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## ARTICLE

# Assisted reproductive technology in the USA: is more regulation needed?



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**Abstract** The regulation of assisted reproductive technologies is a contested area. Some jurisdictions, such as the UK and a number of Australian states, have comprehensive regulation of most aspects of assisted reproductive technologies; others, such as the USA, have taken a more piecemeal approach and rely on professional guidelines and the general regulation of medical practice to govern this area. It will be argued that such a laissez-faire approach is inadequate for regulating the complex area of assisted reproductive technologies. Two key examples, reducing multiple births and registers of donors and offspring, will be considered to illustrate the effects of the regulatory structure of assisted reproductive technologies in the USA on practice. It will be concluded that the regulatory structure in the USA fails to provide an adequate mechanism for ensuring the ethical and safe conduct of ART services, and that more comprehensive regulation is required. 

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**KEYWORDS:** American Society for Reproductive Medicine (ASRM), assisted reproductive technologies, infertility treatment, legislation, policy, regulation

## Introduction

The regulation of assisted reproductive technologies is a contested area. Some jurisdictions, such as the UK and a number of Australian states, have comprehensive regulation of most

aspects of assisted reproductive technologies; others, such as the USA, have taken a more piecemeal approach and rely on professional guidelines and the general regulation of medical practice to govern this area (Ory et al., 2013). In this paper, we argue that such a laissez-faire approach is

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inadequate for regulating the complex area of assisted reproductive technologies, and conclude that more comprehensive regulation is required.

The aim of this paper is to give a perspective on regulation of assisted reproductive technologies in the USA and compare it with other jurisdictions with very different regulatory systems and approaches to government intervention, drawing heavily on examples from the UK. The purpose here is not to argue that the solutions and approaches to regulation adopted in other countries, particularly the UK, could be applicable to the USA. We recognize that the American socio-political context in which assisted reproductive technologies operate, attitudes towards government intervention, particularly at federal level, and the funding structure of US health care means that national legislation on assisted reproductive technologies, such as exists in the UK, is highly unlikely to be either practical or ideologically acceptable to most stakeholders in the USA. Our purpose is merely to open up the discussion by using examples of radically different regulatory systems, with a view to finding compromises between regulatory oversight and the autonomy and privacy of practitioners and users that would be acceptable in the USA. Regulatory structures and provisions are not set in stone, and the lively debate in the UK over the Government's plans to abolish the Human Fertilisation and Embryology Authority (HFEA), with strong arguments on either side (Johnson, 2013), show that these matters are never completely resolved even by comprehensive legislation.

## Background

In the USA, forms of assisted reproductive technology regulation exist at federal and state level. At federal level, assisted reproductive technologies are overseen by the Fertility Clinic Success Rate and Certification Act 1992, Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services. Medical practice is also regulated at individual state level. This can include specific regulations on assisted reproductive technologies (in the main relating to insurance coverage). Considerable inter-state variation, however, exists; some states have limited or non-existent regulation and others have more comprehensive oversight. Because of the relative lack of legal regulation at both these levels, professional guidelines and good practice protocols play an important role in overseeing assisted reproductive technology practice. The American Society of Reproductive Medicine (ASRM) and its affiliate, the Society for Assisted Reproductive Technology (SART), offer professional self-regulation through guidelines and codes of conduct for fertility clinics and their staff. Key among these are the ASRM Ethics Committee Reports and Practice Committee opinions (ASRM and SART Practice Committee, 2013; ASRM Ethics Committee, 2004).

The ASRM has consistently asserted that, owing to the existence of this framework assisted reproductive technologies are sufficiently well regulated and there is little need for further intervention (Adamson, 2005; Rebar and DeCherney, 2004). Following a meeting to review the oversight of assisted reproductive technologies, the ASRM produced a report in May 2010 re-stating this position that assisted reproductive technologies are, 'one of most highly regulated of all

medical practices in the United States' (ASRM, 2010). We do not necessarily quarrel with that view in this paper, as our purpose is not to examine or compare different regulatory regimes of other areas of medical practice in the USA. The aim is to highlight important omissions in the regulatory structures that govern assisted reproductive technologies in the USA, and to argue that the oversight of assisted reproductive technologies is much less extensive and rigorous than the ASRM claims. Before considering the specifics of US regulation, it is useful to consider what is meant by 'sufficiently well-regulated'. We argue that assisted reproductive technologies are sufficiently well regulated if regulations, which are designed to promote the safe and ethical conduct of these practices, are present and enforceable in some meaningful way and have broad support of all the relevant stakeholders.

