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## COMMENTARY

# Is mandating elective single embryo transfer ethically justifiable in young women?

Kelton Tremellen<sup>a,\*</sup>, Dominic Wilkinson<sup>b,c</sup>, Julian Savulescu<sup>b</sup>

<sup>a</sup> Department of Obstetrics Gynaecology and Reproductive Medicine, Flinders University, Sturt Road, Bedford Park, South Australia 5042, Australia; <sup>b</sup> Oxford Uehiro Centre for Practice Ethics, Faculty of Philosophy, University of Oxford, Oxford, UK; <sup>c</sup> Department of Neonatology, John Radcliffe Hospital, Oxford, UK

\* Corresponding author. E-mail address: [kelton.tremellen@flinders.edu.au](mailto:kelton.tremellen@flinders.edu.au) (K. Tremellen).

**Abstract** Compared with natural conception, IVF is an effective form of fertility treatment associated with higher rates of obstetric complications and poorer neonatal outcomes. While some increased risk is intrinsic to the infertile population requiring treatment, the practice of multiple embryo transfer contributes to these complications and outcomes, especially concerning its role in higher order pregnancies. As a result, several jurisdictions (e.g. Sweden, Belgium, Turkey, and Quebec) have legally mandated elective single-embryo transfer (eSET) for young women. We accept that in very high-risk scenarios (e.g. past history of preterm delivery and poor maternal health), double-embryo transfer (DET) should be prohibited due to unacceptably high risks. However, we argue that mandating eSET for all young women can be considered an unacceptable breach of patient autonomy, especially since DET offers certain women financial and social advantages. We also show that mandated eSET is inconsistent with other practices (e.g. ovulation induction and intrauterine insemination–ovulation induction) that can expose women and their offspring to risks associated with multiple pregnancies. While defending the option of DET for certain women, some recommendations are offered regarding IVF practice (e.g. preimplantation genetic screening and better support of IVF and maternity leave) to incentivise patients to choose eSET.

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## Introduction

It is well recognised that multiple births, usually the result of the transfer of more than one embryo, pose substantial risks to both mother and infants, and therefore elective single embryo transfer (eSET) should be promoted whenever appropriate. The human female body, with its single uterine cavity and predominance of mono-ovular cycles, has evolved to carry optimally only one baby at a time. Therefore, it can be argued that double-embryo transfer (DET) and its associated risk of twin pregnancy goes against what nature intended, courting obstetric complications. Overall, pre-term delivery rates in IVF conceptions are threefold higher

than in the general population, with low birth weight also being more common (Sunderam et al., 2014). These differences are even more marked in IVF twin pregnancies, with rates of preterm delivery being five times higher than singleton IVF pregnancies, and six times more likely to result in a low birth weight child (Sunderam et al., 2014).

Due to the increased risks associated with IVF twin pregnancies, a number of European countries have now moved to mandated eSET in good prognosis patients (Bissonnette et al., 2011; Maheshwari et al., 2011). For example, Turkey introduced legislation in 2010 which mandates, regardless of embryo quality, that clinicians may transfer a maximum of one embryo in the first one or two cycles in women under the age of 35 (and two embryos

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for subsequent cycles), and a maximum of two embryos in women 35 years or older (Ercan et al., 2014). Sweden and Belgium have similar restrictions mandating eSET in young individuals, with rates of eSET also exceeding 50% in many European countries (Maheshwari et al., 2011; Kupka et al., 2014). In the UK, the National Institute for Clinical Effectiveness (NICE) issued guidance in 2013 that instructs clinicians to use SET for first cycles in women under 37 years of age and for second cycles if a top quality embryo is available (NICE, 2013), while in Australia and New Zealand, the vast majority (85.2%) of embryo transfer cycles for women under 35 years of age are currently conducted as SET (Macaldowie et al., 2014). In the USA, the American Society for Reproductive Medicine (ASRM) guidelines (ASRM, 2013) state that for women under 35 years of age with a favourable prognosis (first cycle of IVF or prior IVF success, good morphology embryos), SET should be offered, while recommending that no more than two embryos should be transferred at a time. However, in the USA the rate of eSET in women under 35 years of age is only 12.2% (Sunderam et al., 2014), despite guidelines suggesting that these patients should be offered eSET (ASRM, 2013). As a result, 46% of infants born from assisted reproduction techniques in the USA were multiple birth deliveries (43% twins, 3% triplets), compared with only 3.4% in the general population (Sunderam et al., 2014).

