

**Who Should Decide How Many Embryos to Transfer?
The Role of Patients, Reproductive Collaborators, Clinicians, Government &
Others**

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June 22, 2007

Outline

I. Internationally, there is a range of approaches to the question of who decides how many embryos to transfer (see IFFS Surveillance 2007, ch. 5, *Fertility & Sterility* 2007;87(4, Supp. 1)). Approaches include:

Federal or state legislation setting a limit (e.g., Germany) or limits by woman's age (e.g., Sweden), or limits by age and number of cycles (e.g., Belgium)

An oversight board setting a limit (e.g., HFEA limits in the U.K.)

Transfer limits in public treatment with voluntary compliance among private patients (New Zealand)

Voluntary guidelines from a professional society (e.g., ASRM Practice Guidelines in the U.S.), leaving the question up to patients in collaboration with their clinicians

No limits, though there may be a customary maximum (e.g., Columbia, Jordan)

Note: Much less is said about how to handle excess follicles produced by superovulation without IVF. Also, little is said about gestational surrogacy.

II. The literature has suggested further options:

Impose a transfer limit by U.S. federal legislation or state statute

FDA imposition of a transfer limit

U.S. courts impose a limit through malpractice litigation

Health plans/insurers impose a limit by limiting what ART they will fund or possibly what sequelae in offspring and gestator/egg source they will cover

III. A number of interests are at stake (of child-to-be, rearing parents, reproductive collaborators, clinicians, funders). Most important are the health interests of children-to-be, patients, and gestational collaborators.

IV. Progress requires analysis of those health interests & the tension among them:
the interest of the child-to-be in minimizing medical harm (e.g., from prematurity)
the interest of the rearing woman or couple in maximizing offspring health
the interest of the gestating woman in minimizing medical risk (e.g., preeclampsia, preterm labor)
the interest of the ovulating/gestating/rearing woman (or women) and in minimizing the number of cycles of IVF and/or superovulation

As in the case of other (non-ART) tensions between maternal and fetal interests, ethics and U.S. law generally allow the woman to balance her health interests with those of the child-to-be. The basis for this is:

- ◆ respect for persons as autonomous agents
- ◆ confidence that women seeking children will generally try to maximize their welfare
- ◆ recognition that even in the case of children already born, parents are not expected to completely ignore or sacrifice their own interests to serve those of the child
- ◆ reliance on clinicians to inform & counsel patients re risks/benefits
- ◆ nondiscrimination

V. Applications:

A rigid single-embryo-transfer (SET) policy fails to consider factors (e.g., age, failed cycles, embryo quality) that influence risk of multiples and likelihood of success. It also attempts to reduce risk of multiples to near zero, without considering concomitant burden to woman (e.g., repeat cycles, cost).

When the patient is genetic, gestational, and rearing parent, there is a strong case for deference to the *informed* patient's preference. However, clinicians may refuse to impose significant risk of higher-order multiples (triplets or higher) due to obligations to avoid doing harm to child-to-be and woman. The risk that a twin pregnancy may impose on the woman and children-to-be should be evaluated case-by-case, but in most cases, the risks will probably be modest enough to justify continued deference to the woman's choice. Available perinatology/neonatology experience is relevant.

When a surrogate is involved (whether gestational or full), the goal should be a singleton pregnancy. The gestator gains no benefit from multiple pregnancy, only risk (unlike a patient who has failed multiple cycles and sees twins as a net benefit to avoid further cycles). Ethically, payment does not justify heightened risks of multiples such as preeclampsia.

VI. Policy Critique & Recommendations—ASRM Practice Committee, “Guidelines on Number of Embryos Transferred,” *Fertility & Sterility* 2006;86(4):S51-52.

Does not address priority of patient decision-making, clinician limits on patient discretion, and patient/clinician disagreement.

Does not take patient-centered view. Approaches the transfer number question as primarily a matter of medical complications for fetus and mother, mother's age, embryo quality, cryopreservation options, and available techniques. But choice of number to be transferred also involves patient's view of psychological and physical burden of failed cycles, option for future cycles, projected ability to handle multiples (esp. twins).

Does not address the critical question of what constitutes adequate counseling of patients considering transfer number. The policy refers to “informed consent documents,” but these mean little absent a robust effort to achieve informed consent on transfer number. Consider whether information should come not just from infertility specialists, but also from perinatologists and families coping with

multiples. Standardized materials would save programs from reinventing the wheel.

Says clinician/patient agreement should be reached and documented on number of embryos to be transferred, but does not specify when. If at start of treatment, can only state preliminary agreement subject to modification when embryo quality is clear. If on verge of transfer, may not be fully considered. Needs to be addressed at both points.

Recommended guidelines are based only on woman's age, prognosis, and cleavage-stage vs. blastocyst. While these are important factors, they are not the only determinants.

Stated goal of policy is to avoid higher-order multiples (triplets or higher). But some of the hardest decisions are whether to try to avoid twins. Only for patients under 35 with "a more favorable prognosis" is consideration of SET recommended. Policy should address twins issues.

Little guidance offered for cycles after 2nd and patients "with a less favorable prognosis"—"additional embryos may be transferred according to individual circumstances after appropriate consultation." More guidance on this is needed. Nothing on gestational surrogates. Needs to be addressed.

VI. Conclusion

Decisions on transfer number are, like most clinical decisions, a matter of patient values, medical expertise, and clinician responsibility. Considerable work remains to be done to establish the zone of patient decisional discretion, how best to support informed patient choice, and what limits should appropriately be placed on that choice.