## Limitations of regulation

At the federal level, the sole statute regulating assisted conception, the Wyden Law (the colloquial term for the Fertility Clinic Success Rate and Certification Act) is limited in scope. It is primarily designed to make publicly available accurate information about fertility clinic success rates by requiring annual data reporting to the CDC. It has been commented, however, that this publically available outcome data can be misleading, and a small number of clinics have reported data in such a way as to give an inflated picture of their pregnancy rates. For example, the analysis by Kushnir et al. (2013) of SART and CDC reporting data showed that some centres were excluding cycles started in women over the age of 38 years. By doing this, these clinics reported significantly better pregnancy rates than average and were able to increase their market share by 19.9%. Kushnir et al. (2013) conclude that future data collection and reporting need to be more patient-centred so that success rates of clinics can be more accurately and fairly compared. The HFEA, for example, organized a public consultation on how clinic success rates should be reported, to allow patients to make the most informed choices when selecting a clinic (HFEA, 2008). The outcomes of this are reflected on the HFEA's website where information is presented in an accessible way to help people understand the meaning of the statistics used in making clinic comparisons and aid them in making treatment choices (HFEA, 2014).

In the USA, such comprehensive data do not exist on clinics, not all of them file reports to CDC, and each year about 12% of them fail to do so. In 2009, 43 clinics did not report (Centers for Disease Control and Prevention, 2011), in 2010, 31 clinics failed to report (Centers for Disease Control and Prevention, 2012) and, in 2011 (the latest figures available), 30 clinics failed to report (Centers for Disease Control and Prevention, 2013). Data from clinics are also collected by SART on a voluntary basis, and these are shared with the CDC. Not all clinics report to SART either; of those that did, 113 (28.1%) did not report a complete data set (Kushnir et al., 2013). Further, it is unclear if every practising fertility clinic is known to the CDC and therefore included in these figures, as they state: 'We will continue to make every effort to include in future reports all clinics and practitioners providing ART (assisted reproductive technologies) services.' (CDC Website, commonly asked questions reference). Furthermore, the CDC request any

customer who is aware of a fertility clinic that is operating but not included in their list of assisted reproductive technology centres to notify them.

In addition to this lack of reporting, the data that the CDC requires clinics to collect are more limited than data provided by clinics in the UK to the HFEA and in Australia and New Zealand to the Australian and New Zealand Assisted Reproduction Database (Macaldowie et al., 2012), for example. A key area in which data collected by the CDC are limited is information on the use of donor gametes. The CDC only collect data on the use of donor eggs and do not collect data on donor sperm (i.e. how many treatments are conducted with donor sperm and success rates): 'Some ART procedures use a woman's own eggs, and others use donated eggs or embryos. Although sperm used to create an embryo may also be either from a woman's partner or from a sperm donor, information in the report is presented according to the egg source.' (CDC, Web Tutorial) The CDC only collect data on the age of egg donors and on the use of donor eggs, covering areas such as: are older women undergoing assisted reproductive technologies more likely to use donor eggs or embryos? Do percentages of transfers that result in live births differ by age for women who used assisted reproductive technologies with donor eggs compared with women who used assisted reproductive technologies with their own eggs? How successful is assisted reproductive technology when donor eggs are used? (CDC, Web Tutorial). National records of the numbers of gamete donors, to whom they donated, and medical information are not, however, required by the CDC. This makes it impossible to track gamete donor trends in the USA or determine how many times an individual donor might be used.

The Wyden Law also provides States with a model embryology laboratory certification process. It is not mandatory to implement such a model, and embryology laboratories are not required to have this type of certification because the procedures they perform are not deemed to be diagnostic and therefore do not fall within the remit of the Clinical Laboratory Improvement Act under which compliance is mandatory.

