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SYMPOSIUM: IVF - GLOBAL HISTORIES

IVF global histories, USA: between Rock and a marketplace

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Abstract The USA has played, and continues to play, a distinctive and significant part in the history of IVF and assisted reproductive technology worldwide. American IVF emerged in the scientific context of contraceptive and fertility research, in the social context of a wealthy nation without universal healthcare, and in the political context of the abortion debate and its impact on federal versus state funding and regulation. IVF had its first clinical success in the USA in 1981. Since then, IVF in the USA has become known for procedures involving third, fourth and fifth parties as gamete donors and surrogates. The USA has also been one of the pioneers in domestic and transnational deployment of IVF for lesbian, gay, bisexual, transgender (LGBT) parenthood, and a pioneer of the social egg-freezing revolution. US IVF has been marked by professional and patient advocacy for such things as the honest reporting of success rates, recognition of the risks of postponed childbearing, and the need for insurance coverage. Certain landmark legal custody disputes over IVF embryos and offspring, as well as media attention to gendered, racialized, and class-based access to and pricing of assisted reproductive technology, have also driven the development of IVF in the USA.

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The beginnings: biomedical research in reproductive biology

IVF in the USA began experimentally in the context of hormone and fertility research from the 1930s onwards. US scientists such as Gregory Pincus, clinicians John Rock and Miriam Menkin, and immigrants to the USA including Min Chue Chang,

were pioneers with mammalian IVF – largely in the context of contraceptive research (Clarke, 1998). Pincus published the first reports of successful mammalian IVF in the mid-1930s (Pincus and Enzmann, 1936). Pincus was joined by MC Chang, who was recruited from Cambridge University in 1945 to join the newly formed Worcester Foundation of Experimental Biology in Shrewsbury, Massachusetts (Chang, 1959). Pincus and Chang, along with Rock and Menkin, would go on to

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become experts in mammalian IVF, paving the way for its eventual success in humans in the UK in 1978, and co-developing the oral contraceptive pill (Eig, 2014).

Although it has subsequently been questioned and may not, in fact, have been achieved until 1969 (Edwards et al., 1969), US researchers claimed, with the publication in 1944 of John Rock's and Miriam Menkin's report in *Science*, to have evidence of human fertilization *in vitro*. Relying on the ready availability of surgically excised ovarian tissue, the article records that Rock and Menkin used 'surgical material available at the Free Hospital for Women' and that 'nearly 800 human follicular eggs' were 'isolated and studied during the course of this investigation; of these, 138 have been observed after exposure to spermatozoa' (Rock and Menkin, 1944). Abortion and contraception were controversial in the 1940s, but the idea of creating human embryos for research had not yet become a front line of public ethical and scientific debate in the USA, and gametes retrieved from surgical 'waste' tissue were not considered to be morally controversial (Morgan, 2009). The *TIME* magazine article that reported on Rock and Menkin's research in the same year (*TIME*, 1944) famously summed up the framing of the public debate at the time in terms of man against nature, and an 'affront to' womanhood and motherhood in the face of scientific reproduction:

Man will never be happy until he has proved that he is at least as smart as nature. One thing he would like to show the world is that he can reproduce himself scientifically. Artificial insemination was one step. He took another step last week, with the first recorded fertilization of a human ovum outside the mother's body. In *Science* last week, Harvard gynecologist John Rock and his assistant, Miriam F Menkin, reported this scientific affront to womanhood.

TIME'S 1944 framing, probably one of many even then, would not maintain its domination. Once IVF became a clinical possibility, the media focused more on fears of monsters and religious objections than on a masculinist scientific mastery of nature, and by the time the sector was well developed, into the 21st century, nature would become as much an ally as a victim of assisted reproductive technology with, for example, IVF coming to be seen as a means of restoring 'natural' reproductive function. The claim of an 'affront to womanhood' was equally short-lived. In fact, US genders and sexualities would have multiplied and changed through their encounters with assisted reproductive technology, with IVF enabling biological parenthood for single individuals, same-sex couples, and trans individuals, thus detaching essentialist elisions between a two-gender (male/female) system, heterosexuality and biological reproduction.

