a million treatments every year*” fir-rigward ta' data aggregata u l-HFEA għal dak li jirrigwarda rizorsi umani.

Fil-laqgħa tas-**17 ta' Marzu** Prof. Mark Brincat kien qal:

X'bord regolatorju qed taħsbu fuqu? Mill-esperjenzi li kellna s'issa f'Malta meta pprovajna nergħu *to reinvent the wheel* batejna minħabba fin-nuqqas ta' *human resources*, esperjenzi eċċ. Għandna hafna eżempji fejn minħabba fl-Unjoni Ewropea kellna naghmlu strutturi malajr u sibna li qed inbatu. F'hames snin ivarjaw hafna affarijiet imma hemm hafna affarijiet li applikaw dakinhar u forsi ma japplikawx għalissa. Issa din mhijiex kwestjoni ta' għax konna kolonja, xejn minn dan, pero aħna dejjem konna aktar marbuta mas-sistema Brittannika. Kieku kont avukat forsi kont nħares lejn is-sistema Taljana.

Jekk hemm struttura diġà ezistenti li hija pijuniera, li l-Ewropa thares lejha bħala *gold standard* hija l-HFEA. Aħna ma ddejjaqniex naghmlu UK *foundation programme* hawn Malta. Il-*foundation programme* tagħna mhuwiex *foundation programme* ieħor rikonoxxut mill-UK imma parti integra mill-*foundation programme*.

THE CHAIRMAN: Għaliex l-HFEA u mhux l-ESHRE? *Why would you go for the UK and not the European?*

PROF. MARK BRINCAT: Ma jkolli xejn kontra li l-ESHRE tagħmel *monitoring* hawn Malta anzi nieħu gost hafna. *I am the last one* biex nitkellem kontra l-ESHRE, imma l-ohra hija iktar stabbilita u għandhom hafna iktar esperjenza.

THE CHAIRMAN: Hija iktar liberali minn xi pajjiżi fl-Ewropa.

PROF. MARK BRINCAT: Hija aktar liberali? Ma nafx. Dik dejjem tista' thassaraha skont l-esiġenzi tagħna. Tgħid aħna rridu naħdmu f'dawn il-*parameters*, inti għamlilna *monitoring* kemm trid imma għandna dawn il-*parameters* li ma nixtixq immorru *oltre*. Ma nara l-ebda problema li l-HFEA nagħtuha *parameters* imbagħad inħalluha biex tagħmlilna *monitoring* jew l-ESHRE *for that matter*, araw intom. M'għandi l-ebda problema bl-HFEA jew bl-ESHRE imma sempliciment dawn għandhom il-*manpower* ezistenti. L-HFEA għandhom l-*standing committee* ta' serjetà enormi u ta' esperjenza kbira.

...**ONOR. FRANCIS AGIUS:** Hija *feasible* li jkollok istituzzjoni bħal mhi dik Ingliża li tagħmillek l-*auditing*. Mhijiex xi haġa impossibli hux hekk?

PROF. MARK BRINCAT: Le, mhux impossibli, anzi tajba hafna.

ONOR. FRANCIS AGIUS: Jigifieri *it's done* ghax pajjiż iehor ...

PROF. MARK BRINCAT: Mhux ghax ghandna sigrieti imma nahseb irridu noqogħdu attenti kif nillegislaw, forsi ċertu *leeway* mhux diffiċli biex tinghata.

Fil-laqgħa tas-**6 ta' April** konna staqsejna lil Dr Gianaroli:

THE CHAIRMAN: Basically, when the law was enacted were all centres forced to give retrospective data? And was it manageable or was it difficult?

DR LUCA GIANAROLI: Yes we had to give retrospective data and it was manageable because we shifted from a voluntary registry to a compulsory registry. By law, like in many countries, we are required to present data every year to our national health institute ... we send the aggregated data. There is no individual data.

...

THE CHAIRMAN: ... regarding the framework that one could have as regarding enforcing standards through your organisation, ... Are there other countries, or maybe cities that have utilised your services.

DR LUCA GIANAROLI: For instance, three years ago we have been embarked with Montenegro, ... we are giving them suggestions or information how to set up a registry, how to keep a track of this treatment and how to present data to the parliament on an annual basis, or whatever is required by the Ministry of Health.

Il-Liġi fir-Renju Unit (*Human Fertilisation and Embryology Act 1990 (c. 37) as amended in the Human Fertilisation and Embryology Act 2008*) tipprowdi b'dan il-mod:

8 General functions of the Authority

(1) The Authority shall

(a) keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State, if he asks it to do so, about those matters,

(b) publicise the services provided to the public by the Authority or provided in pursuance of licences,

(c) provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act, or may wish to do so,

(ca) maintain a statement of the general principles which it considers should be followed –

(i) in the carrying-on of activities governed by this Act, and

(ii) in the carrying-out of its functions in relation to such activities,

(cb) promote, in relation to activities governed by this Act, compliance with –

(i) requirements imposed by or under this Act, and

(ii) the code of practice under section 25 of this Act, and

(d) perform such other functions as may be specified in regulations.

