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Why patients do or don't consent to donate their embryos to stem cell research

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HFEA Research Conference 1st Dec 05

Why patients do or don't consent to donate their embryos to stem cell research

1. Worldwide studies in embryo donation to research.
2. Results of King's study into (PGD) patient attitudes to stem cell research in the Guy's Assisted Conception Unit (Franklin, Throsby, Roberts)
3. Introduction to the work of hESCCO project to gather more data nationally on patient attitudes to stem cell research.

human Embryonic Stem Cell Coordinators hESCCO

MRC has provided funding for two different initiatives:

1. Funds for 7 centres to collaborate with assisted conception units with the aim of deriving human embryonic stem cells.
2. Funds for group representatives to meet twice yearly.

hESCCO

Outcomes from the meetings have been several group initiatives:

- **To produce core patient information and consent forms.**
- The construction of two websites (one for public use and one members-only site).
- Establishing a secure database.
- To work with social scientists from LSE and Newcastle gathering data on public and patient attitudes towards embryo donation.

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1. Worldwide studies into patients attitudes to donating for research:

- > 25 studies in....
US, Australia, UK, Canada, France, Sweden, Finland, Denmark Egg and embryo donation
- Fresh and frozen eggs and embryos
- IVF and PGD treatments

Variable donation rates

Place	Year of study	% Willing to donate
USA	1999	11%
Finland	2001	18%
France	2002	12%
Sweden	2003	92%
Sydney	2003	44%
UK	2004	54%

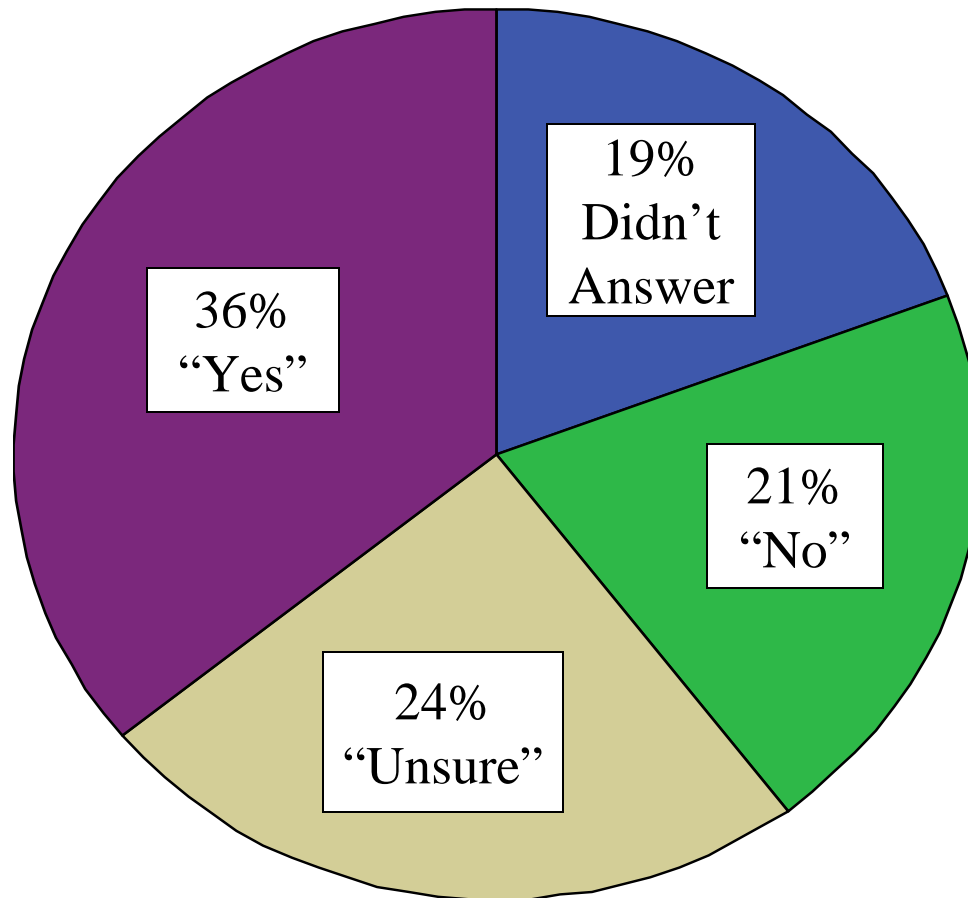
McMahon, et al, 2003; Moutel, et al, 2002; Bjuresten, et al, 2003; Van Voorhuis, et al, 1999; Soderstrom-Antilla, et al, 2001; Choudhary, et al, 2004

