

PGD: Genetic Testing of Embryos in the United States

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Preimplantation Genetic Diagnosis



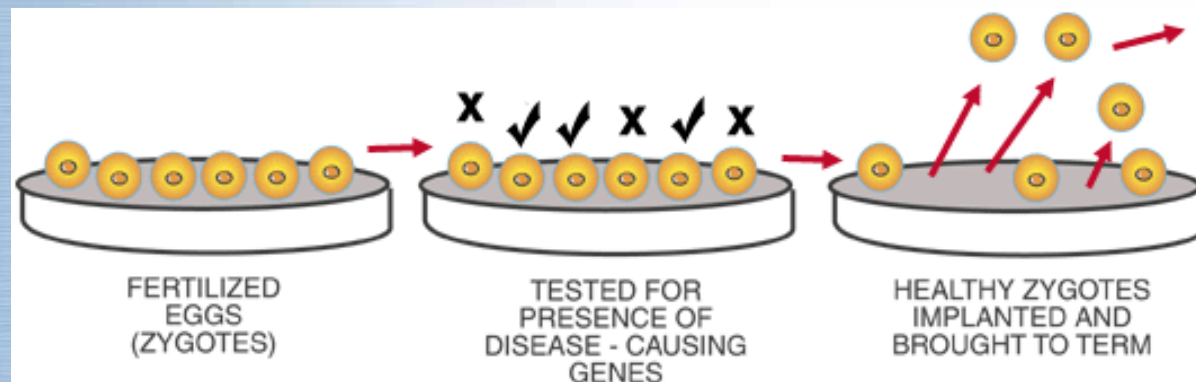
Genetic testing of embryos before implantation:

In vitro fertilization

Embryo biopsy

DNA analysis

Embryo selected for transfer



PGD



Indications (to date)

- Avoid known risk for single gene disorders or chromosomal abnormalities
- Aneuploidy screening in those undergoing IVF (may be called PGS or Preimplantation Genetic Screening)
- HLA matching
 - for sibling, and avoiding disease (Fanconi Anemia)
 - for sibling, but not a genetic disease (leukemia)
- Sex Selection
 - Where X-linked diseases
 - For “family balancing”

The search for data on PGD in the U.S.

PGD data are collected by ESHRE –
but few U.S. centers participate.

IVF data are collected by CDC –
but PGD data are not required.

In 2007 SART, the IVF clinics' organization,
began collecting very limited PGD data.

What we wanted to know about PGD:

- How often
- By whom
- Accuracy
- For what purposes/indications
- With what outcomes

Why we wanted to know it:

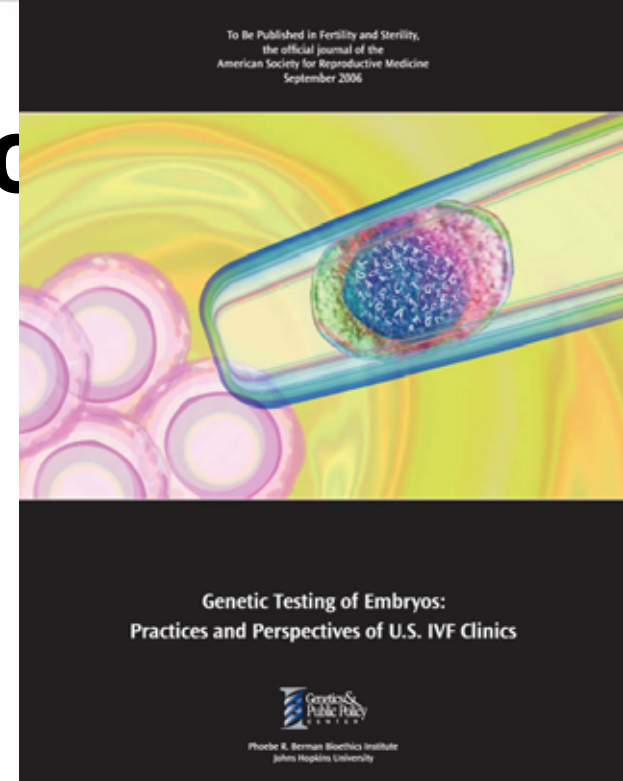
- Concern about US regulation “lite” of both reproductive medicine and genetic testing.
- Questions about success rates and health outcomes of (how many?) babies.
- Consider how data and public opinion interact.
- Data can drive appropriate oversight.

Survey of IVF Clinics

Baruch, S., D. Kaufman, and K. Hudson. 2008. Genetic Testing of Embryos: Practices and Perspectives of U.S. IVF Clinics. *Fertility and Sterility* 89: 1053-1058.