Maverick physician Dr Landrum Shettles, who later became known in another controversial area of assisted reproductive technology, sex selection (Shettles and Rorvik, 1970), and who was based at the NewYork-Presbyterian Hospital, reportedly carried out the first known clinical IVF procedure in the USA 5 years before it eventually succeeded in the UK. Shettles covertly arranged a course of IVF treatment for private patients Doris and John Del-Zio in 1973. The controversial procedure was interrupted prior to embryo transfer by Shettle's senior colleague Raymond Vande Wiele, the Chair of the Department, who objected to it on ethical and moral, as well as legal and professional, grounds (Henig, 2006). Vande Wiele claimed that the procedure violated federal regulations and thus

endangered the hospital's grants, that a resultant child might be abnormal, which might lead to lawsuits, and that the procedure was unsterile. In the first of many US IVF-related lawsuits, the Del-Zios sued the hospital, and eventually won a modest settlement. This case slowed down IVF in the USA, especially NIH-funded research, and it took the successful birth of Louise Brown in the UK to enable US researchers and physicians to resume clinical IVF.

Wife-and-husband physicians Gorgeanna and Howard Jones began to build the first US IVF clinic at the Eastern Virginia Medical School in 1978, buoyed by the news of the world's first successful IVF pregnancy in the UK, and after their official retirement, the Joneses drew on work they had done in the summer of 1965 with Bob Edwards at Johns Hopkins to establish proof of principle for in-vitro human fertilization. They went on to become the doyens of US IVF. Gorgeanna Seegar Jones (1912–2005) was a gynaecological endocrinologist, based at Johns Hopkins School of Medicine. Prior to her role in establishing US IVF, she was already well known for her work on pregnancy testing using placental human chorionic gonadotrophin (HCG), and for pioneering progesterone treatment to prevent miscarriage. Howard W Jones (1910–2015) was a gynaecological surgeon who also spent most of his career at Johns Hopkins (Gosden, 2015). He is known today not only for having established IVF in the USA, but also for having done the biopsy from African American cervical cancer patient, Henrietta Lacks, that led to the immortalization of the HeLa cell line, and for his role in the history of US sex reassignment surgery, having carried out genital feminization surgery upon circumcision injury victim David Reimer, who later committed suicide because of gender dysphoria. In 2010, the year Robert Edwards received the Nobel Prize in Medicine, Howard Jones was honoured by the American Society for Reproductive Medicine. He turned 100 that year (Jones and Crockin, 2010).

The Joneses opened their flagship Jones Institute for Reproductive Medicine at the Eastern Virginia Medical School in March 1980, funded in part by a grateful, wealthy former patient (Jones, 2014). Although the Joneses initially used the Edwards and Steptoe natural cycle protocol that had led to the birth of Louise Brown, they failed to establish any pregnancies prior to the opening of the Institute. Reproductive endocrinologist Gorgeanna Jones decided to try the emerging Australian IVF standard of hormonal stimulation to increase egg yield and to bring the timing of IVF under greater clinical control. Subsequently, most US clinics used hormonal stimulation protocols as the default approach to IVF. On 28 December 1981, Elizabeth Jordan Carr, the first US IVF baby, was born. By the time of Elizabeth Carr's birth, five other women in the USA were pregnant via IVF, four also through the Jones Institute and one at the Los Angeles clinic of Dr Richard Marrs at the University of Southern California Hospital. At least five clinics had opened by this time: in addition to the Jones Institute and Dr Marrs' clinic, Dr Alan DeCherney established a programme at the Yale University Medical School, and two clinics were launched in Texas. US IVF had begun.

Advocacy and research on, about and with IVF accompanied the growth of US IVF itself. For example, since the mid-1980s, feminist scholars have expressed concern regarding the potential exploitation of low-income women working as surrogates, the hyper-medicalization and commodification of reproduction, the ableism implicit in the increased prenatal

screening linked to IVF, and inequities in access along lines of race, class, sexual orientation and family form, disrupting from the start the idea that IVF simply increased reproductive liberty and choice (Asch, 1989; Allen, 1991; Arditti et al., 1984; Corea, 1985; Rothman, 1988; Saxton, 1984). Scholars have also documented the voices and experiences of the infertile in the USA, and the impact of infertility on personal, gender and family identity (Becker, 1997, 2000; Greil et al., 2011; Sandelowski, 1993). Over time, scholars have continued to analyse the racialized, ableist, class-based, heterosexist and gendered organization of assisted reproductive technology as well as its role in challenging heterosexist and nuclear family and reproductive norms (Becker et al., 2006; Bell, 2009; Culley et al., 2009; Mamo, 2007; Quiroga, 2007; Thompson, 2005, 2009). They have also continued to theorize the role of the law and the highly capitalized role of biomedicine in redefining reproduction and the family (Almeling, 2010; Kramer and Cahn, 2013; Spar, 2006).