The FDA's role in overseeing assisted reproductive technologies also has significant limitations. The FDA has jurisdiction over setting standards for screening and testing donors of all forms of human tissue and tissue-based products under Regulation 21 code of Federal Regulations (CFR) Part 1271 (Food and Drug Administration, 2004). These regulations were primarily designed to prevent communicable diseases. The storage and use of reproductive tissue, however, raise distinctive issues that are not covered by these regulations. For instance, they do not incorporate guidance on genetic testing of prospective donors, and this has resulted in wide variation in the practices of sperm donor banks. This was highlighted 14 years ago (Conrad et al., 1996); more recently, Sims et al. (2010) found that routine testing for genetic diseases varied substantially between sperm banks, with different conditions being screened for and a wide range of tests used. Isley and Callum (2013) found similar variability of practice in their study, which included information from 13 out of 26 sperm banks in the USA. This study reported that, although these banks voluntarily followed the testing guidelines from at least one professional organization (such as the ASRM and the American Association of Tissue Banks), the lack of consistency between banks is still an issue. Similar inconsistencies in

practice have been observed in the screening of oocyte donors. Lewis et al. (1999) investigated compliance with ASRM guidelines by 159 oocyte donation programmes, and concluded that, although: 'most programmes follow recommendations made by the . . . ASRM for screening of gamete donors . . . a significant percentage do not use well-established testing.' A 2011 study of 16 oocyte donation agencies and 28 assisted reproductive technologies clinics (out of 59 agencies and 205 clinics invited to take part) concluded that these programmes inconsistently applied genetic screening guidelines from the American College of Obstetricians and Gynecologists, the American College of Medical Genetics, and ASRM (Lim et al., 2011). These wide variations in practice have resulted in unacceptable variations in practice and insufficiently robust genetic screening of donor gametes (Heled, 2010).

Furthermore, reproductive tissue is not included in all of the 21 CFR Part 1271 regulations (Food and Drug Administration, 2004). Only small sections of the Good Tissue Practice regulations, for example, apply to most reproductive establishments (Keel and Schalue, 2010). The FDA itself points out that it is unclear if all facilities that handle reproductive tissue comply with accepted industry standards:

'Facilities handling reproductive tissue. . . represent the greatest area of uncertainty. . . . There is currently no single reliable source of information on fertility center or semen bank adherence to AATB [American Association of Tissue Banks] standards or ASRM guidelines.' (Food and Drug Administration, 2004).

In summary, weaknesses in the federal regulatory structure of assisted reproductive technologies have resulted in inconsistencies in practice and areas that are insufficiently regulated.

Individual states also have the power to pass legislation governing assisted reproductive technologies; however, many states have not legislated in this area. A report published by the National Conference of State Legislatures in 2007 (that has not subsequently been updated) indicates that legislation on embryo and gamete disposition (covering key areas such as legal parenthood of children conceived from donated gametes and consent procedures for use and storage of gametes) has only been enacted in 16 states (The National Conference of State Legislatures, 2007b). Laws relating to health insurance coverage for infertility treatments also vary between states (Martin et al., 2011. The National Conference of State Legislatures, 2012). On the regulation of techniques related to standard IVF, such as cloning and embryonic stem cell research, only 15 states have legislation relating to human cloning, and, within these laws what is covered and prohibited varies (The National Conference of State Legislatures, 2008). More states have legislation governing the use of embryonic stem cells in research, but approaches differ greatly from state to state: some states, such as California and Illinois, allow this kind of research and have guidelines for consent processes and reviews procedures for projects; others, such as South Dakota, prohibit research on embryos (The National Conference of State Legislatures, 2007a). Thirteen states do not have any legislation on assisted reproductive technologies provision, and many only have limited legislative cover (Table 1). Naomi Cahn in her book *Test tube families: why the fertility market needs legal regulation* (Cahn, 2009) discusses some of the problems with piecemeal state legislation in this area, such as conflicting state