Baruch, S., D.J. Kaufman, and K.L. Hudson. 2008. Preimplantation genetic screening: a survey of in vitro fertilization clinics. *Genetics in Medicine* 10: 685-690.

- 415 ART clinics contacted April/May 06 (SART/CDC)
- Directors at clinics offering IVF
- 186 respondents
- 45% response rate



Results

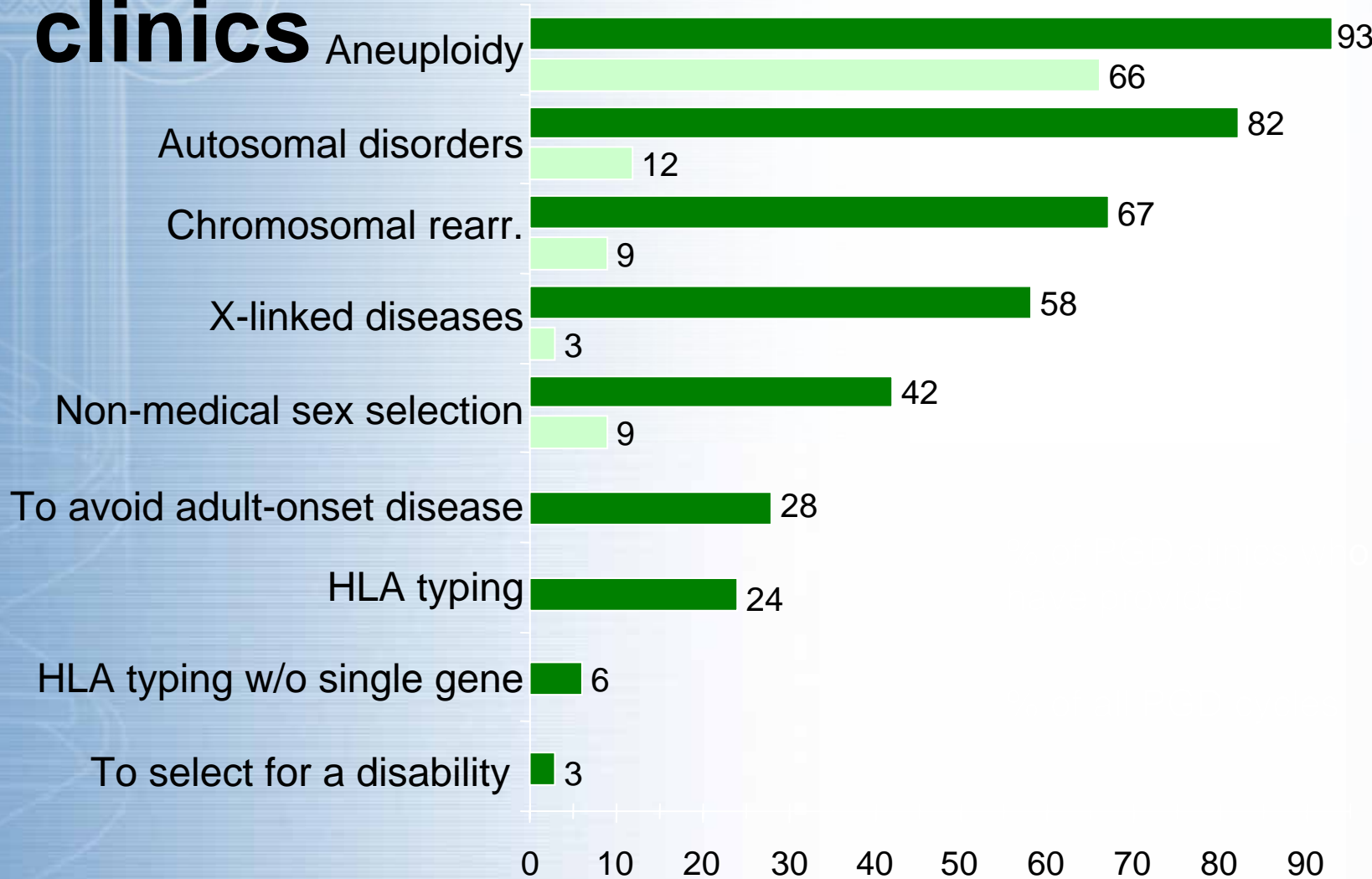
- Nearly three-quarters (74%) of IVF clinics provide PGD.
- Approximately 3,000 PGD cycles in 2005.
- We estimate 4-6% of IVF cycles include PGD.

IVF Clinics Offering PGD?

