

Public interest or public meddling? Towards an objective framework for the regulation of assisted reproduction technologies

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BACKGROUND: Assisted reproductive technologies (ART) bear a heavy regulatory burden in some jurisdictions. This burden constrains patient autonomy and the professional autonomy of doctors and scientists. **METHODS:** We question why this should be by analyzing the possible public interests in ART regulation under the headings: health, financial, ethico-legal and socio-political. Throughout, we try to identify whether comparable public interest claims are made for other areas of medicine, but accommodated without the requirement for specialized statutory frameworks such as those exemplified in the UK and Victoria (Australia). **RESULTS:** We identify a small core of public interest concerns that seem to justify some sort of special regulatory structure, but not one as elaborate as those currently in place. We then develop a five-step quality control model, familiar to biomedical practice but novel in the context of legal thinking, to aid development and review of regulatory policy and practice. This model is applied both prospectively to the proposal to record ‘by donation’ on birth certificates, and retrospectively to the regulation of parental choice about the genetic make-up of offspring in UK and Victorian jurisdictions. **CONCLUSIONS:** The model provides a useful and robust framework for pin-pointing problems with regulatory regimes, to stimulate empirical research, and to facilitate both the review and development of regulatory policy.

Keywords: assisted reproduction technology; public interest; regulatory policy; legislation; IVF

Introduction

The range of medical and related research procedures under the general heading of assisted reproductive technology (ART) derives from the successful IVF of a human egg *in vitro* (Edwards *et al.*, 1969; Steptoe and Edwards, 1978; Cohen *et al.*, 2005; Horsey, 2005). Reproductive ART now includes not only IVF and closely related technologies (ICSI, gamete intra-Fallopian transfer, embryo and gamete donation, artificial insemination, cryopreservation and surrogacy), but also preimplantation genetic diagnosis (PGD), preimplantation genetic haplotyping and preimplantation genetic screening. Research ART encompasses the derivation and *in vitro* differentiation of embryonic stem (ES) cells, somatic cell nuclear transfer, cytoplasmic and mitochondrial transfer, the creation of artificial gametes, the molecular manipulation of cell fate, the use of parthenogenetically activated oocytes and the creation of various animal:human hybrids and chimaeras (Johnson, 2000, 2001a; Toyooka *et al.*, 2003; Jansen and Burton, 2004; Rogers *et al.*, 2004; Takeda *et al.*, 2005; Zhong *et al.*, 2005; HFEA, 2007a,b). Thus ART covers a wide spectrum of clinical and research activities centred on the creation of human embryos.

From the outset, the use of ART has been considered an exceptional branch of medicine that has attracted special regulatory attention (Petersen and Johnson, 2007). However, not all jurisdictions regulate ART legislatively. Some have an essentially unregulated free market (Adamson, 2002; Robertson, 2004a; Spar, 2006), relying on existing general legislation and/or professional self-regulation. Others have very rigid prescriptive laws (Robertson, 2004b). The UK and Australia lie in between (see Petersen and Johnson, 2007). Nonetheless, in both these jurisdictions, the various legal instruments and Codes of Practice intrude deeply into the both the clinical and the personal aspects of the doctor:patient decision-making processes. In effect, a remote body determines or influences detailed elements of treatment and research. Given the variation in regulatory practice, even among very similar jurisdictions, it is reasonable to question whether the burden and the accompanying additional costs of special legislation, administered by such bodies as the Human Fertilisation and Embryology Authority (HFEA) in the UK and the Infertility Treatment Authority (ITA) in the State of Victoria, Australia, are necessary and justifiable?

The traditional presumption underlying liberal democracies is that individuals have the right to determine and choose their own ends, through their autonomous informed choices (Gavaghan, 2007). Thus, state interference in, and criminalization of, activities is not acceptable if defined only by the perceived morality of the conduct. Proportionately serious potential harm, or at least offence, to the public interest must be demonstrated in order to legitimate the imposition of criminal sanctions to restrict rights and harm interests (Feinberg, 1984, 1985). Moreover, the greater the perceived benefit of an ART procedure to an individual, the stronger must be the public interest justification (the greater the anticipated social harm) for constraining it. Conversely, the greater the actual or perceived threat to the community, the stronger must be the benefit to the individual.

In practice, when it comes to matters of sex and reproduction, there has been a long and strong illiberal democratic tradition restricting autonomy in both the UK and Australia, often driven by religiously-inspired moralities, but also by considerations of economic inheritance. Women's sexuality has been controlled through criminal abortion laws and by attaching social and legal consequences to behaviour perceived as immoral (e.g. divorce laws, illegitimacy and 'single motherhood'). A formal civil union for non-heterosexuals is novel in the UK and lacking in Australia, indeed homosexuality was criminalized until late last century in both jurisdictions. So the question must be asked: is the illiberality marked by legislative and bureaucratic restrictions on use of ART similarly inspired? If not, how is the special regulation of ART justified within a liberal democratic framework?

In this paper, we examine the nature and strength of the public interest arguments that might justify the regulators placing restrictions on both the reproductive autonomy of those being treated and the professional autonomy of those treating them. In a democratic state, such arguments should inform the general principles underlying legislation as well as the specific purpose(s) of each proposed regulation. We suggest that current understandings of a public interest justification in reproductive and research ART are hazy and outdated. We argue that, because of this, it is often difficult to see what exactly the regulatory objective is and how it is justified. Without such a clear regulatory objective, how can empirical research-based evidence be obtained to show the effectiveness of the regulation in relation to any costs or burdens imposed by it? Not surprisingly, there is a dearth of such evidence. In an attempt to remedy this deficiency, we propose a five-step approach to the development and review of regulatory policy and practice, applicable to the regulators and somewhat akin to the 'quality control' procedures applied by them to clinical practice. This approach requires the identification of explicit rather than implicit goals and objectives for any proposed legislation, the selection of regulatory instruments appropriate to the objectives, and finally research to check the cost-effectiveness of their use in relation to objectives as part of continuing regulatory review.

What is 'public interest'?

While the term 'public interest' is used widely, its meaning is vague and contested (Francis, 1993; Feintuck, 2004). Contemporary ideas about the role of public interest in regulation can be conceptualized into three broad classes, each class characterized in terms of an individual's relationship to society and thus also of the nature of that society.