**Table 1** State regulation of assisted reproductive technologies in the USA.

State	Gamete donation disposition	Human cloning	Stem cell research	Insurance
Alabama				
Alaska				
Arizona		✓	✓	
Arkansas		✓	✓	✓
California	✓	✓	✓	✓
Colorado	✓			
Connecticut	✓	✓	✓	✓
Delaware				
Florida	✓		✓	
Georgia				
Hawaii				✓
Idaho				
Illinois			✓	✓
Indiana		✓	✓	
Iowa		✓	✓	
Kansas				
Kentucky			✓	
Louisiana	✓		✓	✓
Maine			✓	
Maryland	✓	✓	✓	✓
Massachusetts	✓	✓	✓	✓
Michigan		✓	✓	
Minnesota			✓	✓
Mississippi				
Missouri		✓	✓	
Montana			✓	✓
Nebraska			✓	
Nevada				
New Hampshire			✓	
New Jersey	✓	✓	✓	✓
New Mexico			✓	
New York	✓		✓	✓
North Carolina				
North Dakota	✓	✓	✓	
Ohio			✓	✓
Oklahoma	✓		✓	
Oregon				
Pennsylvania			✓	
Rhode Island		✓	✓	✓
South Carolina				
South Dakota		✓	✓	
Tennessee			✓	
Texas	✓		✓	✓
Utah			✓	
Vermont				
Virginia	✓	✓	✓	
Washington	✓			
West Virginia				✓
Wisconsin				
Wyoming	✓		✓	

Source: The National Conference of State Legislatures (NCSL). The data used for this table are taken from the NCSL and, in some cases, have not been updated recently. Hence, these data should be seen as illustrative and not as providing a comprehensive overview of all the legislation in this area across US states. For further details see [Appendix S1](#).

laws that govern surrogacy, lack of clear legal regulation in some states over who is the legal parent of children produced from gamete, embryo donation, or both, which creates particular uncertainty for same-sex couples and single women over who has parental rights. This evidence suggests that state oversight of assisted reproductive technologies is incomplete and patchy, leaving the population in some areas with little state level regulation of key areas of assisted reproductive technologies.

One argument to be made is that local areas should be able to legislate for local need and in accordance with local values; therefore, this state-wide variation is not, in itself, problematic. Assisted reproductive technologies, however, are medical treatments that operate across state and national borders, and people will travel out of state if better treatment options are available. About 16% of assisted reproductive technologies cycles in the USA in 2009 were performed on out-of-state residents (Sunderam et al., 2012). This is an issue that affects all countries, and is just as much a problem within Europe. Individuals can always travel to different jurisdictions to access treatments that are not available locally (either due to resources or regulatory prohibition) and, therefore, to a degree, even national legislation can become piecemeal in a global context (Gürtin and Inhorn, 2011). In a country the size of the USA, however, national consistency would be a desirable end.

The final area of oversight of assisted reproductive technologies is through professional regulation. A major plank in this regulation, the ASRM and SART professional codes and guidelines, are essentially voluntarily recommending, rather than enforcing, good practice. Membership of SART guarantees certain standards of practice (following ASRM guidelines, reporting to the CDC, accredited embryology laboratories and staff training standards, for example), but if membership is rescinded owing to non-compliance, clinics may still operate. As mentioned previously, not all clinics report to the CDC. Therefore, a clinic's failure to submit an annual report to CDC does not seem to adversely affect its ability to continue to offer services.

### Consequences of regulatory structure: examples from practice

To illustrate the limitations of the regulatory model in the USA, we will take two examples from practice, reducing multiple births and registers of gamete donors and offspring, to show how the piecemeal and voluntary regulatory structure of assisted reproductive technologies in the USA provides an inadequate mechanism for ensuring the ethical and safe conduct of assisted reproductive technology services.

#### Multiple births

It is widely acknowledged that multiple pregnancies represent the most significant health problem associated with assisted reproductive technology for both mothers and babies (Rebar and DeCherney, 2004). This is a phenomenon largely attributable to the number of embryos transferred in a single IVF cycle. The ASRM first issued guidelines proposing limits

on the numbers of transferred embryos in 1999 (ASRM, 1999), recommending the transfer of no more than three embryos for women aged under 35 years, no more than four for women aged 35–40 years, and no more than five for women aged over 40 years. Following several revisions, the most recent guidance issued in 2013 (ASRM, 2013) recommends that, for women aged under 35 years, consideration should be given to transferring one embryo and no more than two (although the effects of this latest guidance will not be apparent for a number of years). The practice of member clinics is also monitored by SART, and an onsite inspection would be triggered if unwarranted deviation from the national mean of multiple births is evident.