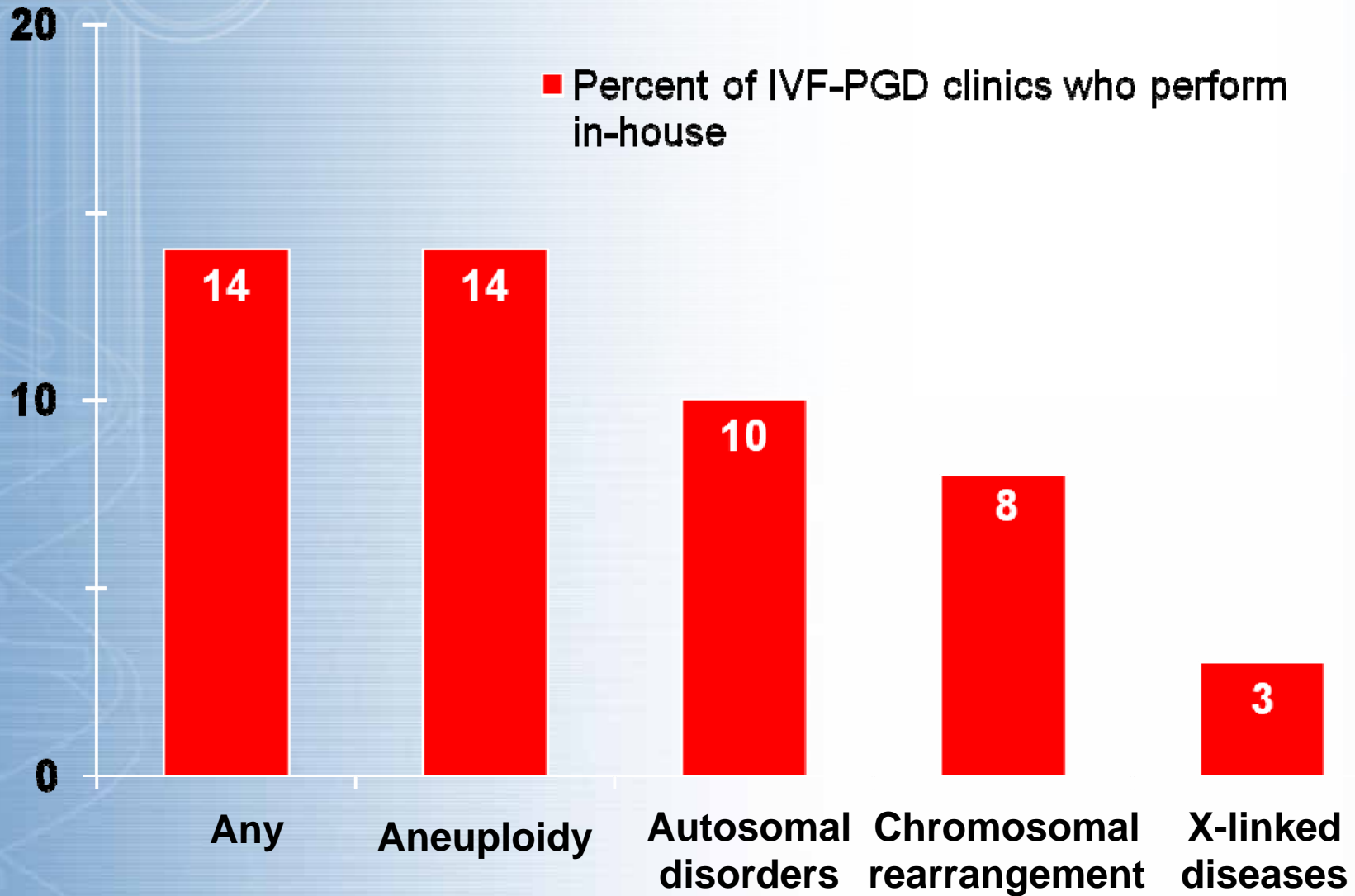


- Offer and provide PGD
- Offer it, but no patient has requested
- Would like to offer PGD, but resources unavailable
- Do not offer for other reasons