Pure market regulation

A fashionable approach (Elkin, 1986) to public interest is essentially economic, viewing society as being made up of providers (health teams) and consumers (patients, donors and surrogates). Public interest is equated more or less with the promotion of individual choice. The efficiency of the market then determines outcomes, and thus ultimately social organization, shaped by the aggregate free choices of individuals. The market approach at its best is held to be less prey to distortion through influence by sectional interest groups (Posner, 1974; Breyer, 1982), which, in the context of ART, might include the medical profession, well-organized patient groups, pharmaceutical companies or religious organizations. This belief in relative immunity from sectional interest is a key theoretical consideration for free market advocates, and is very much the spirit of the US ART model (Spar, 2006). Whether it is an argument supported fully by evidence is less clear (see below).

Regulatory public interest considerations intrude into market mechanisms only to the extent of ensuring that the markets work properly (fair competition)—an important consideration in an 'industry' such as ART provision, which is perceived to combine high cost (or at least charges) with relatively restricted supply and low success rates (Spar, 2006). Advocates of this regulatory model argue that outcomes, and the impact of market regulatory interventions on them, can be measured in financial terms that make comparisons of different regulatory approaches quantitative and thus 'robust' (Stigler, 1975, 1988). Under this model of public interest, regulatory failure is equated with market failure and is thought to be due to free-market conditions not being met, whether through regulatory neglect or inadequate regulatory policy.

Values-influenced market regulation

Recent problems of wholesale market scandals and collapses have prompted doubts about the ability to achieve pure markets, and indeed about the values espoused by them. A particular concern has been that their aspired isolation from cultural input may actually mean that they harm the common good (Dunlop, 2006), a perception that has led to calls for more complex forms of market regulation. What these calls are effectively acknowledging is that cultural factors will inevitably affect political decisions about regulation, even in a supposedly pure market economy (Ogus, 1992, 1995). For example, the decision whether or not to provide health insurance and/or NHS/Medicare cover for infertility treatment (and if so, on what access terms) is heavily value-laden even though masquerading as economics (Brown, 2006). Indeed, the current emphasis on public interest being solely economic

could be said to represent its capture by property-holding stakeholders for sectional ends.

The explicit acknowledgement that culture does influence market regulation makes this inevitability a transparent part of the policy formulation process, and offers the possibility to identify explicitly how sectional interests distort the market operation and outcomes. Indeed, cultural influences can be used deliberately as tools based on clearly identified public interest values and objectives (Shapiro, 1995), e.g. a requirement to build in to its pricing the total environmental costs of an industrial process, including factors such as deforestation and pollution. Thus regulation must take account of these cultural factors in both its genesis (how Government goes about setting up and reviewing regulatory practice) and its process (how the regulatory regime works in practice as a servant of the consumer society as a whole, not its ruler). Under this model of public interest, regulatory failure is equated with poorly thought through and/or applied values-based elements in regulatory policies.

Values-based regulation

The values-influenced regulatory approach in its idealized form represents just a more sophisticated and informed (or corrupted: Kahn, 1990!) market regulation. A new element is added to take us further from the market philosophy. Market regulation concerns primarily those active in the market place: patients, donors, surrogates, health professionals, scientists and biotechnologists. However, the very existence of this ART market place is of wider or even universal concern for social values and meaning (Johnson, 2002; Franklin, 2007). This more complex model of society is seen as being more than simply the sum of its market-aggregated individual consumer/provider interests. Rather, society is viewed as a community of citizens bound together by common shared or 'collective' values that make it the society it is. Thus, any justification for the intrusion of public interest beyond market regulation should be able to articulate these shared values explicitly and relate them to the regulatory objectives, methods and outcomes. This requirement poses a significant problem for the modern pluralist multi-cultural and social-democratic state, where difference is celebrated, and in which the identification of core common values, beyond those of the 'individual's rights' and the associated ethical values of the free market, is underdeveloped. The dominant language of contemporary ethics is centred on the individual rather than society as a whole, which constrains discussion of a 'public ethical interest' and notions of 'social harm'. Such an individualized language is understandable, given the historical (and in many parts of the world contemporary) record of reproductive and sexual discrimination by sectional (religious, political or class) interests capturing the social ethic and imposing it on all as 'quasi-collective' (Inglehart, 1999; McLean, 2006).

Reactions against the de-socialized market approach to ethics have attempted to articulate a social ethic, i.e. more rooted in core humanistic values about 'the whole population' not just the aggregated interests of its individual consumers and providers, nor of powerful sectional interests such as business

or religious communities (Saul, 1997; Holloway, 1999, 2005; Neuberger, 2005). In the arguments raised in support of regulatory intervention into ART, some values recur across disparate beliefs and sectional cultural interests. These include our custodial responsibility for future generations of humans (and especially the next generation), the sense of communal responsibility that commands individual restraint in service of the social order necessary for that community to survive and evolve (as opposed to destruct or revolt; in essence 'the rule of law'), and the protection of both the sanctity of human life and the dignity of human beings in a generic rather than an individual sense. A major criticism by market enthusiasts is that these factors are qualitative and ill-defined (especially human dignity: Schuklenk and Ashcroft, 2000), making outcomes of their application harder to measure and compare, and thus rendering processes even more susceptible to hijacking by special sectional interest groups or even to simple majoritarianism. Costs are indeed easier to measure than values, which are not, this model would suggest, any less important simply because of that. However, it is true that a more rigorously intellectual defense of a social ethic, especially given its discriminatory historical associations, is required for values-based regulation to gain broad acceptance.

The public interest regulatory continuum

These three conceptualizations of public interest are not so purely separable as the theoretical frameworks outlined above may suggest. Indeed, the three form a continuum. However, we are not concerned with the detail of these wider theoretical issues here. What is important for our purpose is that the issues, arguments and assumptions that have informed these views may be useful when trying to frame a coherent approach to the concept of public interest in the context of ART. In what follows, we use the shorthand phrases 'market regulation' and 'values-based regulation' to distinguish between the two poles of regulatory philosophy, with 'values-influenced market regulation' interposed.

Public interest in the context of ART regulation

We identify four main classes of potential public interest in ART. Two (public health and public financial interests) correspond mostly to a view of the patient as consumer, and two (public ethico-legal and public socio-political interests) more to a view of patient as citizen. These four classes thus fall on different points along the market-values spectrum described above, and so the combinatorial use of these two conceptual frameworks provides a logical 4×3 cellular basis for critical exploration of the 'public interest' in ART regulation (summarized in Table I). In this exploration, we try to identify comparable claims from medicine generally, and non-ART reproductive medicine in particular, that have been accommodated without a requirement for the elaborate statutory framework and regulatory body represented by the HFEA and ITA.