(2) The Authority may, if it thinks fit, charge a fee for any advice provided under subsection (1)(c).

8ZA Duties in relation to carrying out its functions

(1) The Authority must carry out its functions effectively, efficiently and economically.

(2) In carrying out its functions, the Authority must, so far as relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).

8A Duty of Authority to communicate with competent authorities of other EEA states:

The Authority shall communicate to the competent authorities of EEA states other than the United Kingdom or of Gibraltar, and to the European Commission, such information in relation to serious adverse events and serious adverse reactions as is necessary for the purpose of enabling appropriate action to be taken, including where necessary the withdrawal from use of gametes and embryos that are intended for human application but are known or suspected to be unsuitable for such application.

8B Agency arrangements and provision of services

(1) Arrangements may be made between the Authority and a government department, a public authority or the holder of a public office ("the other authority") for –

(a) any functions of the Authority to be exercised by, or by members of the staff of, the other authority, or

(b) the provision by the other authority of administrative, professional or technical services to the Authority.

(2) Arrangements under subsection (1)(a) do not affect responsibility for the carrying-out of the Authority's functions.

(3) Subsection (1)(a) does not apply to any function of making subordinate legislation (within the meaning of the Interpretation Act 1978).

8C Contracting out functions of Authority

(1) This section applies to any function of the Authority other than –

(a) any function which, by virtue of any enactment, may be exercised only by members of the Authority,

(b) a function excluded from this section by subsection (2), or

(c) a function excluded from this section by the Secretary of State by order.

(2) A function is excluded from this section if –

(a) it relates to the grant, revocation or variation of any licence,

(b) it is a power or right of entry, search or seizure into or of any property, or

(c) it is a function of making subordinate legislation (within the meaning of the Interpretation Act 1978).

(3) The Authority may make arrangements with any person ("the authorised person") for the exercise by that person, or by the employees of that person, of any function of the Authority to which this section applies.

(4) Any arrangements made by the Authority under this section –

(a) may be revoked at any time by the Authority, and

(b) do not prevent the Authority from exercising any function to which the arrangements relate.

(5) Subject to subsection (6), anything done or omitted to be done by or in relation to the authorised person (or an employee of the authorised person) in, or in connection with, the exercise or purported exercise of any function to which the arrangements relate is to be treated for all purposes as done or omitted to be done by or in relation to the Authority.

(6) Subsection (5) does not apply –

(a) for the purposes of so much of any contract between the authorised person and the Authority as relates to the exercise of the function, or

(b) for the purposes of any criminal proceedings brought in respect of anything done or omitted to be done by the authorised person (or any employee of the authorised person).

(7) Section 38A(2) of this Act (which relates to the keeping of embryos, human admixed embryos and gametes) applies in relation to the authorised person or any employee of the authorised person, when exercising functions of the Authority, as it applies in relation to any member or employee of the Authority exercising functions as member or employee.

8D Disclosure of information where functions of Authority exercised by others

(1) This section applies to -

- (a) the Authority,*
 - (b) any public authority or other person exercising functions of the Authority by virtue of section 8B,*
 - (c) any member of staff of any person falling within paragraph (b),*
 - (d) any person exercising functions of the Authority by virtue of section 8C,*
 - (e) an employee of any person falling within paragraph (d), or*
 - (f) any person engaged by the Authority to provide services to the Authority.*
- (2) No obligation of confidence is to prevent the disclosure of information by a person to whom this section applies to another such person if the disclosure is necessary or expedient for the purposes of the exercise of any function of the Authority.*

8E Power to assist other public authorities

- (1) The Authority may if it thinks it appropriate to do so provide assistance to any other public authority in the United Kingdom for the purpose of the exercise by that authority of its functions.*
- (2) Assistance provided by the Authority under this section may be provided on such terms, including terms as to payment, as it thinks fit.*

9A Power to delegate and establish committees

- (1) The Authority may delegate a function to a committee, to a member or to staff.*
- (2) The Authority may establish such committees or sub-committees as it thinks fit (whether to advise the Authority or to exercise a function delegated to it by the Authority).*
- (4) Subject to any provision made by regulations under section 20A (appeals committees), the members of the committees or sub-committees may include persons who are not members of the Authority.*
- (5) Subsection (1) has effect subject to any enactment requiring a decision to be taken by members of the Authority or by a committee consisting of members of the Authority.*