Types of PGD provided by clinics



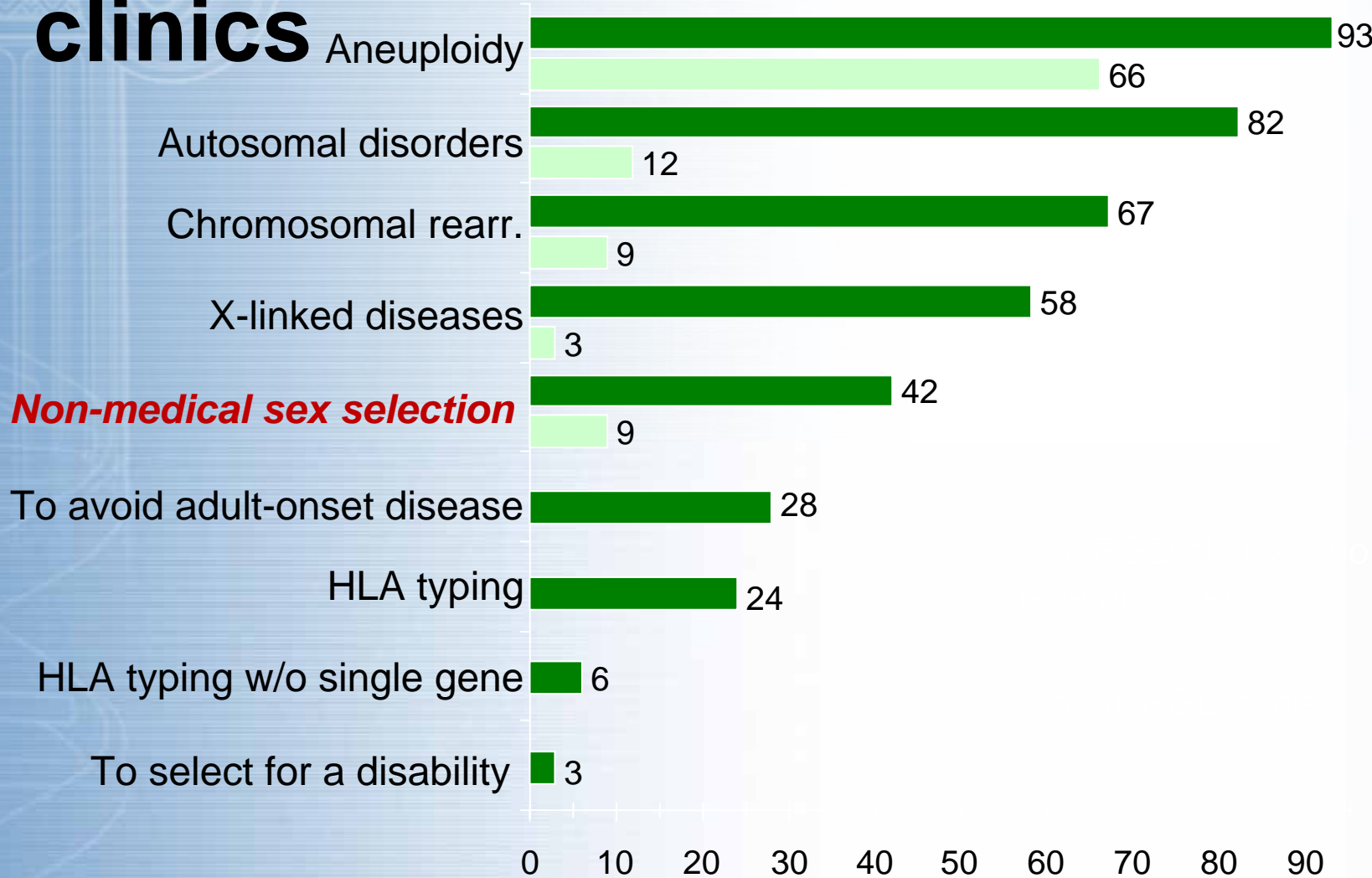
PGD performed in-house



Safety and Accuracy

- 21% of clinic directors are aware of inconsistencies between PGD and later genetic testing.

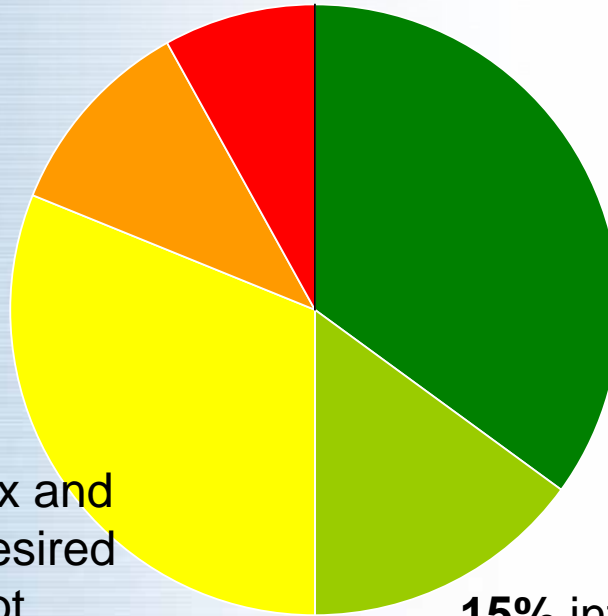
Types of PGD provided by clinics



Clinic policies on sex of embryos

10% never reveal sex of the embryos in absence of an X-linked disorder.

8% transfer the best embryo without regard to sex.