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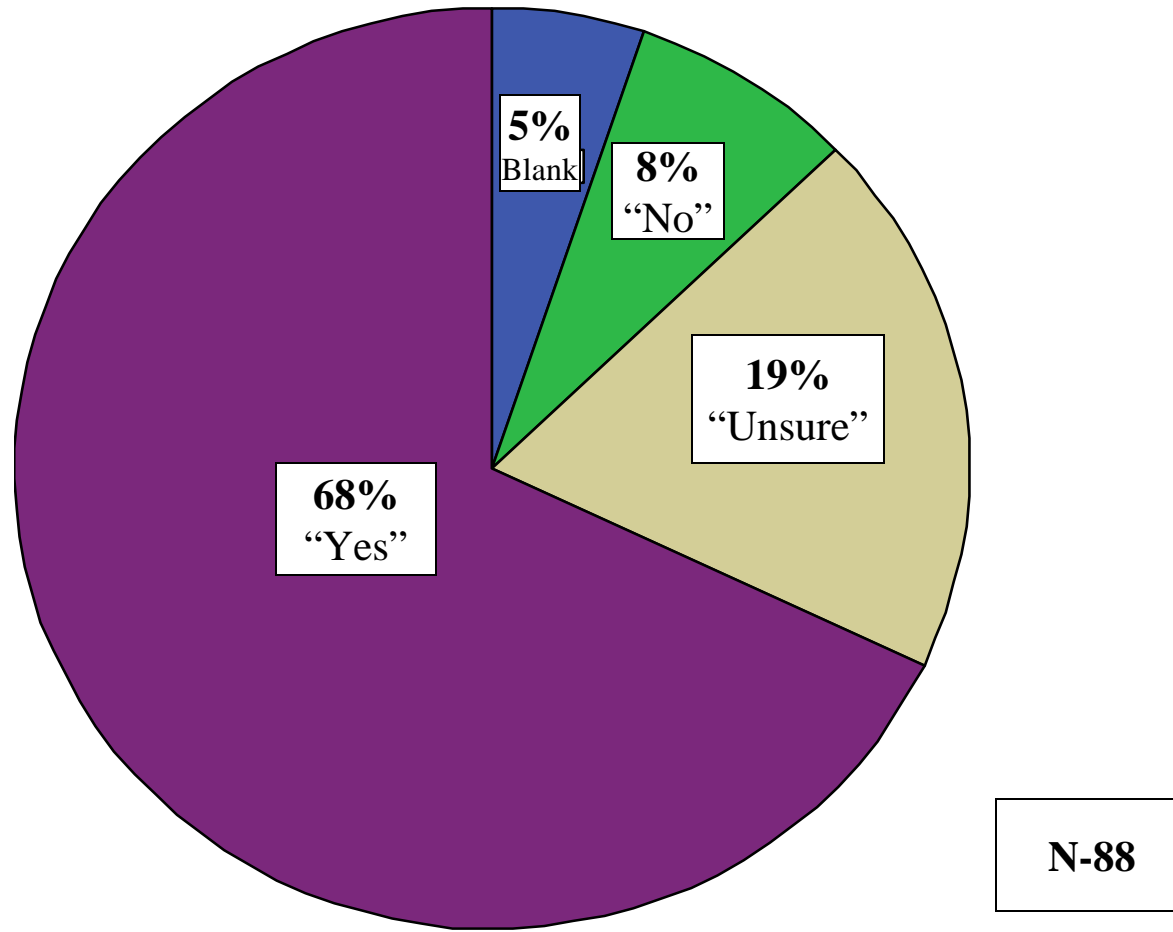
2. Professor Franklin's Study

- Questionnaire-based study at Guy's ACU of factors affecting PGD patients' willingness to donate embryos to stem cell research
- **88 patients** filled in a **9 page** questionnaire with **25 questions**
- Study duration: Jan 2003 - Feb 2005
- 100% response rate