Similarly, natural scientists, clinicians, industry researchers and university-based researchers in the USA have engaged in research to improve the efficiency and success rates of assisted reproductive technology, to understand fundamental embryology, reproduction and pregnancy, and to leverage the biological potential of the leftover products of IVF. Shortly after the 1973 Supreme Court decision in *Roe vs Wade* made abortion legal in the USA, the US Congress made it illegal to provide federal government funding for human embryo research. Members of Congress wanted to make sure that the government wasn't in the business of encouraging women to have abortions so as to provide materials for research. It was a rockier road setting up the interface between infertility clinics and human embryonic stem cell research in the USA than in some other countries, although private funding and various state initiatives, such as California's Proposition 71, pushed the research ahead (Thompson, 2007, 2008, 2013). Thus, the stipulation against federal funding for research using human embryos has persisted since 1995 as the Dickey-Wicker Amendment, despite numerous national commissions, exemptions for foetal tissue research, the rise of clinical IVF and the stem cell wars. (The text known as the Dickey-Wicker Amendment is at Section 509 of Title V in the Omnibus Appropriations Bill of 2009, signed by President Obama after his repeal of former President Bush's stem cell policy: see <http://www.gpo.gov/fdsys/pkg/BILLS-111hr1105ih/pdf/BILLS-111hr1105ih.pdf>).

The rise of easy-to-use, accurate CRISPR-associated protein systems for gene editing, and the 2015 publication of a scientific paper on human germline genome editing using unwanted, non-viable embryos from IVF, suggest that these complex constitutional relations between the ongoing moratorium on federal funding for research that destroys embryos, IVF and cutting edge biomedical research will continue in the US context (see <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=09142015>).

The social, political and religious context

The abortion debate also shaped the social, political and religious context of the emergence of US IVF. Although many patients and practitioners are secular, it is not uncommon for religion to be evident in US IVF clinics, not only through

its shaping of the abortion debate, but also in the values and practices patients and physicians bring to their treatment (Thompson, 2006). Despite restrictions on embryo research, there is no official national position on the beginning of life in the USA from which to regulate IVF. Catholics and Evangelical Protestants tend to believe life begins at conception, and this view is associated with, although by no means confined to, members of the Republican Party. Many US Anglicans, Muslims, Mormons and Jews, and many secular Americans, consider the beginning of life to be a post-conception version of personhood, based on such things as implantation, foetal ability to suffer, or viability, which might be marked by the development of the primitive streak, quickening, or the ability of a foetus to live outside the mother's body. Scientific facts about embryonic and foetal development, the state of medical care of premature infants, whether or not the pregnancy in question is the result of rape or incest, whether the mother's physical or mental health is at risk, whether there are foetal 'anomalies', or whether there are severe economic stressors, are all factors known to affect people's views on the acceptability of abortion in the USA. Practitioners and intended parents in IVF clinics, regardless of their views on abortion, treat embryos in ways that foreground the embryo's life potential. Restrictions on federal funding of embryo research after the passage of *Roe vs Wade* set the fundamental structure of US IVF, whereby it was not federally funded or specifically federally regulated, but was permitted with private funding in those states with appropriate legislation. This private and devolved picture has continued to this day, with assisted reproductive technology market pricing quickly getting established in permissive states. The absence of public funding has been exacerbated by, and become part of, the unequal access to healthcare. US residents' access to IVF has been stratified from the start by ability to pay. Because of correlations with socioeconomic status, a person's chance of accessing IVF as a form of reproductive assistance in the USA correlates with their race, class, disability and citizenship status, as well as with where they live and their age. In sum, IVF entered the clinical field within a longstanding US history of healthcare disparities.

