

IVF Programs and Embryo Storage: New Technologies, Old Public Health Issues

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Background

- In 2004, 127,977 ART cycles resulted in the birth of 49,458 infants (ART summary report CDC.gov)
- Not all embryos are not transferred in each IVF cycle. Embryo freezing and storage is a component of ART treatment
- The majority of frozen embryos are reserved for ongoing fertility purposes
- Loss of contact with families related to the future disposition of frozen embryos poses enormous clinical practice problems for IVF programs.

Study Objectives

- **To learn what policies and practices IVF programs have regarding embryo storage**
- **To assist in the development of model clinical guidelines for embryo storage informed consent/agreement**

Methods

- A survey instrument was developed with input from content experts in medicine, law, biostatistics and public health
- The survey was distributed by mail to IVF program directors
- A listing of program directors and addresses obtained from the CDC web site, 2003 ART summary report
- Along with the survey instrument, a letter was included requesting that a copy of the program's informed consent be returned with the completed survey

Results

- **399 surveys were distributed**
- **Responses were received from 102 programs; 99 surveys with complete information were included in this phase of the data analysis**
- **16 were returned with no forwarding address**
- **Among the programs participating, approximately one fourth shared a copy of their informed consent. Written educational materials were also received from several programs**

Has embryo storage posed problems for your program?

- Almost half (48) of the programs responded that embryo storage had presented problems for their clinical program
- The most frequently reported problems: abandoned embryos, inability/difficulty in contacting parents, refusal to pay storage fees

Characteristics of the IVF Programs Participating in the Study

- 22 of the programs are university-based medical center practices
- 20 are hospital-based
- 55 are private practices
- 2 did not specify

Characteristics of the IVF Programs Participating in the Study

■ Number of fresh IVF cycles in the past year

<100	18
100 - 500	61
501 -1000	10
>1,000	4

■ Number of frozen embryo transfers in the past year

>50	45
50 - 100	24
101 - 200	17
>200	5

Characteristics of the IVF Programs Participating in the Study

- All (99) of the programs offer cryopreservation
- 58 of the programs own their cryopreservation lab
- 31 are owned by the hospital/medical center or university

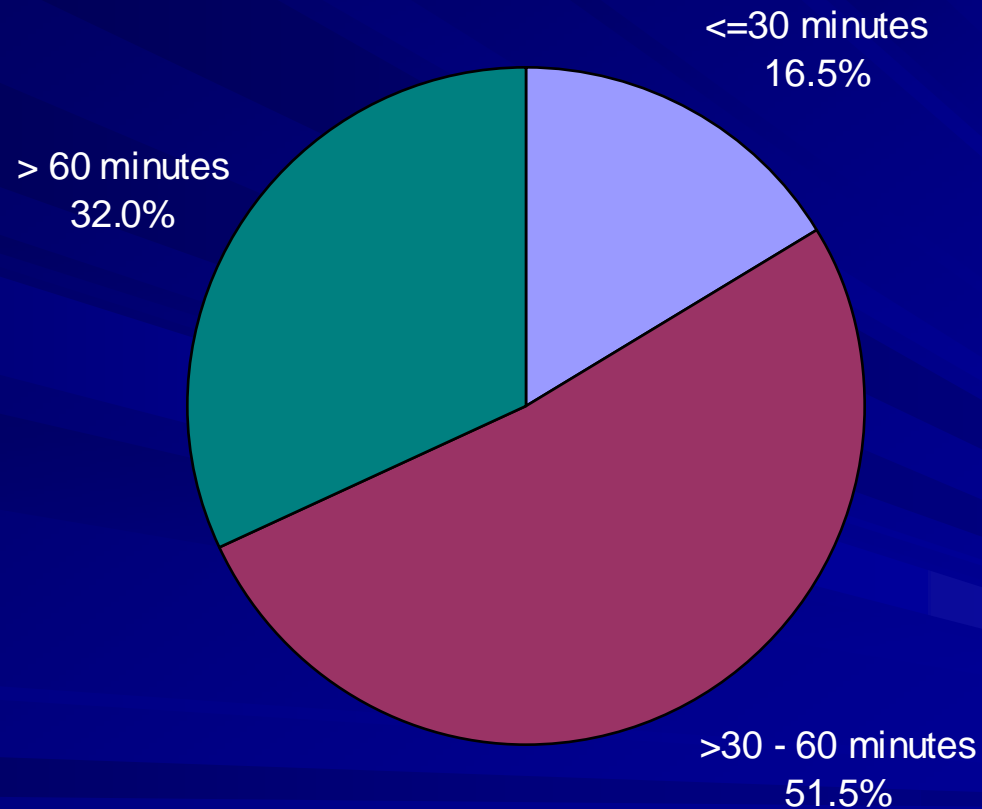
Characteristics of the IVF Programs Participating in the Study

- 95 of the programs require education and counseling for all couples considering ART
- 80 of the programs reported that both parents are required to participate in the counseling
- 95 of the programs provide written materials for the parents review before they make a final decision

Counseling Session related to ART

- The length of the counseling sessions ranged from 10 minutes to 4 hours
- The most frequently reported time was 60 minutes (33)