25 Code of practice

- (1) The Authority shall maintain a code of practice giving guidance about the proper conduct of activities carried on in pursuance of a licence under this Act and the proper discharge of the functions of the person responsible and other persons to whom the licence applies.*
- (2) The guidance given by the code shall include guidance for those providing treatment services about the account to be taken of the welfare of children who may be born as a result of treatment services (including a child's need for supportive parenting), and of other children who may be affected by such births.*
- (2A) The code shall also give guidance about -*
- (a) the giving of a suitable opportunity to receive proper counselling, and*
 - (b) the provision of such relevant information as is proper,*
- in accordance with any condition that is by virtue of section 13(6) or (6A) a condition of a licence under paragraph 1 of Schedule 2.*
- (3) The code may also give guidance about the use of any technique involving the placing of sperm and eggs in a woman.*
- (4) The Authority may from time to time revise the whole or any part of the code.*
- (5) The Authority shall publish the code as for the time being in force.*
- (6) A failure on the part of any person to observe any provision of the code shall not of itself render the person liable to any proceedings, but -*

(a) the Authority shall, in considering whether there has been any failure to comply with any conditions of a licence and, in particular, conditions requiring anything to be "proper" or "suitable", take account of any relevant provision of the code, and
(b) the Authority may, in considering, where it has power to do so, whether or not to vary or revoke a licence, take into account any observance of or failure to observe the provisions of the code.

8.3 L-użu ta' teknoloġiji tal-Ġenetika u tal-Prokreazzjoni Assistita għandhom jiġu pprattikati minn tobbja adekwatament kwalifikati u kif reġistrati mal-Kunsill Mediku.

8.4 Il-kunsens infurmat għandu jingħata bil-miktub minn dawk li qed jipparteċipaw f'dawn il-proċeduri. Dan wara li tigi mghoddija l-informazzjoni neċessarja u jkunu ingħataw il-pariri minn professjonisti kompetenti

8.5 Waqt illi l-kunfidenzjalità għandha tiġi dejjem irrispettata il-gvern għandu jibda jkollu statistika disponibbli, kemm biex isegwi l-iżviluppi tal-bijoteknoloġija u kemm biex ikun f'pożizzjoni li jfassal *policy*. Għal dan il-għan, it-tabib jew l-istituzzjoni li qieghda tospita dawn il-proċeduri, għandu jkollhom l-obbligu li jzommu rekords ta' informazzjoni.

Dan għandu jsehh kemm billi l-Awtorità tiġbor l-informazzjoni mogħtija lilha b'mod aggregat regolarment mill-kliniċi awtorizzati kif ukoll bħala *Code of Practice* lill-professjonisti kollha li jkunu awtorizzati mill-koppja sabiex ikollhom aċċess għall-informazzjoni kollha dwar il-każ tagħhom sew qabel, waqt kif ukoll wara t-tqala.

Sa issa dan jidher ċar li hu nieqes mit-twegibiet mogħtija fl-20 ta' April 2010 għall-mistoqsijiet parlamentari li għamel iċ-Chairman lill-Ministru tas-Saħħa, l-Anzjani u l-Kura fil-Komunità:

PQ 15924 - Jista' l-Ministru jgħid matul l-2009 kemm ġew investigati koppji għall-infertilità? X'kienet l-età u l-istat soċjali tal-mara f'kull każ?

Twegiba:

Ninsab infurmat li dan hu servizz li huwa offrut mid-Dipartiment tal-Outpatients. F'dan id-Dipartiment ma tinzammx statistika dwar ir-raġunijiet għalfejn il-pazjenti jkunu ġew riferuti u dwar id-dijanjozi. Għaldaqstant m'iniex f'pożizzjoni li nagħti l-informazzjoni mitluba.

PQ15919 - Jista' l-Ministru jgħid fis-snin 2000-2009 kemm kien hemm sena b'sena:

- a) twelid multiplu?
- b) twelid prematur?
- ċ) twelid b'cerebral palsy?
- d) twelid b'respiratory distress syndrome?
- e) still births?

F'kull każ, kemm minnhom irriżulta minn riproduzzjoni medikament assistita?

Tweġiba:

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009		
MULTIPLE BIRTHS	131	73	106	115	120	119	135	87	144	133	1163	
ART	4	5	12	18	20	21	21	11	24	11	147	12.60%
PREMATURE BIRTHS	270	267	267	301	289	253	275	266	309	300	2797	
ART	3	9	13	17	16	16	13	11	17	10	125	4.45%
STILL BIRTHS	16	20	21	18	15	8	11	12	29	28	178	
ART	0	0	0	1	0	0	1	1	3	1	7	3.93%

It-terminu Respiratory Distress jew RDS huwa użat b' mod ġeneriku għal xi forma ta' problema respiratorja tat-trabi minflok bil-propji definizzjoni ta' *full blown* Respiratory Distress Syndrom/Hyaline Membrane Disease assoċjati ma' twelid prematur jew ommijiet diabetiċi. Għal dawn ir-raġunijiet in-National Obstetrics Information System (NOIS) mhumiex f'pożizzjoni li jirrispondu din id-domanda.