Public health interest

We identify three broad potential areas of public health interest.

Table I. Summary of assisted reproduction technology issues according to three regulatory models as indicated

Area of public interest	'Pure' market regulation	Values-influenced market regulation	Values-based regulation
Health	Safety and well-being (e.g. Medical competence, morbidity reduction, quality assurance) Approving use of new technologies, provision of guidance	Avoiding disability (e. g. what PGD allowed?) Avoiding consanguinity by limiting offspring/donor, and through access to record keeping	Protecting 'genetic solidarity'?
Financial	Costs (e.g. consequential health costs, pricing structures, ensuring accurate consumer information, advertising) Commercial activities	Resource allocation and prioritization price fixing	
Ethico-legal	Supporting autonomy of competent individuals (patients, donors, surrogates, health professionals)	Protecting non-competent individuals (children—actual and potential)	Respecting the embryo (protecting human dignity)
Socio-political		Protection from public backlash against the market	Public education Building public trust Risk management

Safety and well-being

The HFEA and ITA emphasize their key public interest roles in the welfare and safety of patients and potential children. However, it is unclear why they are required to perform this role? Welfare and safety provision is a universal issue for all types of health care, including the treatment of infertility by means other than ART, and is already the concern of a range of professional and statutory bodies, which, in the UK, includes the Royal Colleges, the General Medical Council (GMC), the National Institute for Health and Clinical Excellence (NICE), the Health Care Commission (HCC), and the National Patient Safety Agency (NPSA). Moreover, by far the largest agreed source of ART morbidity arises from multi-parity (Hansen *et al.*, 2002; Johnson, 2005; El-Toukhy *et al.*, 2006; Zhu *et al.*, 2006), and evidence that the UK has done much better than all other jurisdictions at reducing this morbidity as a direct result of its statutory regulation is lacking.

Reducing disability

There is a clear public health interest in actively reducing avoidable disability. However, that is not the reason given for statutory regulation of PGD, which is promoted primarily as a matter of family well-being rather than of public health. However, an implicit public health interest does appear in the values-based regulatory arguments used to justify restrictions on the types of genetic test for which couples may be offered PGD. Thus, disease severity, genetic penetrance and age of onset, rather than family well-being, are cited (DoH, 2006). It is interesting to contrast this situation with that of termination of pregnancy, which also places the pregnant woman's well-being at its centre, also considers severity of condition and its likely impact on the family, but does not require a statutory body to intrude on the decision process, leaving this matter in the UK to two doctors in consultation with the pregnant woman concerned (Abortion Act, 1967). PGD does raise the additional possibility of positive trait selection, which is less likely to occur with termination, although sex selection by way of pregnancy termination occurs in some cultures (McLean, 2006) and terminations under the 'social ground' are lawful up to 24 weeks gestation in the UK (Abortion Act, 1967 s1 (1)(a)).

Nevertheless, as doctors are required to act in good faith, it is unlikely that an abortion would be lawful in the UK if performed on grounds of hair colour genes, IQ or sex alone unless the pregnant woman's physical or mental health is also seriously threatened (McLean, 2006). The key point is that a statutory body has not been found necessary to regulate the process of abortion decision-making, so why is a statutory body needed for PGD?

Consanguinity might also be considered a public health issue, in as much as it may increase the chances of developmental abnormalities. There is also a long tradition of prohibiting classes of marriage relationships, at least partly claimed on consanguinity grounds although also addressing the deep social taboo of incest (Wolf and Durham, 2004). Recent American reports of large numbers of (now adult) offspring from a single sperm donor finding their half-siblings over the internet (DSR, 2007) also raise consanguinity issues, given the evidence that unfamiliar similar-looking people may be attracted sexually to each other (Hinsz, 1989; Wolf and Durham, 2004; DeBruine, 2005). However, it is unclear why a Statutory Body is required to regulate the numbers of offspring per donor (HFEA CoP, 2005: paras. 8.29–8.30), which could equally be done through a professional Code of Practice, as occurs in most Australian states (FSA/RTAC CoP, 2005: para. 9.14). Moreover, if the objective is simply to reduce harmful genetic effects through eugenic reproduction, the routine availability of genetic testing facilities for couples (whether using ART or not) intending to procreate can address this objective in a far more targeted way and without requirement for detailed record keeping.

Protecting genetic solidarity

Finally, a public health interest has been expressed in the genetic fitness of the population as a whole. For example, certain IVF treatments, such as ICSI for male hypo-spermatogenesis, may increase the incidence of some forms of genetic infertility and disorder in the population (Schulz *et al.*, 2006). With some 1–3% of births now resulting from ART in the UK and Australia (Bryant *et al.*, 2004; HCCST, 2005), these considerations may start to have a genetic impact at population levels.

The UK Human Genetics Commission (HGC, 2006) coined the phrase ‘genetic solidarity’ to capture this notion of our common gene pool (or at least that of our children) with which we may be tampering. This phrase certainly suggests a social values-based regulatory public health interest. However, genetic salivation via ART is likely to have small effects on population genetic fitness compared with use of antibiotics, immunization or other modern medical procedures and practices. More worrying for the population’s genetic solidarity might be uncontrolled positive selection for social traits such as gender, height, specific talents and physical appearance. This concern has two aspects. First, as long as the PGD technology is expensive, it could lead to economic hierarchies transforming into genetic hierarchies. Second, if PGD technology were to become widely affordable, and if successful pregnancy rates became higher, it is unclear whether mass fashions in genetic choice would more rapidly distort the population’s genetic structure than would negative selection. We see a precautionary values-based health interest here, but one presently too weak to warrant heavy regulation of itself.

Conclusion

We do not see any strong or unique claim of actual or imminent potential harm to the public health interest arising from use of ART sufficient to warrant the restrictions on autonomy imposed by such bodies as the ITA and HFEA. Less intrusive lighter touch regulatory mechanisms would suffice.

Public financial interests

There are two broad categories of identifiable public financial interest.

Costs

The costs interest is related to, but distinct from, public health interests, and encompasses both public and private costs. The issue of resource allocation in public health services is a major political concern, and the direct cost of ART treatment is somewhat variably state-borne by different countries (Ledger, 2006), but many are moving towards at least some public provision whether through insurance or tax-based funding. This provision may exert considerable influence on the market and thereby on medical practice. Price-fixing will tend to occur to keep costs down, and also could be coupled with access restriction related to general rather than individual anticipated medical or social outcomes (i.e. blanket exclusions by age, marital status). Thus, financial interests may conflict with health and ethico-legal interests through values-influenced market distortions.