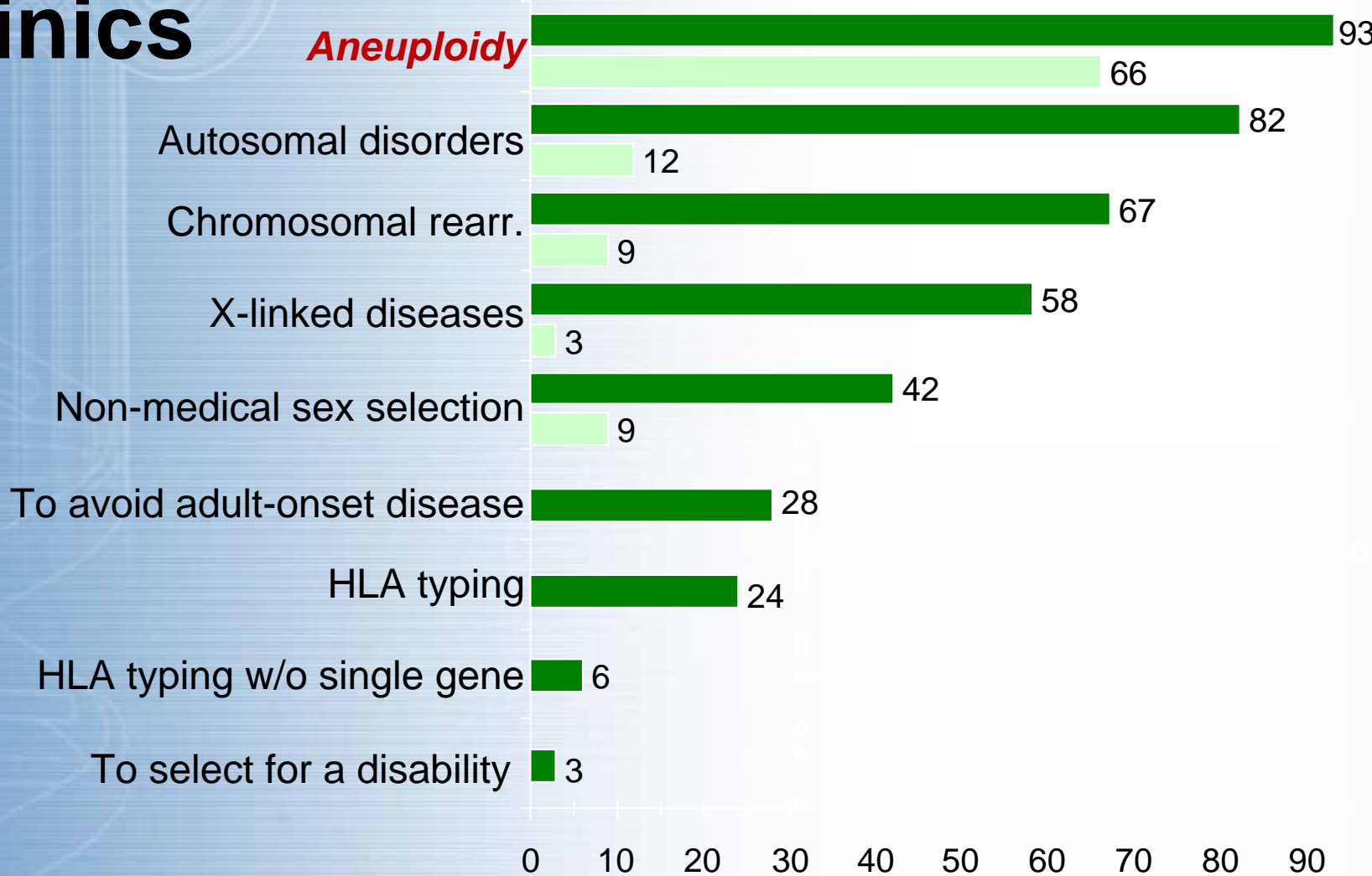


35% inform, comply with parental preferences.

30% will reveal the sex and transfer embryos of desired sex if asked, but do not volunteer the information.

15% inform, comply with parental preferences only for second or subsequent children.

Types of PGD provided by clinics



Practice of PGS in the U.S.

- 93% of IVF clinics offering PGD, and 68% of *all* IVF clinics offer PGS.
- Opinions of the effectiveness of PGS vary widely, even among those who offer it.
 - i.e. 79% of those offering for AMA felt it was valid
- 85% of clinic directors of clinics providing PGS believe more data are needed to determine whether and to whom it should be offered.

In their own words

“Obvious benefits of improving delivery rates by reducing miscarriage rates.”

“Literature evaluations say to do it.”