Statistika dwar is-Cerebral Palsy li hi kundizzjoni attribwita lil trawma fit-twelid, mhijiex attwalment miġbura mid-Department of Health Information Research (DHIR).

8.6 Membri tal-*istaff* mediku m'għandhomx jiġu mġieghla sabiex jipparteċipaw fi proċeduri mediċi li għandhom xi oġġezzjoni morali għalihom. Min-naħa l-oħra huma jibqgħu obbligati li jipprovdu informazzjoni dwar il-possibiltà ta' metodi alternattivi legali.

Il-liġi Taljana tipprovdi kif ġej:

ART. 16.
(*Obiezione di coscienza*).

1. *Il personale sanitario ed esercente le attività sanitarie ausiliarie non è tenuto a prendere parte alle procedure per l'applicazione delle tecniche di procreazione medicalmente assistita disciplinate dalla presente legge quando sollevi obiezione di coscienza con preventiva dichiarazione. La dichiarazione dell'obiettore deve essere comunicata entro tre mesi dalla data di entrata in vigore della presente legge al direttore dell'azienda unità sanitaria locale o dell'azienda ospedaliera, nel caso di personale dipendente, al direttore sanitario, nel caso di personale dipendente da strutture private autorizzate o accreditate.*

2. *L'obiezione può essere sempre revocata o venire proposta anche al di fuori dei termini di cui al comma 1, ma in tale caso la dichiarazione produce effetto dopo un mese dalla sua presentazione agli organismi di cui al comma 1.*

3. *L'obiezione di coscienza esonera il personale sanitario ed esercente le attività sanitarie ausiliarie dal compimento delle procedure e delle attività specificatamente e necessariamente dirette a determinare l'intervento di procreazione medicalmente assistita e non dall'assistenza antecedente e conseguente l'intervento.*

9 Kunsiderazzjonijiet Ohra:

9.1 Il-Kumitat dwar l-Affarijiet Soċjali jinnota li l-isptar pubbliku ma jipprovdi it-trattamenti kollha tal-infertilità u l-prokreazzjoni assistita. Il-Kumitat għalhekk jirrakkomanda li l-Gvern serjament jikkonsidra biex dawn it-trattamenti jibdwu jingħataw mill-isptar pubbliku.

Fis-17 ta' Marzu kienet intalbet informazzjoni dwar kemm qed iħallu l-pazjenti għal dan is-servizz privat illum u x'inhu joffri l-Gvern.

THE CHAIRMAN: X'costs hemm?

PROF. MARK BRINCAT: L-ikbar *cost* jekk tkun fuq l-NHS għaliha huwa dak tal-medicini, il-*cost* tal-*consumables*.

THE CHAIRMAN: Digà qed jingħataw hux hekk?

PROF. MARK BRINCAT: Le, l-NHS ma jagħtix medicini b'xejn preżentement. Is-sena l-oħra għamilt applikazzjoni għaliha però s'issa għadha mhijiex hemm. Dik kwazi kwazi *it halves* il-*cost* preżenti tal-IVF.

THE CHAIRMAN: Il-*pre-procedure management* huwa b'xejn.

PROF. MARK BRINCAT: Qed jingħata l-*work up* li huwa hafna xogħol u niringrazzja l-kollegi tiegħi, fuq koppji li qed nimmanigjawhom aħna u allura għandna hafna visti bl-*ultrasound* Mater Dei li huwa b'xejn.... Huwa erba' gimghat xogħol. Dak li nistgħu nagħtu nagħtuh. F'Mater Dei nimxu bil-prinċipju li dak li nistgħu nagħtu nagħtuh, imbagħad jekk xi hadd *he opts* għal affarijiet li mhumiex *available* m'hemm x'tagħmel.

THE CHAIRMAN: Bl-NHS eventwalment il-prezzijiet għandhom jinżlu min-naħa tal-privat.

PROF. MARK BRINCAT: Jien hekk naħseb. Fl-opinjoni tiegħi l-privat għandu problema ta' *consumables*, ta' *embryologists* u ta' *drugs* iktar milli ta' *hands on*. Il-problema l-kbira mhijiex tal-*hands on* imma tal-*consumables* u tal-*embryologists*. Il-*consumables* huma, hafna drabi mil-laboratorji, kwestjoni ta' kemm jixtri *medium*. Il-*medium* tal-*sperm* hija haġa u l-*medium* tal-*oocytes* hija haġa oħra. *Medium* ta' *oocyte* ta' *one day* hija haġa u *medium* ta' *oocyte* ta' *three days* hija haġa oħra. Dan il-*medium* huwa għali immens. Jekk tagħmlu għal koppja waħda l-flixkun kollu tarmih, jekk tagħmlu għal għaxar koppji ma jinħeliex daqshekk.