Consequential costs to a public health service can also be considerable, regardless of whether the treatment itself is funded publicly or privately. Particularly, costly have been the maternal and paediatric costs arising from the high levels of prematurity and multi-parity associated with ART (El-Toukhy *et al.*, 2006), and such costs may also be incurred from the rarer clinical interventions consequential on post-operative infection, ovarian stimulation and surgical mishap at oocyte recovery or embryo transfer.

There is also the issue of how, within a public health service, the prioritizing of different treatments is determined. Prioritizing issues arise not only when infertility is in competition for resources with other types of clinical treatment, but also when deciding between the funding for different sorts of infertility treatment options: ‘wait and see’ or go straight to ICSI?

In most countries, the private sector dominates ART treatment. There are public financial interests in the regulation of the private sector, which amount essentially to competition regulatory issues, encompassing matters such as: the honest presentation of treatment outcome rates in a clearly understandable and comparable form to ensure effective patient information, the clear and inclusive display of costs, the prevention of cartels and monopolies and the honest advertising of services. All of these interests would fall under a market regulatory framework.

Finally, the denial of state funding for research and development in ART-related areas (notably human embryo research and stem cell derivation in the USA) has been values-driven but has also paradoxically isolated such work in the unregulated private commercial sector.

Commercialism

The commercial public financial interest concerns ART clinics and research centres as contributors directly to economic growth through provision of private treatment in clinical centres of international repute, and thereby sources of foreign earnings. This trade is facilitated by the varying international regulatory practices. Thus, more relaxed and/or high reputation jurisdictions become international ‘baby making centres’. Trade in gametes, embryos, surrogate uteri and stem cells can involve massive sums of money and so stimulate the economy (Spar, 2006), often appearing to exploit the poor from one country to benefit the rich from another with clinics acting as brokers to fix the deals. The highly commercial approach to treatment gives clinics considerable economic leverage. Pharmaceutical companies also make large profits from fertility drugs. Less tangible invisible earnings come with being an internationally acknowledged centre of excellence through sources such as training programmes, grant income and benefactions. But potentially even more lucrative is the wider exploitation of ART discoveries commercially, e.g. from ES cell research (Bonnicksen, 2001), which may bring earnings both through patents and commercial products and services. Such financial considerations, whether justified or not, were widely believed to be one driving force for legislative changes on embryo research (Szoke *et al.*, 2006) and ES cell derivation in Australia.

Conclusion

These identifiable public financial interest imperatives for regulation seem to be almost entirely about market issues: whether through regulation of competitive practice or attempts to regulate reproductive tourism—by both patients and by doctors and scientists. Neither of these issues is unique to ART, nor do either seem to require an elaborate regulatory structure that intrudes in such a detailed way directly into the doctor:patient consultation itself, since such structures are

lacking in other areas of medicine. There is also little evidence that existing special statutory regulatory bodies have had a major impact on the charges made to patients.

Public ethico-legal interests

Evaluating the public ethico-legal interest requires us to distinguish between state intervention on behalf of an individual and interventions on behalf of society as a whole. It is possible to think of the former actions as offering values-influenced support to individual consumers, and the latter as values-based actions on behalf of citizens as a whole. However, this distinction is not always easy to make.

Non-competent individuals—protection

The public interest duty to protect children is well-established under the ancient common law doctrine *parens patriae* (Wellesley v Duke of Beaufort, 1827), and provides ethical justification for introducing mandatory ‘child welfare’ provisions in ART statutes (Coady, 2002), notwithstanding the difficulty of their implementation (Patel and Johnson, 1998; HFEA, 2005). In doing so, it thereby extends the duty of care to non-existing persons who may be born as a result of ART treatment (HFE Act, 1990 s13(5); IT Act, 1995 s5(1)). However, the same ethical duty presumably applies to other non-ART forms of infertility treatment, and even to unassisted reproduction, neither of which require or suffer from anticipatory regulatory legislation? For example, parents with a seriously ill child whose life may be saved by a donation with matching tissues would be free to consent to a donation if they had, or were able to have, a genetically matching child naturally, as long as they were acting in that child’s best interests (Gillick v WNAHA, 1986). In this example the state does not intervene preventatively. However, if the option of a sibling match is not available, parents might turn to the use of PGD to select a matching embryo and here the regulators in the UK and the Australian State of Victoria intervene. Why? It is usually argued that restrictions are appropriate because of the apparent instrumentalization of the desired child (conceived to serve the interests of another), an argument that then widens the issue from that child into a public ethical interest in protecting future humanity from making children for ulterior purposes without adequate justification, as well as avoiding positive genetic selection for social traits (Watt, 2004; Gavaghan, 2007). These values-based public interest arguments lack empirical supporting evidence and do not seem to stand close scrutiny (Johnson, 2004, 2006b; McLean, 2006; Joint Committee, 2007).

Competent individuals—supporting autonomy

Consent requirements (Chatterton v Gerson, 1881; Sidaway v BGBH, 1985; Rogers v Whitaker, 1992) exemplify the public interest in protecting people from being pressured into undergoing ART treatment without adequate information about, e.g. any health risks involved in treatment or the likelihood of taking home a baby. Likewise consent requirements (voluntariness) act as a bulwark against strong family pressure to donate gametes (especially oocytes) or to be a surrogate mother. A poor woman may also be at risk of institutional coercion,

especially if she is both infertile and pressured to ‘egg share’ in order to obtain treatment for herself (Johnson, 1999; Lieberman, 2005), or to sell oocytes to wealthy overseas buyers (Spar, 2006). Finally, consent to the use of genetic material procreatively is considered too important to leave to the common law consent rules, witness the (unsuccessful) challenges to the explicit consent provisions in the HFE Act (R v HFEA, 1997; Evans v UK, 2006, 2007), notwithstanding, advocacy of a socially-oriented general ethico-legal argument about sex discrimination (Lind, 2006). In each of these examples, specific regulatory intervention has been advocated or imposed as providing ‘consumer’ protection, despite the protection available under common law. Why should a special regulatory structure be imposed on ART procedures? How is the case for ART so different from that for donation of a living kidney or consent to fertility treatment by induced ovulation? Could not professional guidance provide a framework capable of supporting autonomy within the therapeutic relationship, backed by professional sanctions, and so provide adequate protection, as occurs, for example, in three of the Australian States? And if not, why not first address this issue for all types of clinical treatment with professional and patient bodies rather than leaping straight to elaborate regulatory intrusion on autonomy?