“There is no data that shows PGD for aneuploidy is helpful.”

“PGD is a waste of money and resources.”



PUBLIC OPINION ABOUT PGD

GPPC Public Opinion 2004

Do you think there should be limits set for acceptable and unacceptable uses of reproductive genetic testing?

Yes

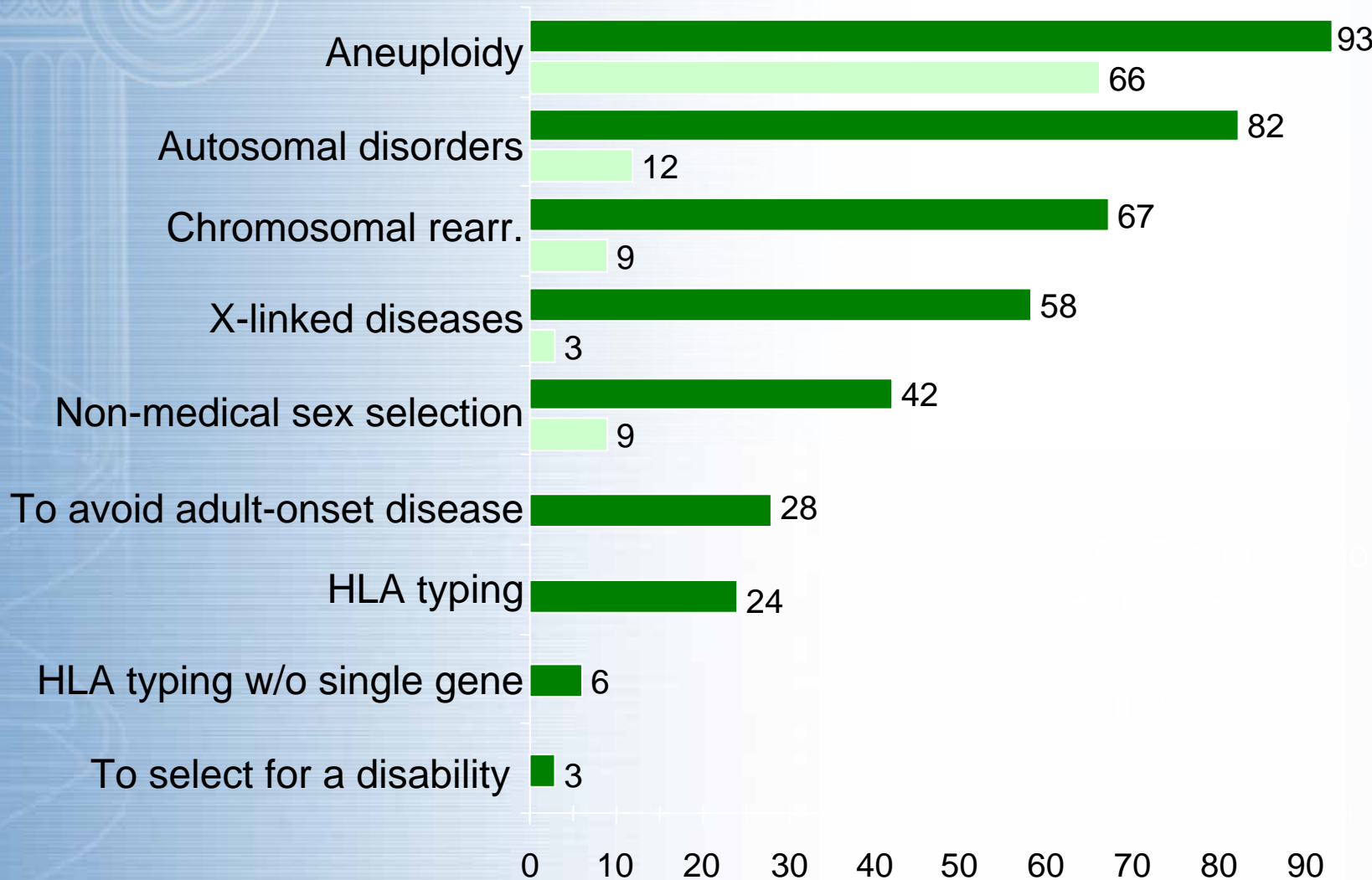
88%

No

12%

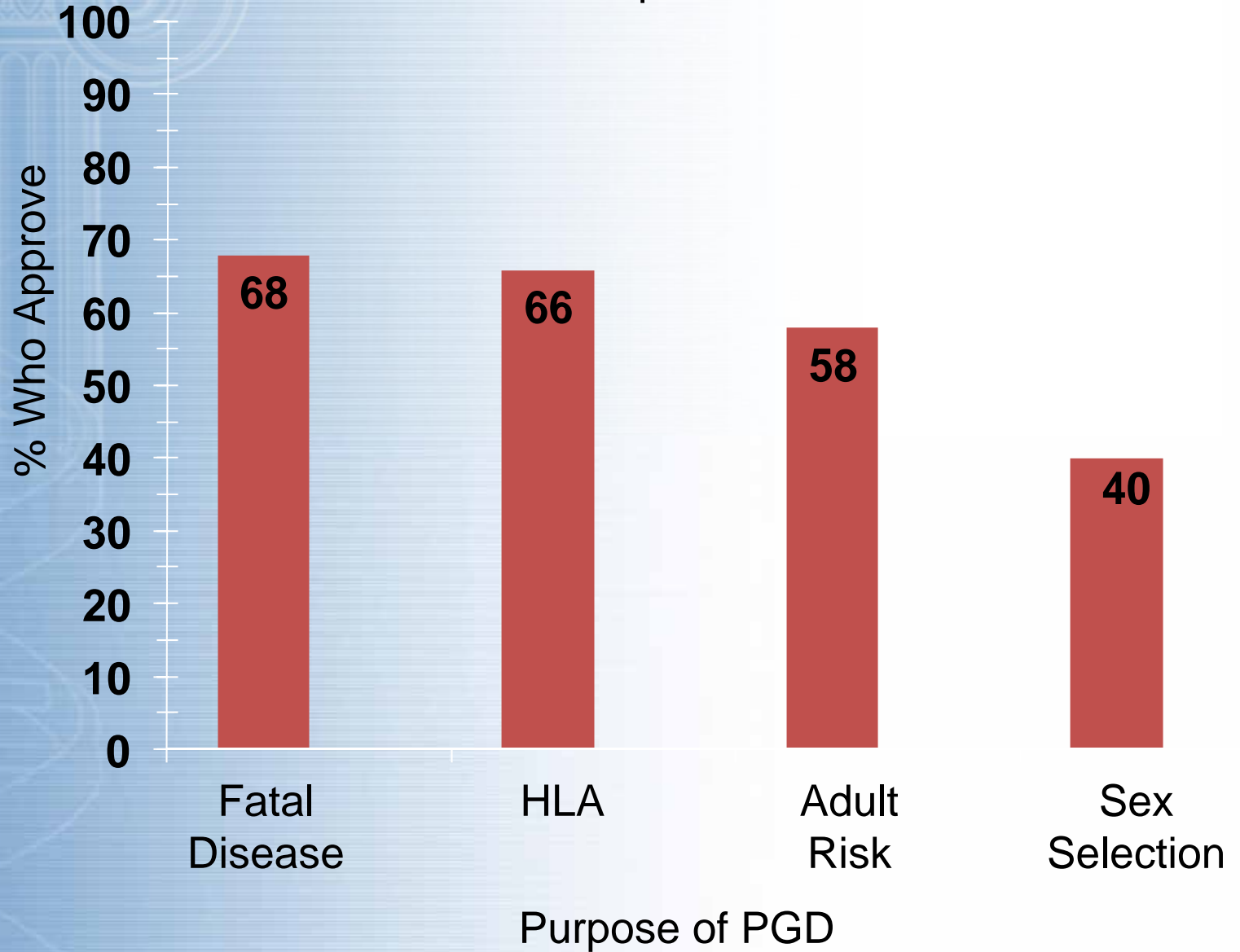
Public

Types of PGD provided by clinics



For What Purpose?