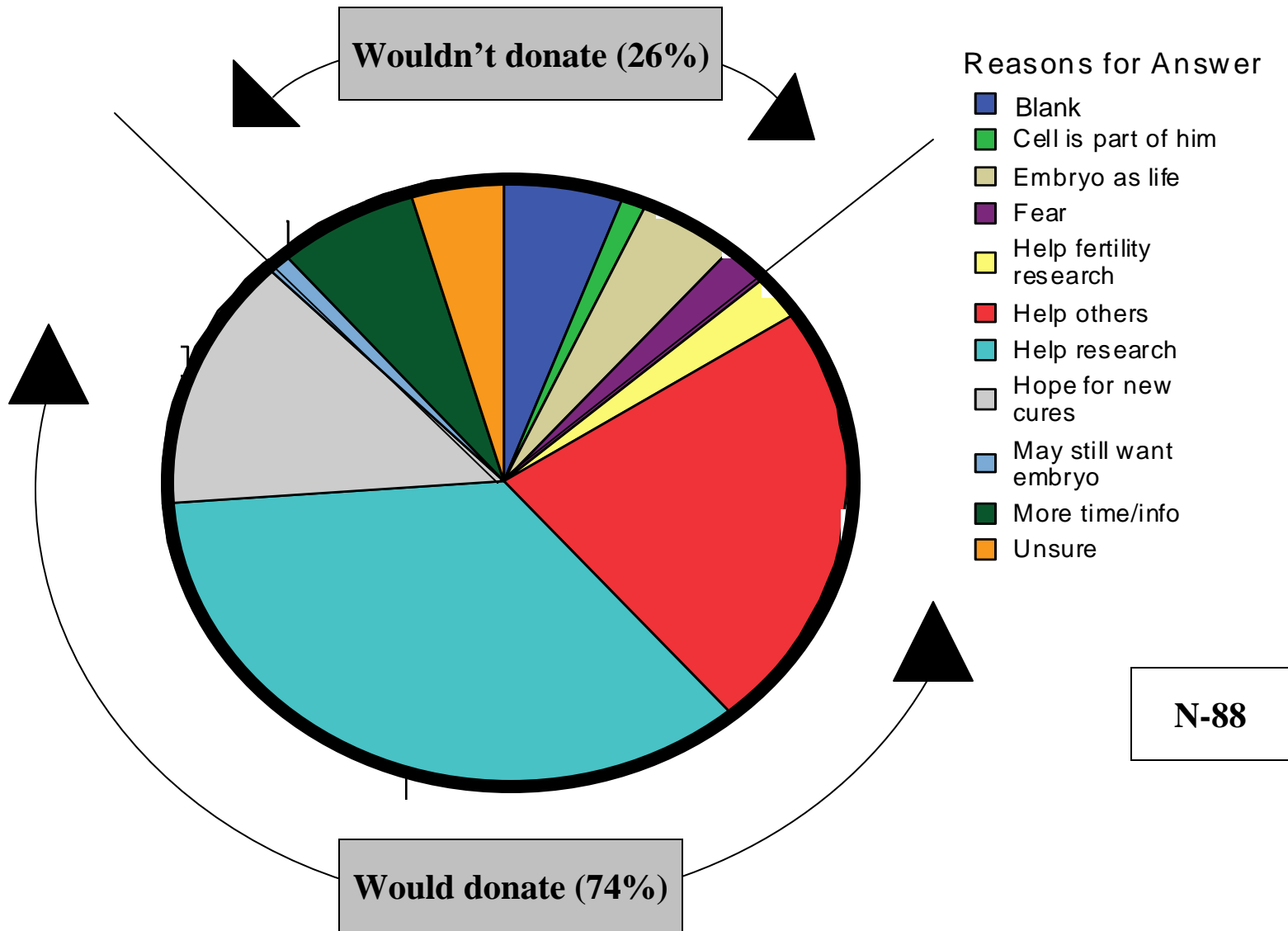
**Patients response to question:
“Have you heard of stem cells?”**



“Would you donate your spare embryos to research on stem cells?”



Reasons for Decision (To Donate or Not)



Relationship between knowledge of what a stem cell is and whether patients are willing to donate:

Know	Donate	Total
Yes	Yes	20
No	Yes	32
Yes	No	4
Unsure	Unsure	12
No	No	2
Yes	Unsure	3
No	Unsure	2

(N = 75)

A mixed picture....

- Largest category is NY (32)
- Second-largest is YY (20)
- Third-largest is UU (12)
- Almost equal numbers of YU and NU (3:2)
- Twice as many YY as NN (4:2)

N = No

Y = Yes

U = Unsure

Some patient opinions.....

Those who **WOULD** like to donate

‘We feel lucky to be offered PGD IVF in the hope of having another one or two children. Any extra medical research to improve the chances of successful treatment for ourselves and others would be welcomed.’

Patient in response to question ‘Would you donate your spare embryos to research on stem cells?’.....

‘If the spare embryos are definitely NOT going to be suitable for our use during the PGD cycle, then I have no objection to them being used for scientific research as opposed to being destroyed.’

Some patient opinions.....

Those who would **NOT** like to donate

‘Having lost two babies I feel that I could not use the beginnings of another baby for research.’

‘I do not feel I know enough about embryo donation.’

Some patient opinions....

Those who were **UNSURE** of whether to donate

‘So much depends on what they would be used for and how long they would be stored. I am not always confident that research is being done for the ‘right’ reasons rather than because it is simply advancing medical science.’