It has also been argued that health professionals themselves may find helpful the legal protection of an ART statutory/regulatory provision concerning their clinical discretion to refuse treatment (English, 2006), especially now that consumer protection and anti-discrimination legislation can extend the liability of health professionals beyond common law requirements. Most of the focus has been on denying treatment access to single and lesbian women. However, there may also be a public interest in protecting the clinician from allegations of discrimination where fertility treatment is refused on *bona fide* grounds because of mental illness or emotional instability, in the same way that health professionals with conscientious objections can refuse to participate in abortion, ART treatment or ART-related research (HFE Act, 1990 s.38; Kennedy and Grubb, 1994; IT Act, 1995 s.152; Skene, 2004). Is there also a public interest in protecting clinicians who are pressured by a patient to transfer more than two embryos in spite of the health risks? It appears so, since professional regulatory guidance in Australia, for example, limits the transfer of more than two embryos or oocytes in a treatment cycle because of the serious risks to the woman and the potential child (ITA CfL 2002, para. 2.5.4; FSA/RTAC CoP, 2005 paras. 4–6). But why then does this professional guidance not of itself provide adequate additional protection for the profession by the profession, without a requirement for interventionist legal regulation?

The in vitro embryo

Where a potential child exists *in utero*, the law requires that the pregnant woman must give consent to authorize a procedure such as fetal surgery or lawfully indicated abortion. Otherwise, it would be an assault (battery) on the woman, not the embryo. Once born alive, but only then, does the neonate attain the legal rights of full personhood (Warnock, 1984, para 11.17; Evans v UK, 2006). These rights then can reach back into antenatal or

even anteconceptional life (Watt v Rama, 1972; Kosky v TSC, 1982; B v IHA, 1991). The UK approach to the legal status of the human embryo *in vitro* is consistent with its approach to the human embryo *in vivo*, in that it acknowledges that it has a 'special status' (Warnock, 1984), but not that it is equivalent to a person. These legal positions derive from an ethical understanding of human identity that is gradualist and developmental (Johnson, 2001b). This ethical position acknowledges the reality that most *in vitro* generated human embryos will not be placed in uteri nor, if they are, will they develop to be persons, a reality reaffirmed in the courts through the subsequent distinction drawn between the 'reproductive embryo' and the 'non-reproductive embryo' (R v SSH, 2002, 2003; Johnson, 2006a). Thus, clear ethico-legal distinctions are now emerging between human 'embryos for replacement'—potential babies—and those embryos for 'discarding or use in research' (as evidenced explicitly in the notion of the 'permitted embryo' in the recently published HTE Bill, 2007). There is thus scope for quite distinct regulatory approaches being adopted for the reproductive (permitted) and non-reproductive embryos (Johnson, 2006a; HFEA, 2007a,b).

A contrasting ethical view claims that the full status of human personhood does not gradually emerge but is conferred categorically on the embryo from the moment of fertilization. From such a viewpoint, it can then be argued that any improper treatment of the newly fertilized egg affronts the sanctity and dignity not only of that embryo but also of humanity as a whole, and so articulates a social ethic. This ethical position poses a major problem for the practice of ART, with potentially adverse consequences for patients when it dominates regulatory legislation, as seen in Italy and Germany (Italy, Law 40/2004 'Norms on the Matter of Medically Assisted Procreation'; Germany-Embryo Protection Act, 1990; Benagiano and Gianaroli, 2004; Robertson, 2004b).

Conclusions

The above examples start to tease apart values-influenced and values-based interests, reflected broadly in individual and social ethical reasoning. However, this distinction is not always easy to make and ethico-legal cases that start with the individual often drift into the social. In considering the regulatory context, issues of autonomy, whether of competent or non-competent individuals, constitute a values-influenced market regulatory strand. There does not appear to be a profound public interest specific to ART sufficiently strong to justify a complex regulatory intrusion. On the question of the status of the embryo, it is clear that both historically and contemporaneously values-based ethico-legal public interests in the human embryo have shaped legislation considerably and differently in different jurisdictions.

Public socio-political interests

It will be evident from the preceding sections that we believe socio-political beliefs, and the cultural traditions and institutions underlying and mediating their expression, have exerted strong influences on regulatory structure. Hence the strong attachment of the USA to individualized and free market economic theories for the models and purposes of

ART regulation, and the equally strong impact of the socialized and (Catholic) Christian values-based approach to regulation in Italy, and more variably elsewhere in Europe and Australia. For most of the public interests identified above, we consider the case for statutory regulation to be weak at best.

However, there is another important socio-political arena to consider common to all these cultural backgrounds. IVF is indeed now a standard and familiar clinical procedure. Unconventional family forms are now also commonplace and widely accepted. The levels of public concern about these issues that existed in the 1980s appear to be subsiding. However, there remains evidence of continuing public concern (Kass, 2002, but see Joint Committee, 2007) about any novel reproductive development that seems to be moving in new and risky directions too rapidly and driving 'market' demand unreflectively. ART is more than IVF. Public anxiety about the inherent uncertainty or provisionality (Johnson, 2002) of medical science remains a characteristic of our time and is not restricted to ART (Bauman, 1991; Beck, 1992), but is acutely and uniquely roused by ART through the very personal nature of reproduction, lineage and family. This arousal highlights the strong emotional and cultural undercurrents involved, which means that simple intellectually quantifiable risk assessments cannot of themselves address the social concern. Lay and professional risk perceptions will differ and both are coloured by non-rationality and the uncertainty of probability-grounded risk analysis (Wynne, 2002; Tulloch and Lupton, 2003), which, too often, is unfortunately presented to the public as 'experts being wrong again' (even by experts who should know better, see Hooper *et al.*, 2006 for an example). Public abreactions, if left unaddressed, may then become prejudicial to long-term public education and debate, and thereby to public health and financial interests, witness the premature regulation of ART in Victoria (Szoke, 2004).

How to handle this uncertainty? It is unwise to ignore it, and neither, given the inherent provisionality of science, can it be removed. It has therefore to be accepted, explained and managed in ways that diffuse its worse effects but retain its value: uncertainty and perceptions of risk can exercise both positive and negative effects and some sort of balance needs to be sought (Johnson, 2006b). Regulatory systems that acknowledge and respond to public fears and doubts provide a sense of control, offer the public access and influence, and provide a forum and time for discussion and education in that space between knowledge and ignorance that trust must occupy (Edwards and Sharpe, 1971; Caulfield *et al.*, 2004; English, 2006; Johnson, 2006b). They thus provide one route to build public trust, and to optimize the chances of uncertainty being productive by allowing the creativity of the scientists and doctors to flourish, but within limits (Johnson, 2006b). The nature of those limits, and how they are set and policed, is at the core of this paper.