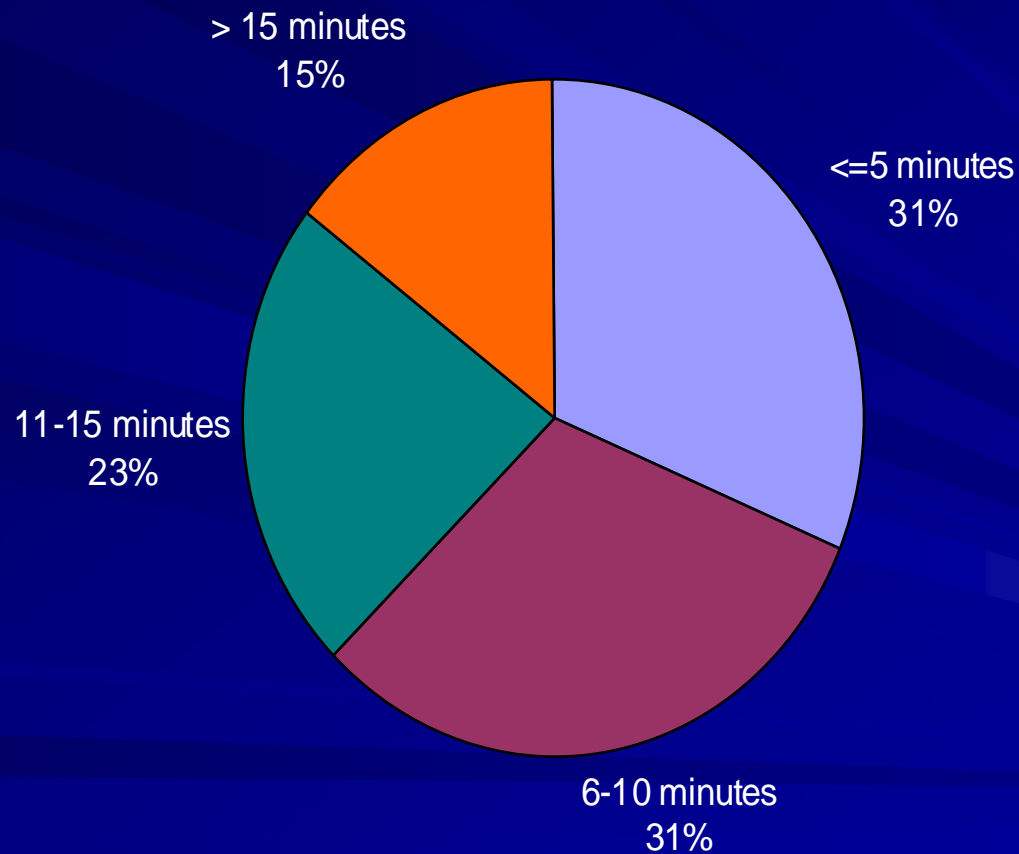
Counseling Session related to ART



Counseling session time devoted to embryo storage

- The time devoted to embryo storage ranged from 0 – 30 minutes
- The most frequently reported time was 5 minutes (27), followed by 10 minutes (22)

Counseling session time devoted to embryo storage



Counseling session – embryo storage

- One third (33) of the programs reported the content of the counseling related embryo storage had changed in the past 2 years in some the following ways:
 - ‘emphasizing the need to stay in touch and not abandon embryos’
 - ‘added questions related to divorce and death’
 - ‘now refuse to store embryos more than 5 years’
 - ‘if they abandon embryos, they lose all rights’

Informed consent related to embryo storage

- 97 of the programs have a separate informed consent/agreement for embryo storage. The agreements specify what will happen in the event of the following:

– Death	93 programs
– Divorce	89 programs
– Separation	76 programs
– Dispute	60 programs
– Disappearance	45 programs

Informed consent – mutual agreement

- 98 of the programs require mutual consent of both parents at the time they enter the agreement
- The program not requiring mutual consent reported that in the event of a dispute, ‘the court decides custody’
- 3 programs made special notes, including:
 - 2 programs refuse treatment if no mutual consent
 - 1 program stated ‘we let the lawyers sort it out’

Informed consent – maximum length of storage time

- 64 programs reported the agreement specifies a maximum storage time
- If the maximum time has expired, the agreement specifies plans for future disposition including:
 - Destruction 50
 - Donation 32
 - Transfer 24
 - Release on request 16
 - Partner posthumously 9

Informed consent – contact information

- 47 programs include detailed contact information on how to reach parents for the next 5 years
- Among the 47, 21 programs specify the methods and number of attempts to locate the parents if the storage time frame has expired

Informed consent – storage fees

- 69 programs include storage fees in the agreement
- Among the programs including storage fees, 44 detail what actions will be taken if the parents do not pay the fees

Informed consent - documentation

- 95 require signatures of both parents
- 54 require notarization
- 23 specify other requirements e.g.,
photo ID, physician witness

Current work

- **Expert leadership and consultation from colleagues in the Law School with the following:**
 - **Comprehensive review of the informed consent documents received from the programs participating in the study**
 - **Detailed review/synthesis of existing case law**
 - **Drafting guidelines for the development of embryo storage agreements**

Future Directions

- **Complete a set of model clinical guidelines to offer IVF programs as they develop or review their informed consent form/agreement**
- **Disseminate the model guidelines by working with reproductive medicine professional organizations**