With such vastly different IVF practices existing around the world, it is timely to ask the question, 'What is the correct approach?' There are two main arguments proposed in favour of a mandated eSET approach. Firstly, DET and a potential multiple pregnancy increases the obstetric risks for women, as well as risks for the children conceived (McLernon et al., 2010; Pinborg et al., 2003; Sazonova et al., 2013). Therefore many commentators argue from a risk minimisation perspective that DET should be avoided at all costs, with the European Society of Human Reproduction and Embryology (ESHRE) Task Force on Ethics and Law even going as far as stating that multiple pregnancies should be reported as IVF complications, not successes (ESHRE Task Force on Ethics and Law, 2003). Secondly, as health care costs related to management of obstetric complications and prematurity are increased in multiple pregnancies, one can also argue from a health economics perspective that eSET should be mandated (Chambers et al., 2014). However, this paper will critically analyse each of these arguments, drawing on four widely endorsed bioethical principles (beneficence, non-maleficence, justice, and respect for patient autonomy) (Beauchamp and Childress, 2001), all commonly used in clinical decision making (Ebbesen and Pedersen, 2007). We argue that in the countries such as the USA, where the majority of IVF costs are borne by the patient, mandated SET is not ethically justifiable.

### **Beneficence and non-maleficence—Reward is always proportional to risk!**

The principle of beneficence requires that doctors' actions benefit patients. However, whenever doctors attempt to produce a medical benefit for patients through treatment, they also place them at risk of harm, since every medical intervention has the potential for adverse outcome. During

medical training, physicians are taught the importance of first avoiding doing harm to patients, or at least minimising any such harm (non-maleficence). The key to being an effective physician, the 'art' of medical practice, is for the doctor to make a balanced judgement of the risks versus benefits of a particular therapy. They are then able to provide a treatment recommendation in light of individual patients' needs and risk profile.

IVF treatment is relatively unique in medical care in that it potentially leads to benefits and risks to both the prospective mother and a third party—the resulting child. Therefore, there is a potential tension between the wishes or interests of one party (the parents) and that of another (the child). It can be argued that a physician has a duty of care to both their current patients (parents) and the future child as several jurisdictions mandate that the doctor must consider the welfare of the child when making decisions regarding fertility treatment (HFEA, 2015; NHMRC, 2007).

The argument in favour of eSET is based on non-maleficence, since it is clear that IVF pregnancies carry higher risk than naturally conceived pregnancies, with this risk being further compounded in multiple pregnancies compared with singletons (ESHRE, 2000; Kjellberg et al., 2006; Sullivan et al., 2012; Sutcliffe and Ludwig, 2007). Furthermore, some may feel that eSET is equally beneficent, since studies from Europe have reported that cumulative pregnancy rates from consecutive eSET are not inferior to those obtained from DET, yet result in a significantly reduced risk of twins (Grady et al., 2012; Lukassen et al., 2005; McLernon et al., 2010; Pandian et al., 2013; Thurin et al., 2004). Does this justify a mandated policy of eSET in all young women?

Firstly, being born prematurely is not necessarily in itself a poor medical outcome. The majority of children born prematurely (between 32 and 37 weeks) ultimately do very well, leading productive adult lives with no major health impediments (Teune et al., 2011). Although such children have an increased risk of short-term and long-term problems, the absolute magnitude of this risk is low (for example, 0.43% of late preterm infants develop cerebral palsy, 0.81% suffer mental retardation, an increase of approximately 0.3% compared with term infants) (Teune et al., 2011). In order to put these risks into perspective, it should be noted that an average individual's life time risk of death as a result of a car accident in the USA is 0.52% (Bandolier, 2015). In everyday life, as well as health care, it is impossible to remove all risk without compromising quality of life or potential benefits.

It is primarily the children born before 32 weeks, and especially those born before 28 weeks, that run significant risk of handicap, chronic health impairment, or even death (Sagal and Doyle, 2008; Serenius et al., 2013). While statistically such very premature deliveries are more common with IVF twins, numerically they are still relatively rare events. The Centers for Disease Control and Prevention (CDC) data on IVF outcomes in the USA report that only 6.7% of IVF twins deliver very prematurely (<32 weeks gestation) (Sunderam et al., 2014). In another study comparing obstetric outcomes resulting from eSET versus DET, the risk of very premature delivery in the DET group was also 6% (McLernon et al., 2010). Overall, a large Danish study reported no significant increase in the rate of cerebral

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