Public interest: some conclusions

Our analysis leads us to the view that there are identifiable public interests in ART under each of the four headings used above, but the interests take different forms (summarized in Table I). The public health and financial interests in ART are concerned

largely with service provision, as were major identifiable public ethico-legal interests based around supporting autonomy. All of these three interests are essentially addressing the level of the competitive playing field, are primarily of restricted concern to the players in the market, and arguably can be met through market regulatory principles and mechanisms (left and middle columns in Table I) that need not extend to the cumbersome regulatory structures exemplified by the HFEA and the ITA. Moreover, none is unique to ART, as values-influenced market elements abound elsewhere in medicine. However, one area of public ethico-legal interest does not easily fit this regulatory model, but invokes the concept of collective social harm/benefit beyond the interests of the players in the market.

The treatment of the embryo *in vitro* is unique to ART, a health-team working with a couple to produce embryos the fate of which can be influenced by all involved parties and potentially by others such as commercial concerns. How we treat these embryos is seen by some to have implications for our collective view of humanity, and so has provided a minority sectional stimulus for values-based regulation. This concern about the embryo *per se* combines powerfully with a much wider public socio-political interest, namely a generalized anxiety about the abuse of embryo technology against society's well-being. Implicit in this latter interest is a view of the embryo *in vitro* as an intended, or at the least potential, child. A regulatory structure, it is argued, can and should provide a trust-building function.

It is important to emphasize that these values-based public interest stimuli to regulation represent a tiny component of the total public interest in ART. Questions therefore arise. Is regulation disproportionately intrusive? Has there been regulatory creep—witness the seventh edition of the HFEA Code of Practice (HFEA CoP, 2007), which runs to 25 sections and 2 large appendices, the last of which refers on to a further 47 Good Practice Guidelines to which licensed centres are also expected to conform? Why do currently routine treatments require such intrusive regulation? And why cannot human embryo basic research involving no possibility of transfer to women be accommodated within the standard ethical committee framework? Is the whole area of ART now over-regulated unnecessarily? Why cannot such intrusive regulation be limited to the control of translational issues, determining whether, when and how novel technologies move from the research laboratory to treatment in the clinic, thereby addressing the critical trust-building function? Since our analysis has helped us to frame these searching questions, also taken up in a recent Joint House Committee Report in the UK (Joint Committee, 2007), we have attempted to use our analytic approach to provide a generic structure that might help to prevent over-regulation by scrutinizing the regulator and the regulatory process more robustly. This structure draws on a standard quality-control model familiar to medical practice.

A model for developing and reviewing ART regulatory policy

Trust-building is a key element in the argument for regulation, and thus any regulatory structure must inspire public

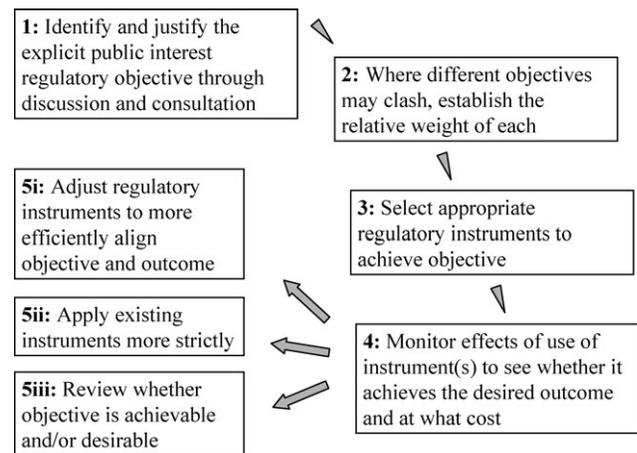


Figure 1: Schematic view of steps to smart regulation of assisted reproduction technology

confidence by being authoritative, accountable, and having a transparency of process and clarity of evidence throughout the formulation, establishment, administration and review of regulatory policy. Without proper process, it is difficult to call the regulator and the processes that they are using to account. In this context, we suggest a five-step model to help shift the focus of regulation from simply enforcing regulatory objectives towards questioning and testing those objectives and the methods being used to implement them (Fig. 1):

- (i) A fundamental step in our model is the clear and explicit articulation of what each regulatory element is trying to achieve in the public interest and why. Such an approach should justify the values and present the evidence underlying the objectives as collective, and not just as sectional or majority-based, and will be able to identify the intended outcomes.
- (ii) A second step is proposed to account for the fact that there may be more than one objective within a regulatory framework, and so a clear idea of the relative priority and weighting of each is required.
- (iii) This clarity of intention allows the selection of regulatory instruments appropriate to the task (the range of available instruments and the strengths and weaknesses of each is considered in more detail in Johnson and Petersen, 2008).
- (iv) A system for monitoring will then compare outcome against objective and determine whether the cost incurred is proportionate.
- (v) Finally, where mis-alignment of objective and outcome, and/or heavy cost, is detected, there are three options. One option (Fig. 1.5i) is to change the regulatory instrument to improve alignment: the smartest regulatory model that may also reduce cost. A second option (Fig. 1.5ii) is to apply firmer enforcement (the punitive model which may increase cost further). A third option (Fig. 1.5iii) is to question whether the regulatory objective is achievable or desirable, and if it is not to change or abandon the objective.

Steps (iv) and (v), and especially the first and third options of step (v), imply a reactive flexibility inherent in both the

Table II. Application of the five-step regulatory assessment model prospectively to a proposal made by the Joint Parliamentary Committee scrutinising the Human Tissue and Embryos (Draft) Bill, namely the issue of parental honesty about genetic origins to their children conceived by donation.