The ASRM argues that an 80% decrease in the number of triplet births between 1999 and 2007 demonstrates the success of this 'self-policing' (ASRM, 2010). Writing over 14 years ago, Jones and Schnorr (2001) argued that: 'It seems clear that the voluntary guideline system in the United States has not solved the problem of multiple gestations,' and we see little evidence that the situation has improved significantly since then. In 2006, transfer of three or more embryos was still common practice in the USA (Centers for Disease Control and Prevention, 2009). In a detailed analysis of the 2009 surveillance data conducted by the CDC in 2012, Sunderam et al. (2012) conclude that more than one embryo was transferred in most IVF cycles for all age groups. The national average for embryos transferred was 2.1 among women aged 35 years and under and 2.5 for women aged 35–40 years. As a result, about 32% of assisted reproductive technologies infants born in 2009 were pre-term, compared with about 8% of pre-term births in the general US population, and 47% were born in multiple-birth deliveries, compared with 3% in the general US population. The twin rate was 43.7%, compared with 3.3% in the general US population, and the rate of triplets and higher-order multiples was 3.6%, about 25 times higher than the general US population rate. Babies born from assisted reproductive technologies contributed to 34.4% of all triplets or higher order multiple births in the population, but only 1.4% of all infants born in the USA were conceived using ART. The authors conclude: 'More than one embryo was transferred per procedure in most states and territories for all age groups, influencing the overall multiple birth rates in the United States' (Sunderam et al., 2012). One study found that at least one-half of the clinicians surveyed would deviate from ASRM embryo transfer number guidelines in certain situations (Jungheim et al., 2010) Hence, it is clear that not all clinics are following the ASRM guidelines, and single embryo transfer (SET) is still not a common treatment option.

Reductions in the number of embryos transferred have been much slower in the USA compared with European countries, where external constraints and regulation have been more stringent (Gleicher et al., 2007). In the UK, for example, policies on the number of embryos that should be transferred were introduced in the form of national, legally enforceable rules (although in a specific case whether the HFEA can make such a reduction a condition of the clinic's licence has been challenged on procedural grounds (England and Wales High Court, 2013)). In 2001, the HFEA, introduced a two-embryo transfer policy for women under the age of 40 years, and only allowed three embryos to be transferred in exceptional circumstances. In 2004, this policy was revised so that a maximum

of two embryos could be transferred to women under the age of 40 years, and a maximum of three embryos could be transferred in women aged 40 years and over. These policies have had an important effect on the triplet rate. By 2007, the triplet rate was 1 in 4975 births, compared with its peak of 1 in 2130 births in 1998 (HEFA, 2013c). In 2009, the HFEA implemented a policy that required clinics to have a 'multiple pregnancy minimisation strategy' to increase the numbers of SET, and clinics have to meet targets for reducing their numbers of multiple births. Following the introduction of this policy, the numbers of elective SET have risen: in 2008, 4.8% of embryo transfers were elective SET, whereas, in 2011, 16.8% were elective SET. Consequently, the multiple pregnancy rate has fallen from 26.6% in 2008 to 20.1% in 2011 (HFEA, 2013a). Belgium also introduced a legal restriction on the numbers of embryos that could be transferred in 2003 (alongside reimbursement of laboratory costs), and this has resulted in a reduction in the multiple pregnancy rate from 27 to 11% (De Neubourg et al., 2013). Concerns have also been expressed over these type of policies (Gleicher, 2011), namely that they could adversely affect pregnancy rates. The most recent figures published by the HFEA, however, do not support this, and the pregnancy rate increased from 2008–2009, and remained steady in the early part of 2010 (HFEA, 2013a).