3. Konkluzjoni

Il-Parlament Ewropew fi Frar 2008 sejjah lill-Istati Membri sabiex “jiżguraw id-dritt ta’ koppji għal aċċess universali dwar trattament għall-infertilità”.

Wara li għarbilna l-fehma tal-esperti mediċi, inheggu l-Gvern iħabrek iressaq **Abbozz fil-Parlament** li jirrifletti dawn il-proposti. Ir-Rapport estensiv tal-Kumitat Magħżul għandu jservi ta’ għajjnuna għal kull membru parlamentari li jixtieq jinforma ruħu aktar dwar is-suġġett sabiex **b’mod meqjus u hieles** iwassal għal liġi li tirregola l-prokreazzjoni medikament assistita f’Malta.

Għandu jixprunana kliem id-Direttur taċ-Ċentru Fidi u Ġustizzja:

“It is better to have a law which permits certain things I am against from a moral point of view rather than have no law at all”.

Anness 1: Mozzjoni 113

IL-VIĊI PRIM MINISTRU U MINISTRU TAL-AFFARIJJIET BARRANIN Jipproponi

Billi huwa xieraq illi l-kwestjoni tar-regolamentazzjoni tal-prokreazzjoni medikament assistita tkun dibattuta bis-sħiħ sabiex ikun hemm iktar konsultazzjoni wiesgħa dwar dan is-sugġett;

Billi l-assenza ta' ligi dwar dan is-sugġett thalli liberta assoluta f' dal-qasam b' mod li ċerti prattici huma permessi fin-nuqqas ta' legislazzjoni, u dana a skapitu tal-persuna li tassogġetta ruhha għal intervent mediku, kif ukoll kontra l-interessi tat-tfal li jitwiellu b' dan il-metodu;

Billi l-Kumitat Permanenti dwar l-Affarijjet Soċjali ta' din il-Kamra fit-Tielet Rapport tiegħu ta' Settembru 2009 osserva diskussjoni iktar wiesgħa trid tkompli fuq livell mediku u legali dwar (a) liema koppji ikunu eliġibbli għas-servizzi tal-prokreazzjoni assistita (b) il-kwestjoni jekk għandux jiġi permess jew le l-iffriżar tal-embrijuni u (ċ) id-donazzjoni ta' gamete minn terzi persuni;

Billi huwa xieraq illi l-persuni kollha interessati f' dal-qasam ikunu involuti f' dan il-proċess, u jkunu jistgħu jissottomettu bil-miktub jew bil-fomm l-idejat tagħhom u b'hekk iġhinu fit-tfassil ta' legislazzjoni li jkollha l-iktar appoġġ wiesgħa possibbli.

Din il-Kamra tirrisolvi illi:

- (a) Tahtar Kumitat Magħżul sabiex jeżamina u jgħarbel il-kwestjonijiet kollha konnessi ma' din il-materja u jelenka l-elementi baġiċi ta' legislazzjoni futura dwar il-prokreazzjoni medikament assistita;
- (b) Dan il-Kumitat ikun magħmul minn l-Onorevoli Jean Pierre Farrugia bħala President u żewġ deputati wiehed minn kull naħa tal-Kamra bħala membri;
- (c) In-naħa tal-Gvern u tal-Oppożizzjoni ikunu jistgħu liberament jinnominaw id-deputati tagħhom fil-Kumitat billi jinnotifikaw l-ismijiet relattivi lis-Segretarju tal-Kumitat Permanenti dwar ix-Xogħol tal-Kamra; u l-ħatra tagħhom issir effettiva ma' tali notifikazzjoni;
- (d) Il-Kumitat ikollu d-dritt illi jirċievi kull komunikazzjoni bil-miktub, inkluż abbozz ta' ligi mill-Gvern, awtoritajiet pubbliċi u għaqdiet mhux governattivi;
- (e) Dan il-Kumitat ikun jista' jirregola il-proċedura tiegħu minkejja kull provvediment ta' l-Ordinijiet Permanenti tal-Kamra u li jisma' jew jirċievi opinjoni, sugġerimenti u rakkomandazzjonijiet tas-soċjeta ċivili;
- (f) In-numru tal-Quorum fil-Kumitat ikun dak ta' żewġ membri.

Il-Kumitat għandu jlesti r-Rapport tiegħu fl-inqas żmien possibbli u fi kwalunkwe każ mhux iktar tard minn tliet xhur mil-lum.