Regulatory step	Recording the fact of 'conception by donation' on the long form of a child's birth certificate	Setting up a dedicated post-natal support system for couples conceiving through donation
Identification of public interest objective(s) that underpins regulatory policy	Encouragement of parents to tell child about its genetic origins (public ethical interest in protection of non-competent individual's interests and autonomy; possible public health interest in reducing genetic disease) Avoidance of State collusion in dishonesty in an official State record (public ethical interest)	Encouragement of parents to tell child about its genetic origins (public ethical and health interests)
Priority and weight of objective vis a vis other regulatory objectives	May conflict with the right to privacy of the offspring as the long form of the birth certificate is required to be presented for certain activities Also conflicts with the right of the parents to a private family life Objective's priority within this hierarchy is unclear and not argued	Potential increase to the cost of treatment, thereby perhaps restricting access. Cost could initially be high as it is clear that most parents do NOT currently tell offspring about origins—so this measure would need to be given a high priority to override cost Costs (and therefore priority and even necessity?) may reduce if parental views about telling change
Possible regulatory instrument for implementing regulation	Statutory requirement on parents when registering the birth	Establish an independent national voluntary or statutory support agency contracted to provide pre- and post-natal support for women/couples using donated gametes or require clinics themselves to provide post-natal support
Possible monitoring process(es) in place to determine whether instrument achieves objective	Compare the number of births registered with the HFEA as conceived by donation with the number of births registered as such with the Public Records Office. This adds costs as currently these data are not recorded and compared. These costs are potentially transferable to patients, which may encourage them to use non-licensed sperm providers with attendant personal and public health risks. Possible outcomes are full, partial or low concordance of the data sets (see below)	Obligatory feed-back on outcomes from agency or clinics. Either of the above approaches is potentially high cost (see box to left). Both approaches also risk invasion of the privacy of the parents and their offspring. However, this regulatory approach might facilitate the collection of sound research evidence on the size of the problem, which the objective seeks to address. Current evidence is anecdotal and it is unclear whether the introduction (and cost) of regulatory instruments (statutory or non-statutory) to address the objective is disproportionate
Corrective possibilities available in case regulatory instrument fails 5(i) Adjust regulatory instruments to more efficiently align objective and outcome 5(ii) Apply existing instruments more strictly 5(iii) review whether objective is achievable and/or desirable	Mis-match will occur should parents be dis-honest at birth registration. Decide whether to: 5(i) Require clinics to check birth certificates (high additional cost) or simply accept low efficiency of instrument (as a non-enforceable legal encouragement to be honest—are unenforceable laws desirable?), or 5(ii) Try and trace and thereby criminalize the dishonest parents (undesirable), or 5(iii) Decide that policy is not working, as dishonesty by parents is being increased rather than reduced and so remove requirement	Since the purpose of this form of regulatory instrument is encouragement and support rather than enforcement, the corrective possibilities could include: 5(i) Determine whether some areas of UK and/or some clinics gain better outcomes than others and identify best practice features for wider dissemination, or 5(ii) Apply punitive sanctions to clinics performing poorly (may drive them out of donation market?), or 5(iii) Decide cost is dis-proportionately high in relation to the problem, and instead strive to change the social climate generating secrecy by a sustained campaign through media, clinics, general practitioners etc?

Two possible types of regulatory instrument to achieve this objective are used to illustrate the possible application of the model (Joint Committee, 2007, section 276).

regulator and the regulatory process that are not allowed by rigidly prescriptive statutes and not encouraged by current regulatory practices.

We have attempted to apply this five-step model analytically to two examples. A prospective use of the model is shown in Table II, which considers a proposal raised by the Joint Scrutiny Committee on the Human Tissue and Embryos (Draft) Bill. This proposal is designed to encourage parents to tell children born by donation the fact of their conception, specifically by recording it on the long form of the birth certificate (Joint

Committee, 2007, S276). We have extracted our understanding of the legislative objectives and their priority and weighting from a reading of the report and the published evidence that informed it. Two possible instruments for regulatory achievement of this objective are compared. The analysis suggests that compliance and cost may vary according to the instrument selected, demonstrating the value of use of the analytical framework. We have also applied this framework retrospectively to several existing regulatory examples, one of which is shown in Table III, namely the regulation of parental choice about the

Table III. Application of the five-step regulatory assessment model retrospectively to the regulation of parental choice about the genetic make-up of offspring in two jurisdictions.

Regulatory step	UK	State of Victoria
Identification of public interest objective(s) that underpins regulatory policy	<p><i>Implicit</i> public health interest in avoidance of genetic disease; implicit public ethical interest in welfare of existing child ('saviour siblings') and in genetic solidarity (prohibition for non-medical reasons)</p> <p>The HFE Act does not specify that genetic testing and choice is either allowed or prohibited. It authorizes treatments to determine whether embryos are 'suitable for placing in a woman' (1). Thus, the extent of parental genetic choice is restricted to the interpretation the HFEA places on 'suitable'. In practice, this has been taken to mean for the avoidance of serious genetic disease (welfare of child issue), avoidance of pregnancy loss (PGS), and also, via PGD tissue typing, for the amelioration of life-threatening disease as a last resort in an existing sick child who could not be helped in any other way (2)</p> <p>Social sex selection and other positive genetic selections are thus not explicitly forbidden in the Act, but are in the Code of Practice Appendix A.13.11</p> <p>Parental choice subject to medical approval within the limits set by the regulator</p>	<p><i>Explicit</i> public ethical interest in child welfare by avoidance of genetic disease</p> <p>The Infertility Treatment (IT) Act permits use of PGD when a medical geneticist is satisfied that a genetic abnormality or disease might be transmitted to a person born (3). Applicants must comply with statutory mandatory consent and counselling requirements (4)</p> <p>Sex selection for non-medical reasons is banned. Saviour siblings only allowed if couple require either PGD as well or are naturally infertile (5, 9)</p> <p>Parental choice subject to medical approval within the limits set by the regulator</p>
Priority and weight of objective vis a vis other regulatory objectives	<p>Unclear and subject to interpretation and conditions applied by regulator (6)</p> <p>In practice, interests of some aspirant parents are secondary to those of the potential children and public interest</p>	<p>Interests of potential child have priority over parental autonomy, welfare of existing children and medical autonomy</p>
Regulatory instrument used for implementation	<p>Guidance through HFEA Code of Practice</p> <p>Accreditation of laboratories to ascertain competence (7)</p> <p>Conditional licensing by genetic condition (8)</p> <p>Notification requirements by clinic in writing (10)</p> <p>Inspection and audit</p> <p>Feedback from clinics</p> <p>Additional costs not audited</p>	<p>Guidance from ITA publication (9)</p> <p>Relevant sections of IT Act ss 5, 8(3), 8(3)(b), 50(2)</p>
Monitoring process(es) in place to determine whether instrument achieves objective	<p>Inspection and audit</p> <p>Feedback from clinics</p> <p>Additional costs not audited</p>	<p>Inspection and audit by the ITA and RTAC</p> <p>Additional costs not audited</p>
Corrective possibilities available in case regulatory instrument fails	<p>5(i) No formal option, but HFEA has changed procedures to reduce regulatory load in response to monitoring of and feedback from clinics (11)</p> <p>5(ii) Vary licence condition or withdraw licence to undertake PGD. Could refer to DPP for possible prosecution</p> <p>5(iii) HFEA could cede control over conditions eligible for genetic selection to doctors or patients, but seems unlikely. Defers to legislators. Situation reviewed by Department of Health (DoH, 2007) and Joint Scrutiny Committee (2007). Both agreed to a specific statutory prohibition on non-medical sex selection. Committee suggested 'serious' (not just 'life-threatening') medical conditions should warrant saviour sibling approval. Legislative developments in transition</p>	<p>5(i) ITA can adjust regulatory requirements for any genetic condition (see 9)</p> <p>5(ii) The ITA and the RTAC can revoke or place conditions on a clinic's licence. In case of statutory breaches, the Minister <i>must</i> be advised (12). Breaches are an indictable offence (13).</p> <p>5(iii) Requires legislative review. A report from the Victorian Law Reform Commission (VLRC, 2007) suggests changes to make the Act more responsive to new treatment developments. Recommends that PGD for new genetic conditions is considered by a clinic's ethics committee; other difficult ethical questions may be referred to an ITA review panel. Affirms ban on non-medical sex selection. Legislative developments in transition</p>