Another important context was that surrounding adoption. A perceived shortage of US children available for adoption, critiques of the racial supremacy implicit in inter-racial adoption, and increasing barriers to overseas adoption combined with a rise in genetic ways of thinking of parenthood all push the involuntarily childless to seek out IVF rather than adoption. Legal adoption continued to be difficult to access in the USA and abroad for singles and lesbian, gay, bisexual, transgender (LGBT) singles and couples, and assisted reproductive technology offered a means to parenting for different family formations (see Goldberg and Allen, 2012; Simon and Roorda, 2000).

Public reception and debate

The birth of the first US IVF baby, Elizabeth Carr, was announced in the *New York Times* in an article entitled, '*Test-tube' Baby Born in US, Joining Successes Around the World* (Sullivan, 1981). TV stations and newspapers around the nation carried the story, but probably because, as the article's title makes all too clear, the USA was not one of the

very first countries to have an IVF birth, and because the procedure was politically controversial, it did not have the same resonance as the first births in other nations. Now married and the mother of a 'normally' conceived child, Elizabeth Carr Comeau has never had the same kind of household name recognition as Louise Brown in the UK.

The US public reception of IVF had different phases. James Watson predicted at the 1974 Congressional hearings that followed on from the Roe vs Wade decision legalizing abortion that IVF would provoke widespread moral outrage. In the early days of clinical US IVF, the procedure was controversial among US Catholics; for example, Bishop Edward Head of the Roman Catholic diocese of Buffalo spoke against the opening of what would have been one of the first clinics at the State University of New York in Buffalo. Throughout this early period common concerns were the depersonalization of reproduction and the destruction of unused embryos. By the early 1990s, some states were beginning to pass bipartisan legislation allowing for coverage under health insurance schemes for IVF, on the grounds that IVF promoted family building. Later, Protestant Evangelicals and some Republican politicians with whom they were associated would become vocally opposed to embryo research in politically visible ways. Accordingly, they came out in opposition to any form of assisted reproductive technology that destroyed embryos, arguing that each embryo was a unique and precious person and that there are no such things as 'leftover' embryos from IVF. This led, for example, to showcasing children at Congressional stem cell hearings in 2005 born through the Nightlight Christian Adoptions Snowflakes™ embryo donation and adoption programme (<https://www.nightlight.org/snowflakes-embryo-donation-adoption/>).

Over time, class-, race- and gender-drenched stories flared up in the media, including in particular stories about high-profile custody-related lawsuits and clinical errors, and exposés of the exorbitant prices paid for certain kinds of egg donors, IVF-created mega-multiple births, and social egg-freezing 'parties'. In *Calvert vs Johnson* (Cal. Sup. Ct., 5 Cal4th 84, 851 P.2d 776 [1993]), a precedent-setting landmark legal case, the commissioning parents and providers of the egg and sperm for IVF with surrogacy, Filipina American Crispina Calvert and Caucasian Mark Calvert, sought a declaration that they were the legal parents of the baby being carried by African American Anna Johnson, their contracted gestational surrogate. The court concurred with the plaintiff, overruling previous California law that granted presumptive motherhood to the woman who gave birth. This ruling played a part in cementing the concept of 'intentional parent' and making the genetic link more important than the gestational or metabolic one in legal determinations of biological motherhood in the USA.

Over the history of US IVF, errors have periodically made the news. With time, it became more and more important to account for every single human gamete and embryo and for their chains of custody to be accurately recorded and respected, in contrast to the days of Rock and Menkin. In 1995, Dr Ricardo Asch, then Chief of the University of California, Irvine's Centre for Reproductive Health, was accused of retrieving eggs without permission from some women and using them in the IVF procedures of other women, leading to the birth of approximately 15 children to the 'wrong' (genetically unrelated) mother. Fertility drug side

effects, such as ovarian hyperstimulation syndrome, and pregnancy complications, have also plagued the sector. As recently as October 2015, an American surrogate carrying twins for a Spanish couple lost her life due to pregnancy complications.