Centrally imposed elective SET levels are not the only way of reducing the multiple birth rate. Chambers et al. (2013) compared the UK's regulatory structure with Australia that has a multiple birth rate less than one-half that of the UK at 8%, and argue that a higher level of public funding for assisted reproductive technologies in Australia (meaning that patients are more likely to accept elective SET), a lighter regulatory touch and lack of clinic league tables has driven up the elective SET rate (to 70% of cycles compared with 31% in the UK). Chambers et al. (2013) have commented that the financial context of infertility treatment has a substantial effect on the acceptability of elective SET to patients, 'presumably because more affordable treatment reduces the financial incentive to achieve pregnancy in the shortest number of treatment cycles.' In the USA, with the variability of insurance coverage for infertility treatment, the resulting high cost may encourage particular practices, such as transferring more embryos (Hamilton and McManus, 2012). These authors found that insurance mandates (i.e. insurance coverage) for infertility treatment not only increased access but also led to the transferring fewer embryos. Hence, in the USA, such centrally imposed regulation might be an appropriate option in light of the funding structure of treatment with varying insurance coverage for assisted reproductive technologies.

### Donor registries

A further example of difficulties raised by the absence of comprehensive legislation in the USA is the lack of any national registry of those who have used assisted reproductive technologies with donor gametes, embryos, or both, and those born from these techniques. As discussed above, the CDC does not require such information to be collected or collated nationally. A nationally mandated donor registry would enable the collection and storage of information on the donor, such as

how many times they had donated, family medical history, recipients of the donation and details of the outcome of the donation. The ASRM and SART have objected to the establishment of both state and national donor registries in the USA (ASRM Office of Public Affairs, 2012), and criticised a bill proposed in New York, AB 9039/SB 6272 that would limit to 10 the number of offspring any one donor can conceive and create a donor registry in the state. The ASRM argued that scientific evidence does not support the limit of 10, and referenced existing professional guidelines, while maintaining that a single state-based registry would not only be ineffective, but also intrusive (ASRM Office of Public Affairs, 2012).

Despite objections, a number of arguments exist for a national registry. First, such a registry would also allow research into ARTs to track long-term trends and follow up that can be used to increase the safety of the procedures (Basu, 2004; Cahn, 2008; D'Orazio, 2006; Sylvester and Burt, 2007). Second, the establishment of donor registries could be used to formulate appropriate limits on the use of donors, as currently without adequate records of how many times a donor is used it is not possible to provide scientific evidence to establish any evidence-based limits and develop robust guidelines for practice (Sawyer, 2009).

Finally, a national registry could facilitate information exchange. If a system was introduced where donors were required to agree to the disclosure of their identity to any offspring (as it has been introduced, in part, in Washington (Washington, 2011)), then accurate records would be available to facilitate the linking of donors and donor offspring. Although such legislation is unlikely to be retrospective, in the UK those who donated before anonymity was abolished in 2005 can voluntarily apply to the HFEA to re-register as non-anonymous donors. This allows any offspring who might want to find out the identity of their donor to access this information if their donor has taken up this option. This re-registration would not be possible without the national records kept by the HFEA. This presupposes that non-anonymity is deemed to be a desirable way of organising gamete donation. There has been great debate over this, and it is argued that it is unethical to practice gamete donation under conditions of anonymity (Allen, 2012; Tobin, 2012). Therefore, for some commentators, the existence of a national register could facilitate a more ethical approach to gamete donation.

The Practice Committee of the ASRM and SART (2013) have recently issued recommendations for clinics and sperm banks to establish permanent records of donor recruitment and follow-up evaluations. Although this would provide some much needed information on donor use and allow some linkage in the event of reported adverse outcomes for donors or offspring, this proposal falls short of establishing a national registry and achieving the benefits that would accrue from this.

## Discussion

Although the ASRM claim that assisted reproductive technologies are adequately regulated, there is clearly room for greater non-voluntary regulation of this area. A number of objections, however, could be made to these suggestions for increased regulation. First, it has been debated whether such extended legislation, particularly at federal level, would be

constitutional. Jones and Schnorr (2001) say that there seems to be a constitutional requirement that such legislation be enacted at state level. Heled (2010), however, argues that federal legislation is not *prima facie* ruled out by constitutional requirements. Whether legislation on assisted reproductive technologies at federal level would fall foul of the constitution would depend on the detail and scope of the proposals. The Supreme Court recognizes that the federal government can set national health and safety standards (Heled, 2010), and therefore such a possibility of greater federal regulation of assisted reproductive technologies cannot be automatically ruled out.