‘If people hadn't already done this, we may not be able to benefit from treatment but it is the start of a living thing...and that makes it a difficult decision’

3. hESCCO

Gathering national data on patient attitudes - pilot study

Questionnaire devised amongst group to collect (anonymous) data to try to find out:

- More about the consenting process
- Looking at feedback issues
- What information is supplied to patients
- Different methods of supplying information

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SECRET

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Q2. Did the patients ask any particular questions about donation of embryos to stem cell research (for example technical details, ethical concerns, anonymity)?

- Using eggs for nuclear transfer (3) (ethical concerns about) Cloning research (3)
- That reproductive cloning was good as there was no rejection
- 'Quite happy as long as not cloning babies'
- Sperm donation and consent
- HFEA licensing
- How many could they donate?
- (Reversible) Anonymity (3)?
- 1 question about technical details, ethical concerns and anonymity
- Heard something on TV. Asked about embryo selection for saviour siblings.
- Would it grow into a tissue in a dish?
- Long term goals of research (7). Would they help to treat people?
- How long would a stem cell last in the freezer? Or in the MRC bank?
- Whether PGD embryos/stem cells useful if affected.
- Would PGD condition be one of the eventual benefits of research on (stem cell) lines?
- Would research be into a specific condition?
- Research into diabetes
- Specific questions about Parkinson's disease
- Feedback - whether they would be contacted?
- About passaging cells in a dish and PCR
- Other in-house research projects (if stem cell lines frozen)

(Approx 77 patients asked - approx 30 had questions and 47 asked nothing) (answers up to Nov 05)

Q3. Did patients express any particular motivations for donating embryos to stem cell research? (For example wanting to give back, wanting not to waste embryos, etc.)

Replies could be mainly categorised into 4 subtypes:

- **Wanting to help** - (Research Project, themselves, others, society)
Approximately **28** responses of this nature
- **Not wanting to waste materials** - (no good/use to them)
Approximately **14** responses of this nature
- **Altruism** - (wanting to give something back)
Approximately **2** responses of this nature
- **Open to the idea of research** (as being necessary/important)
Approximately **9** responses of this nature

Approx 77 people asked. 25 people did not answer the question. Some of the answers were in multiple categories (answers up to Nov 05)

Q4 *Did the patients express any hesitations about donation of embryos for stem cell research? (e.g. religious objections, not enough information, etc.)*

- Previously they had declined as not enough information was available. This was before there was a research sister in post.
- Asked if they would be able to change their mind after signing consent forms.
- Did not give indication either way, (although took consent forms).
- Roman Catholics, but wanted to go ahead.
- **Never truly anonymous.**
- Said the implications would take time to consider.
- **Concerns about reproductive cloning**
- Wanted to make sure that embryos used for research project definitely couldn't be used for their own treatment
- **Whether research done outside of the UK would be sufficiently regulated (2)**
- Don't want embryos to be used for 'bad science' - wanted them used for good ends.
- Were worried how long the embryos would be grown for.

(Approx 77 patients asked - 12 expressed hesitations) (answers up to Nov 05)

Q5. Do you feel you received adequate information about donating stem cell research?

Yes: 43

No: 0

Q6a. Would you have liked to have feedback about whether stem cell lines are created from your embryos?

Yes: 28

No: 30

Q6b. Would you have liked to be able to choose to receive feedback about genetic information about individual stem cell lines?

Yes: 30

No: 25

(Approx 60 patients asked) (answers up to Nov 05)

Q7a. *If information were to be made available about stem cell research in the UK (including any medical findings from stem cell lines) would you like to receive an annual newsletter?*

Yes: 21
No: 35
Don't know: 1

Q7b. *If information were to be made available about stem cell research in the UK (including medical findings from stem cell lines) would you be likely to visit a national website?*

Yes: 33
No: 21
Maybe: 3

(Approx 60 patients asked) (answers up to Nov 05)

hESCCO - Future initiatives

hESCCO pilot study:

- Represents the first coordinated multi-centre national initiative on data collection of patient attitudes of donating embryos for stem cell research.
- Much scope for this to be expanded and studied in greater depth - unique and valuable data to feed back to public

Is the consenting process a factor in itself?

- Much multi-disciplinary work to formulate uniform criteria which patients must be informed of and consent to.
- Work on a national form - currently being piloted.

Acknowledgments...

- **Professor Sarah Franklin, Karen Throsby, Celia Roberts and their team.**
- **LSE and BIOS centre.**
- **hESCCO colleagues.**
- **Funding councils, HFEA, UK Stem Cell Bank.**
- **Team at the Guy's Assisted Conception Unit.**