21.10.09

Anness 2: Lista ta' dokumenti li saru referenza ghalihom matul il-laqghat tal-Kumitat Magħżul¹¹

Laqgħa	Data	Aġenda u Karti mqieghda	Audio
1	03.02.10	<p>Regolamentazzjoni tal-proċedura li fuqha ser jimxi l-Kumitat Magħżul</p> <ul style="list-style-type: none"> - Direttiva 2004/23/KE tal-Parlament Ewropew u tal-Kunsill fir-rigward tal-kondizzjonijiet tar-rintraċċabbiltà, notifikazzjoni dwar rejazzjonijiet u avvenimenti ta' ħsara serja u ċerti kondizzjonijiet tekniċi għall-ikkowdjar, l-ipproċessar, il-preżervazzjoni, il-ħażna u d-distribuzzjoni ta' tessuti u ċelluli umani Liġi Taljana dwar il-prokreazzjoni medikament assistita; - kopja ta' Direttiva 2006/17/KE tat-8 ta' Frar 2006 rigward ċerti rekwiziti tekniċi għad-donazzjoni, għall-ksib u għall-ittestjar tat-tessuti u taċ-ċelloli umani; - pożizzjoni tal-European Society of Human Reproduction and Embryology dwar it-trattament kliniku tajjeb f'riproduzzjoni assistita; - kopja tal-liġi Taljana tad-19 ta' Frar tal-2004, li tirrigwarda l-prokreazzjoni medikament assistita: Norme in materia di procreazione medicalmente assistita - kopja tax-xhieda ta' Prof Mark Brincat li nġhatat lill-kumitat tal-10 Legiżlatura (Laqgħa 19 17.01.2005) - kopja tax-xhieda ta' Dr Ruth Farrugia li nġhatat lill-kumitat tal-10 Legiżlatura (Laqgħa 28 08.03.2005) - kopja tax-xhieda ta' Dr Deborah Schembri Tabone li nġhatat lill-kumitat tal-10 Legiżlatura (Laqgħa 31 11.04.2005); - kopja tax-xhieda ta' Dr Simon Attard Montalto li nġhatat lill-kumitat tal-10 Legiżlatura (Laqgħa 40 06.06.2005) 	(isma')
2	09.02.10	<p>Diskussjoni dwar l-ewwel tema indikata fil-Mozzjoni 113 li tistabbilixxi l-Kumitat Magħżul dwar ir-regolamentazzjoni tal-prokreazzjoni medikament assistita: liema koppji jkunu eligibbli għas-servizzi tal-prokreazzjoni assistita</p> <ul style="list-style-type: none"> - kopja tal-artiklu <i>Famiglie di Fatto</i> tal-15 ta' 	(isma')

¹¹ Kopja ta' dawn id-dokumenti tinsab fuq CD imqassam ma' dan ir-rapport billi tikklikja fuq id-dokument relavanti.

		<p>Diċembru 2006 ta' Rocco Buttiglione;</p> <ul style="list-style-type: none"> - korrispondenza mill-ETC dwar każ fejn il-korporazzjoni riedet tistabilixxi li tnejn min-nies huma f' relazzjoni stabbli 	
3	03.03.10	<p>Diskussjoni dwar it-tieni tema indikata fil-Mozzjoni 113 li tistabilixxi l-Kumitat Magħżul dwar ir-regolamentazzjoni tal-prokreazzjoni medikament assistita: jekk għandux jiġi permess jew le l-iffriżar tal-embrijuni</p> <p>Sottomissjonijiet lill-Kumitat</p> <ul style="list-style-type: none"> - 11-il sottomissjoni lill-Kumitat¹² - Kopja tax-xhieda mogħtija mill-Prof Peter Seracino Inglott lill-Kumitat dwar l-Affarijiet Soċjali fl-X Legislatura - Artiklu bl-isem ta' IVF and twins mehud mill-website tas-Center for Human Reproduction 	(isma')
4	17.03.10	<p>Prezentazzjoni minn Prof Mark Brincat, Kap tad-Dipartiment tal-Obstetrija u l-Ġinekologġja; u Diskussjoni dwar it-tielet tema indikata fil-Mozzjoni 113 li tistabilixxi l-Kumitat Magħżul dwar ir-regolamentazzjoni tal-prokreazzjoni medikament assistita: Donazzjoni ta' gameti minn terzi persuni.</p> <ul style="list-style-type: none"> - zewġ artikli 'Guidelines for sperm donation' u 'Guidelines for oocyte donation' mislutin mill-pubblikazzjoni 'Fertility and Sterility' Vol 77, Nru 6, Suppl.5 ta' Gunju 2002 tal-American Society for Reproductive Medicine; u - kopja tal-artiklu 'L'ultima spallata alla legge 40 partono i ricorsi contro l'eterologa' li deher fuq il-ġurnal la Repubblica.it tas-6 ta' Frar 2010. 	(isma')
5	23.03.10	<p>Prezentazzjoni minn Dr Paul Soler, Kap tan-Neonatal Intensive Care Unit fl-Isptar Mater Dei, dwar kumplikazzjonijiet fi trabi minn proċeduri ta' prokreazzjoni medikament assistita</p> <ul style="list-style-type: none"> - Statistika fil-qosor dwar multiple pregnancies migbura minn Dr Paul Soler, Consultant Neonatal Paediatrician fl-SCBU fit-30 ta' Novembru 2006 - Artiklu Congenital malformations in infants born after IVF: a population-based study ta' Ericson A. u Källen B. mill-ġurnal Human Reproduction tal-European Society of Human Reproduction and Embryology (ESHRE), Vol 16, Nru 3 tat-22 ta' Settembru 2000 - Artiklu Neonatal outcome and congenital 	(isma')