(1) HFE ACT 1990 Schedule 2, para 1; (2) HFEA Code of Practice (7th edn), Section G.12.5 & Appendix A.13.8 (Johnson, 2006b); (3) Infertility Treatment Act 1995 (Vic) ss 5, 8(3)(b), (4) *Ibid* ss 9–11, (5) *Ibid* s 50; (6) seventh Code of Practice, Section G.12; (7) HFE Act s. 17 and seventh Code of Practice Appendix A.13.7(e); (8) seventh Code of Practice, Section G and Appendix A.13.8, 9 and 11; (9) ITA approved Genetic Testing (May 2007); Genetic testing and the Requirements of the *Infertility Treatment Act* 1995: Policy in Relation to the Use of Preimplantation Genetic Diagnosis for Genetic Testing (2004). The IT Act does not define 'a genetic abnormality or a disease'. Confirmation by a doctor with a specialist qualification in genetics satisfies the condition for admission. Applicants who are not 'genetic carriers' may satisfy the 'clinical infertility' ground if the purpose of genetic testing is to identify chromosomal abnormalities that may contribute to infertility. The ITA permits PGS and PGD to be used without special notification for medical indications in List A and B. List A sets out the cases where PGD can be used to detect chromosomal disorders and List B sets out cases where an embryo can be excluded because of sex-linked disorders, known chromosome re-arrangements, and single gene disorders of autosomes. Disorders such as Huntington's disease, BRAC1, familial adenomatous polyposis and Fragile X are included. List C sets out conditions where the Approval is required on a case-by-case basis. The ITA cannot license Preimplantation Tissue Typing *per se* because there is no legal pathway for fertile people, who are not at risk of transmitting a genetic disease, unless they can qualify as clinically infertile under the licence conditions; (10) HFE ACT 1990 Schedule 2, para 1; (11) Procedure for licensing new genetic conditions stream-lined for established clinics with a track record of competence at PGD; Chair's letter 10th August 2005 (<http://www.hfea.gov.uk/HFEAGuidance/ChairsLettersArchive/2005-2006/CH0503>); (12) *Infertility Treatment Act* 1990 (Vic) s122 (2), (13) *Ibid* s163.

genetic make-up of offspring in UK and the state of Victoria (see also Johnson and Petersen, 2008, for three further examples). We find that the public interest objectives of regulatory policy are not explicit in the UK, enabling the regulator discretion to reinforce or to moderate the lack of patient autonomy. In Victoria, explicit statutes require the regulator and the doctor to work together but only in a limited medical domain, and the patient has no choice other than to apply. Significantly, we find little or no evidence of sound empirically-based research on the impact and cost of regulation (step iv), and so a slender basis for re-evaluation and/or reform of regulatory structure (step v). Moreover, review of whether the objectives (implicit or explicit) are achievable and/or desirable seems to be ceded to a statutory level, which is slow and cumbersome (see Petersen and Johnson, 2007, for a critique of the current process of reform of the HFE Act, and Joint Committee, 2007, for a similar critique of the HTE Bill, 2007).

Thus, the application of this research framework both prospectively and retrospectively seems to provide a useful research and review tool for wider use in calling regulators and their methods to account.

Conclusions

This five-step approach has two major advantages. First, it provides an analytic framework (that is currently lacking) for the identification and evaluation of public interests in current regulatory structures. In the process, it also provides a stronger defense against over-regulation by patrolling the regulatory borders to prevent undue creep, as has arguably occurred in the UK. It may also be useful as a historical research tool to help explain why similar jurisdictions (e.g. the UK and Victoria) can end up in such different positions (addressed in part by Szoke, 2004). Second, this approach should encourage public trust and confidence-building and act as a bulwark against adverse and hasty abreaction. It commits society to consider its values and their implications by providing both time and a meaningful forum for public education, policy development and decision-making on contested areas. Given the technological and conceptual pace of the science, such a space is likely to be needed for some time. Respecting the principle of proportionality, the process by which public interest is determined must be transparent to those affected by its intrusion into their personal autonomy. It should be clear what universal ethical principle is offended by a proposed course of action? How large is that offence and under what circumstances? What evidence bears on these questions? And how is intervention justified? Without this minimal analytic process, intrusions will seem arbitrary, and the level at which regulation should be set will also be difficult to justify. For example, if a regulatory body determines that non-medical sex selection should not be allowed, it has a duty to make clear why and how it reached its decision, and to demonstrate that it has taken account of different views and, if it has appeared to ignore them, why it did so. For this reason, it is our view that the process should apply regardless of whether or not the level of regulation is statutory.

We have attempted to set out a less *ad hoc* and more objective analytical framework for establishing and revising the regulation of ART and for justifying its boundaries. We cannot make firm recommendations based on this analysis, as remarkably few of the required empirical research data are available (Petersen and Johnson, 2007). It is extra-ordinary, given the volume of discussion about regulation, how few research data are available on the impact and effectiveness of regulation. It is also ironic that the system we are proposing, which provides a well-established quality control for clinicians and scientists, is not applied rigorously by regulators and legislators to their own activities. Perhaps having an analytical tool will encourage regulators, and those legislating to set them up, to think more analytically and evidentially about what they are trying to achieve, why and how best to do it? It is possible that better regulatory proposals might then result (Joint Committee, 2007).

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