The advent of IVF dramatically increased multiple birth rates in the USA, causing significant risk to mother and babies, and requiring ongoing expense and care, but also lighting up the news. In January 2009, Nadya Suleman, the so-called 'Octomom', gave birth to IVF octuplets. At first, the media and the public greeted it as a miracle that the babies all survived. It soon transpired, however, that Suleman already had six children and was unemployed; she was excoriated in the media for having more children than she could afford and for taking public assistance. The case shone a spotlight on the risks of IVF without mandatory state or federal embryo transfer rules. Suleman did not want to be pregnant more than once again and she did not want to destroy any of her embryos, and her physician, Dr Michael Kamrava, was willing to transfer more embryos than recommended in guidelines issued by the American Society for Reproductive Medicine (ASRM). Kamrava subsequently lost his medical licence.

Media coverage of US IVF has also played a part in new kinds of gendered embodiment among elites related to relentless pressures to get and stay ahead. By the late 1990s, egg donation clinics and couples looking for egg donors began to offer large sums for the right kinds of donors, targeting elite college campuses. Sums upwards of \$50,000 were rumoured, in exchange for donors claiming the right ethnicity, high SAT scores and good looks, although specific claims cannot be confirmed. In the mid-2010s, following the declaration by the ASRM that egg freezing was no longer experimental (ASRM, 2013), egg-freezing cocktail parties took the nation by storm, as corporations such as Facebook and Apple offered egg-freezing coverage, promising women a rain check on reproduction so as to compete effectively with men in the tech industry (Cussins, 2014).

The current scope of US IVF

Growth of US IVF since Elizabeth Carr's birth in 1981 has been rapid. In 2013, the latest year for which there is full data, there were 467 reporting assisted reproductive technology clinics in the USA. Reporting to the government agency Centres for Disease Control and Prevention (CDC) is mandatory, and the *Fertility Clinic Success Rates Report* from 2013 puts the number of assisted reproductive technology cycles performed in the USA in that year at 190,773, approximately 50% higher than 10 years previously. For the 2014 report, efforts were made to make the data more accurate by accounting for egg and embryo freezing, which can separate egg retrieval and pregnancy by many years. Approximately 1.5% of children born in the USA in 2013 were born via assisted reproductive technology. This masks regional variations, with a high in Massachusetts (4.8%), and a low in Puerto Rico (0.2%) (Sunderam et al., 2015).

This data-rich snapshot of the contemporary scope of US IVF is possible because of the unique history of IVF in the USA. In the distinctive and comparative regulatory vacuum of the USA described above, data collection emerged as a

major policy tool, helping the sector to make the case to and with professionals, patients/consumers and the government that the industry could adequately self-regulate. In 1986, the Society for Assisted Reproductive Technology (SART), a professional society set up for results reporting, began collecting data from member clinics in collaboration with the CDC. In response to concerns about false advertising, and in conjunction with patient activism and the Federal Trade Commission, *The Clinic Success Rate and Certification Act of 1992* [Section 2(a) of P.L. 102–493 (42 USC. 263a-1(a))] was passed, mandating that the CDC collect data on clinic success rates. Since 1997, SART and the CDC have collected yearly data on assisted reproductive technology treatment types and outcomes per cycle, by clinic, state and nationwide, covering over 95% of US clinics. In 2001, the CDC established the States Monitoring ART (SMART) Collaborative, which links state surveillance data on pregnancy outcomes to assisted reproductive technology success rates. In 2002, the CDC published the first assisted reproductive technology surveillance summary, and in 2006, the National ART Surveillance System (NASS) was formed in conjunction with patient advocacy (RESOLVE, Path2Parenthood and Livestrong Fertility) and professional partners (the American Society for Reproductive Medicine and SART).

IVF-related data collection became an area of constant innovation that provided reliable comparative data on clinics to consumers. As the data collection efforts became more sophisticated, they began to make it possible to pose and answer questions that would forge links with public health that in other countries were built in from the start. As well as data on diagnosis, clinic procedure and outcome, the 2006 NASS included data on patient demographics and on multiple births, prematurity and low birthweight. These additional factors provided data for the first time to address social and public health problems of the risks of assisted reproductive technology and unequal access, and to help policymakers effect change, for example through recommendations to reduce the number of embryos transferred and so reduce multiple and low birthweight births. At the time of writing, the SART clinic outcome reporting system database (SART CORS) has been linked in a collaboration with the Massachusetts Pregnancy to Early Life Longitudinal (PELL) data system to make the MOSART database, which will eventually provide access to long-term epidemiological data for women undergoing assisted reproductive technology procedures and the children born through the procedures. Data may not seem like a conventional form of governance, but it has emerged as such in the US context, to an impressive degree.