¹² Ara Anness 3

		<p><i>malformations in children born after in-vitro fertilization</i> ta' Koivurova et al. mill-ġurnal Human Reproduction tal-European Society of Human Reproduction and Embryology (ESHRE), Vol 17, Nru 5 tal-20 ta' Settembru 2001</p> <ul style="list-style-type: none"> - Artiklu <i>In Vitro Fertilization (IVF) in Sweden: Risk for Congenital Malformations after Different IVF Methods</i> ta' Källen et al. mill-ġurnal Birth Defects Research (Part A) Vol 73, Nru 3 tal-11 ta' Novembru 2004 - Artiklu <i>Risks of Birth Defects and Other Adverse Outcomes Associated with Assisted Reproductive Technologies</i> ta' Nancy S. Green mill-ġurnal Pediatrics, Vol. 114 tal-1 ta' Lulju 2004 - Artiklu <i>In Vitro Fertilization in Sweden: child morbidity including cancer risk</i> ta' Källen et. al mill-ġurnal Fertility and Sterility tal-American Society for Reproductive Medicine, Vol 84, Nru 3 tat-3 ta' Settembru 2005 - Artiklu <i>Multiple Pregnancy and Birth: Considering Fertility Treatments</i> tal-ġhaqda March of Dimes (Birth Defects Foundation) tal-2006 - Artiklu <i>Couples face ban in IVF twins</i> mehud minn The Sunday Times (UK) tas-17 ta' Settembru 2006 - Artiklu <i>Time to make IVF treatment your business, infertile couples are told</i> mehud minn The Times (UK) tad-29 ta' Marzu 2006 - Artiklu <i>Fertility treatment regulator steps up warning about multiple births</i> mehud mill-British Medical Journal Vol 332 tal-10 ta' Ġunju 2006 - Artiklu <i>Desperate for a baby</i> mehud mill-ġurnal Guardian Weekly tat-18 ta' Jannar 2007 - Stqarrija għall-istampa <i>What's wrong with Assisted Reproductive Technologies?</i> mahruġa mill-Institute of Science in Society (ISIS) fit- 3 ta' Novembru 2003 - Studju <i>Neonatal Outcome and High-Order Multiple Pregnancies</i> ta' Dr Ray Parascandalo - Kopja tal-<i>Patient's Factsheet – Complications of Multiple Gestation</i> tal-American Society for Reproductive Medicine - Estratt mill-artiklu <i>Incidence of handicaps in multiple births and associated factors</i> tal-Kinki University School of Medicine, Osaka - Estratt mill-artiklu <i>Reducing the incidence of triplets and twins</i> tas-Centre for Fetal Care, Queen Charlotte's and Chelsea Hospital, Londra - Dokument <i>Fertility problems and treatment – facts and figures</i> ippubblikat bhala anness mal-HFEA 2006-2007 Guide to Infertility – treatment and 	
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		<p>success data based on treatment carried out between 1 April 2003 and 31 March 2004</p> <ul style="list-style-type: none"> - Kopja tar-Risoluzzjoni tal-Maltese Paediatric Association tal-21 ta' Lulju 2005 	
6	06.04.10	<p>Prezentazzjoni minn Dr Luca Gianaroli, Chairman tal-European Society of Human Reproduction and Embryology</p> <ul style="list-style-type: none"> - Numru ta' dokumenti pprovduti minn Dr Paul Soler, Kap tan-Neonatal Intensive Care Unit fl-Isptar Mater Dei dwar <i>selective single blastocyst transfer</i>, kumplikazzjonijiet ta' tqaliet multipli, u statistika tar-riżultati tal-IVF fl-Ingilterra 	(isma')
7	26.04.10	<p>Risposta mill-Uffiċċju tal-Avukat Ġenerali għall-mistoqsijiet imqajma mill-Kumitat; u Laqgħa ma' Mrs Simone Attard, Family Therapy Counsellor</p> <ul style="list-style-type: none"> - Ittra mibgħuta minn Dr Peter Grech, Deputat Avukat Ġenerali b'risposta għall-mistoqsijiet legali magħmula lill-Uffiċċju tal-Avukat Ġenerali mill-Kumitat - Numru ta' dokumenti tal-Liverpool Women's Hospital (Reproductive Medicine Unit) li jiġu mghoddija lil koppji li jersqu sabiex jużaw is-servizzi ta' prokreazzjoni medikament assistita, inkluż consent forms, informazzjoni dwar l-iffriżar ta' gameti u embrijuni 	(isma')
8	18.05.10	<p>Komunikazzjoni mal-Justice Unit fi hdan il-Ministeru tal-Ġustizzja u l-Intern u mal-Uffiċċju tal-Avukat Ġenerali; Deċiżjoni tal-Kumitat dwar kwestjonijiet pendenti; u Diskussjoni dwar liġijiet fil-qasam tar-riproduzzjoni medikament assistita ta' diversi pajjiżi barranin</p> <ul style="list-style-type: none"> - Korrispondenza mingħand l-Uffiċċju tal-Avukat Ġenerali datata 6 ta' April 2010 - Korrispondenza mal-Justice Unit datata 6 ta' Mejju 2010 - Korrispondenza mal-Uffiċċju tal-Avukat Ġenerali datata 11 ta' Mejju 2010 - 'Restoring faith in politics – General Election 2010' mahruġ minn The Catholic Union of Great Britain - Sentenza tal-Qorti Kostituzzjonali Taljana 151/2009 tal-1 ta' April 2009 - Sentenza tal-Qorti Ewropea tad-Drittijiet tal-Bniedem tal-1 ta' April 2010 - Liġi Taljana – Legge 40 – Norme in materia di procreazione medicalmente assistita tad-19 ta' Frar tal-2004 (li saret referenza għaliha wkoll f'laqgħat preċedenti) 	(isma')