GPPC Public Opinion 2004

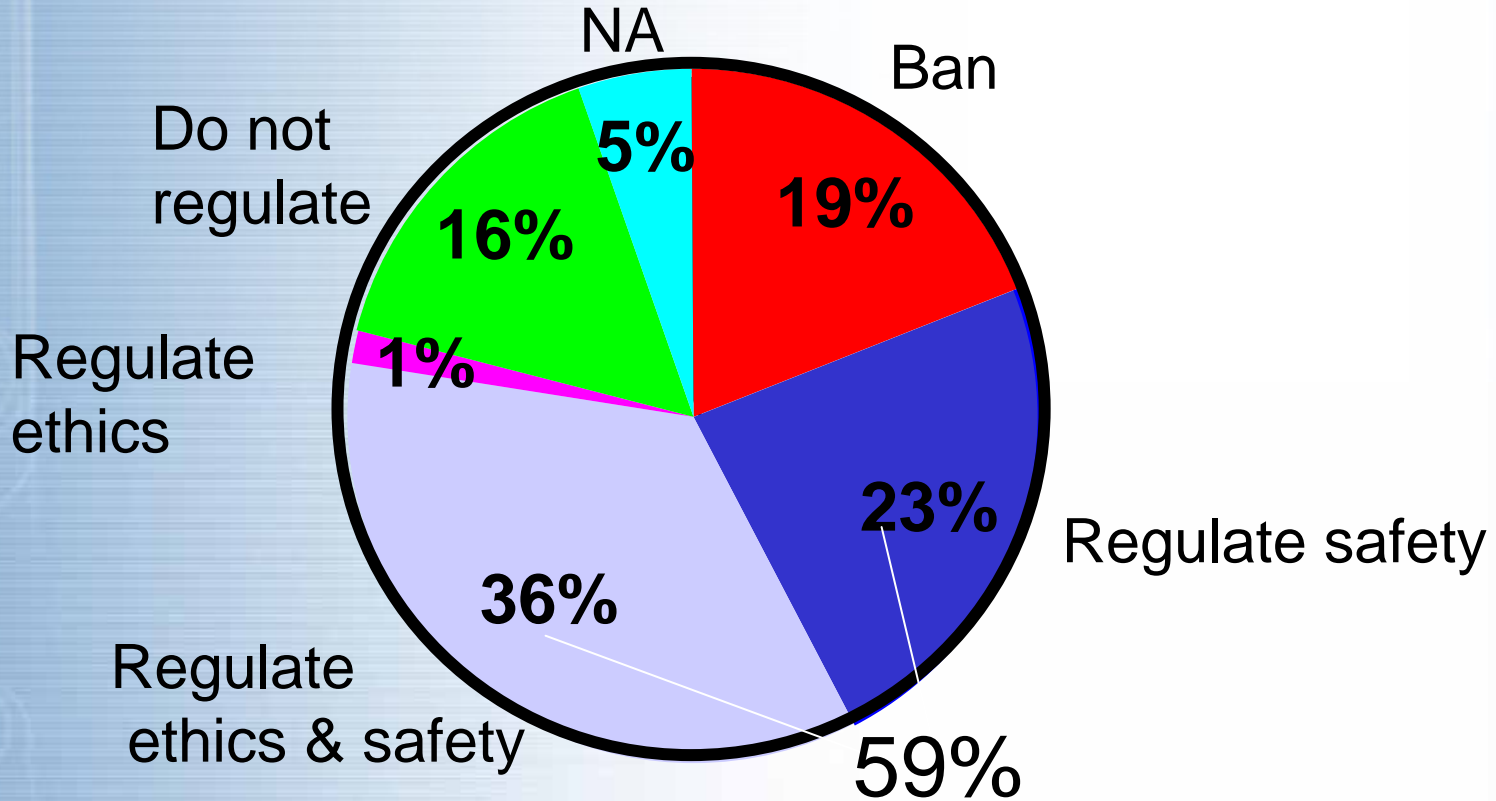


Regulating PGD: Distribution of opinions among Americans

-  Ban
-  Regulate safety
-  Regulate ethics & safety
-  Regulate ethics
-  Do not regulate
-  No questions answered

Regulating PGD:

Distribution of opinions among Americans



Is There a Role for Additional Oversight?

Federal rule

- Ban or limit

- Congress or Agency

State Laws and Regulation

Professional Oversight

Options for Oversight:

Federal Government:

- CLIA
- FDA

Professional guidelines:

- ESHRE, PGDIS, ASRM
- RLAP/CAP certification

Who do you think should set limits?

Leave the decision to individual patients and their doctors.

% of Public
48%

Professional medical societies develop guidelines for acceptable uses.

29%

Federal or state government makes regulations that determine acceptable uses.

16%

Patient groups develop guidelines for acceptable uses.

7%

Clinic Directors' Views on Oversight

95% of directors agree that professional societies are best suited to create standards and guidelines relating to PGD.

85% agree that there *should* be more professional guidelines relating to PGD.

21% agree that there should be more government oversight related to PGD.

The Continuing Quest: A U.S. PGD Registry

“The registry should identify and take action on “outlier” centers just as the CDC registry does.”

“Successful collection and publication of center-specific ART results validate professional self-regulation in the United States as effective and responsive.”

“We submit that self-regulation is the most appropriate policy in the United States.”

Simpson JL, Rebar R, Carson SA. Professional self-regulation for preimplantation genetic diagnosis: experience of the American Society for Reproductive Medicine and other professional societies. Fertil Steril 2006;85(6):1653.

Lingering Questions:

- PGD for aneuploidy (PGS) and the “take-home baby” rate?
 - Mastenbroek et al, NEJM 2007
 - ASRM Practice Committee Opinion
 - Question about techniques, embryo loss, patient groups.
- PGD for sex selection in the United States
- How do the babies do?

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www.DNAPolicy.org

Many thanks to:



and the Pew Charitable Trusts