Second, the legal and political framework in the USA puts a high premium on privacy (Spar, 2005), and establishing a national registry that could track gamete donors and their use could be seen as an infringement of individuals' reproductive privacy (Cohen, 2012). As Spar (2005) notes, state legislation has traditionally exerted authority over reproduction in areas such as contraception and abortion, although there is greater distrust of federal level intervention. However, national data are already collected by federal bodies, the CDC for example. We would argue that, in the case of assisted reproductive technologies, there is value in establishing such a register, and privacy concerns could be addressed by ensuring that the information was adequately safeguarded. It is worth noting that, despite being in existence for a number of years, there has never been any suggestion that the security of data held in such registers in the UK or in Australian states has ever been compromised.

Finally, the cost of such increased regulation might be seen as a barrier. In the UK, the HFEA is funded by a combination of government (Department of Health) funding, about £1.3m per annum, and fees levied on the clinics (HFEA, 2012/13). Currently, clinics are charged £75 for each cycle of IVF they perform and £37.50 for donor insemination with a discount for elective SET (clinics are charged £75 for the first elective SET, after which no charge is made for all subsequent transfers (subject to a small number of exceptions). For every frozen embryo transfer that is not an elective SET, clinics are charged £75 (HFEA, 2013b). Most of the HFEA's costs are met by clinics paying this levy. In 2012–2013, fee income to the HFEA was £3,978,594, with a £778,476 grant from the Department of Health (HFEA, 2012/13). It is important to note that most fertility treatment in the UK is carried out privately (40.3% of IVF treatment was funded by the National Health Service and 59.7% funded privately; with only 17.9% of donor insemination cycles funded by the National Health Service (HFEA, 2013a)) and the cost per cycle is passed on to the consumer either as a specific item on the bill or as part of the general treatment fee. Therefore, in certain respects, the assisted reproductive technology treatment context in the UK and the USA are not as dissimilar as they are for other forms of medicine where, with certain exceptions, the bulk is publically funded in the UK. Any increase in regulation in the USA would incur some financial cost (both to the clinics and to the federal government), raising the cost of treatment, and there would need to be some federal commitment to providing funds to support such a national endeavour. We would argue, however, that this cost would be a small one, and the benefits of a well regulated and safe provision of assisted reproductive technologies would outweigh this.

## Conclusion

In this paper we have argued that existing regulations do not sufficiently regulate assisted reproductive technologies in the USA, as enforceable measures to promote the safe and ethical practice of assisted reproductive technologies is lacking. There have been suggestions within US-fertility circles for how increased regulation might be achieved. Howard W. Jones Jr., a revered figure both in the USA and internationally, together with John Schnorr, argued that one solution would be to create an agency at 'arms length' from government – modelled on the then Voluntary Licensing Authority in the UK – the precursor to the HFEA. Such a body could, in their view, accomplish more effective regulation without government interference (Jones and Schnorr, 2001). They suggested that the National Advisory Board for Ethics in Reproduction, established in 1991 by the American College of Obstetricians and Gynaecologists and the American Fertility Society, could have taken on this role. When this was mooted in the mid-1990s, however, support from practitioners and politically for such a body to be established was lacking and for the NABER to take on this role (Kalfoglou, 2000). The ASRM considered and then dismissed the suggestion to introduce a: 'medical practice act requiring specialists in ART to follow ASRM guidelines,' on the grounds that the area is already sufficiently regulated (ASRM, 2010).

While we recognise that a body like the HFEA or prescriptive national legislation would find little favour in the USA, some form of greater regulation is needed. Greater regulation could ensure that clinics follow ASRM guidelines, comply with federal reporting and certification requirements, and would go some way to ensuring uniformity of practice and maintenance of minimum standards. Greater regulation would also enable better data reporting, ensuring that success rates are more accurately reported and reflect the differences between different patient groups, and a national registry would aid information and data exchange. Any regulatory structure, however, needs to have teeth, and if it is left as a voluntary measure there will always be those who do not comply.

## Appendix: Supplementary Material

Supplementary data to this article can be found online at doi:10.1016/j.rbmo.2014.06.018.

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