		<ul style="list-style-type: none"> - Ligi ta' Victoria fl-Awstralja – Act No 63/1995 – Infertility Treatment Act 1995 - Ligi ta' New Zealand – Public Act 2004 No 92 – Human Assisted Reproductive Technology Act 2004 - Ligi tar-Renju Unit - Human Fertilisation and Embryology Act 1990 - Sentenza tal-Qorti Kostituzzjonali ta' Malta dwar l-adozzjoni 	
9	08.06.10	<p>Deċiżjoni tal-Kumitat dwar kwestjonijiet pendenti (kontinwazzjoni)</p> <ul style="list-style-type: none"> - Djalogu bl-isem ta' 'When does life begin?' bejn il-Kardinal Carlo Maria Martini u l-Ignazio Marino, espert fil-Bijoetika li deher fuq is-sit www.chiesa.espressonline.it fis-26 ta' April 2006 - Studju bl-isem ta' 'Guidelines for the number of embryos to transfer following in vitro fertilisation' li deher fl-International Journal of Gynaecology and Obstetrics fil-Ħarġa 182 ta' Settembru 2006. - Artikli 113 – 130A tal-Kodiċi Ċivili ta' Malta li jittrattaw l-adozzjoni 	(isma')
10	26.06.10	<p>Deċiżjoni tal-Kumitat dwar kwestjonijiet pendenti (kontinwazzjoni)</p> <ul style="list-style-type: none"> - Ittra mibgħuta minn Dr Silvio Camilleri, Avukat Ġenerali b'risposta għall-mistoqsijiet legali magħmula lill-Uffiċċju tal-Avukat Ġenerali mill-Kumitat 	(isma')
11	05.07.10	<p>Deċiżjoni tal-Kumitat dwar kwestjonijiet pendenti (kontinwazzjoni)</p>	(isma')

Anness 3: Sottomissjonijiet bil-miktub lill-Kumitat¹³

1. [Dr Mario Saliba, MD – Specialist in Family Medicine](#)
2. [Mrs Simone Attard – Family Therapy Counsellor](#)
3. [Dr Michael Ascjak, MD](#)
4. [Ms Sonia Camilleri – Kummissarju għat-Tfal fl-2005 meta sar ir-raport tal-Kumitat dwar l-Affarijiet Soċjali](#)
5. [WAW – Waiting and Wanting Infertility Support Group](#)
6. [Dr Stephen Mamo, LLD](#)
7. [Kunsill Malti Persuni b’Dizabilità/Għaqda Ġenituri ta’ Persuni b’Dizabilità](#)
8. [Fr Edgar Busuttil, SJ](#)
9. [Prof. Pierre Mallia, MD – Family Medicine and Patients’ Rights u Artiklu minn Prof. Mallia](#)
10. [Kummissjoni Nazzjonali Persuni b’Dizabilità](#)
11. [Kumitat Konsultattiv tal-Bijoetika](#)
12. [Dr Ruth Farrugia, LLD](#)
13. [Dr Ray Bususttil, MD – Direttur Ġenerali Regolazzjoni għas-Saħħa Pubblika](#)
14. [Mrs Simone Attard – Family Therapy Counsellor](#)
15. [Ms Helen D’Amato – Kummissarju għat-Tfal](#)

¹³ Kopja ta’ dawn id-dokumenti tinsab fuq CD imqassam ma’ dan ir-rapport billi tikklikja fuq id-dokument relavanti.