Paying for IVF

assisted reproductive technology is expensive in the USA for most people, although the cost varies dramatically according to the region and the procedure required. IVF has thus been disproportionately used for wealthier people in the USA, and this manifests in every aspect of the history and current landscape of clinics and debate. In the light of the foregoing discussion of national data collection as a proxy for federal regulation, it is interesting to note that rigorous per cycle and per clinic data is recorded only for the outcome of

procedures and not on cost. Clinic-specific costs and strategies for paying can be found on clinic and patient–consumer websites but they are not part of the national reporting structure.

Per cycle costs of IVF are difficult to estimate but the figure most often cited as typical for a ‘fresh’ cycle (no freezing required) using a couple’s own gametes is around \$8000–15,000, including the fertility drugs and monitoring. Intracytoplasmic sperm insertion (ICSI) adds another \$1000–1500. Third-party involvement usually increases IVF costs considerably. For example, egg donation adds around \$20,000, including agency and legal fees, but can be much higher for desirable egg donor traits. Surrogacy can easily cost more than \$100,000 if legal and medical fees are included, although some US intended parents travel overseas to contract the services of a surrogate to reduce costs. Pre-implantation genetic diagnosis for unexplained infertility and for known carriers of certain diseases adds \$4000–7500 extra per cycle. Egg freezing, although not a treatment *per se*, costs approximately \$15,000 initially, to stimulate the production of eggs and then freeze them, and then up to about \$1000 a year in storage costs to which must then be added the cost of subsequent thawing and IVF. Embryo donation is sometimes marketed as a cheaper option than regular IVF because intended parents do not have to pay for the embryo creation part of the IVF cycle, but given that embryo donation is usually offered after unsuccessful IVF, it also tends to add to total treatment costs.

The insurance picture in the USA is a patchwork. In 15 states some fertility procedures are covered if you have the right health insurance and have opted into the right benefits (Arkansas, California, Connecticut, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Montana, New Jersey, New York, Ohio, Rhode Island, Texas and West Virginia). Of these 15 states, 8 have IVF mandates. These, listed in the temporal order in which coverage was enacted, are Arkansas (1987), Massachusetts (1987/2010), Hawaii (1989/2003), Rhode Island (1989), Illinois (1991/97), Maryland (2000), New Jersey (2001) and Connecticut (2005).

This patchwork leaves those living in states without insurance coverage and those without the right insurance in covered states, with no coverage for IVF. Even within states with IVF insurance mandates, there are exceptions to mandates to offer or cover fertility treatments, such as for small businesses, religious organizations and for the self-employed, and many employers do not offer health insurance at all. In general, the more precarious your socioeconomic situation, the less likely you are to have insurance coverage for IVF (King and Harrington-Meyer, 1997). As ethnographers of US assisted reproductive technology have documented, people have found informal ways of rendering treatment more affordable from its earliest days, by, for example, buying fertility drugs in Mexico or Canada, or by having parts of the treatment and care classified by practitioners under billable codes such as ‘pelvic pain’ (Thompson, 2005).

Caught up with advertising and markets, assisted reproductive technology clinics in the USA have developed a three-pronged approach to paying privately for assisted reproductive technology for those unable to afford up-front out of pocket costs: refunds, financing and low-cost IVF. Refund programmes usually involve buying a package of IVF treatments at a reasonable cost, and if you don’t get pregnant after a set number of cycles, you get your money

back. This financial model is premised on many people getting pregnant in fewer than the paid-for number of cycles. Certain clinics offer low-cost financing specifically for treatment. For example, WINFertilityRx works with clinics nationwide to offer loans for fertility drugs and/or treatments, and is touted for its simple application procedure and the firewall protecting patient credit scores.

Low-cost IVF takes two forms. Some clinics offer discounts to members of certain groups of people such as teachers, military, first responders and low-income couples. For example, Sher Institutes for Reproductive Medicine, which has nationwide clinics, offers free or discounted treatments through its 'Giving Back' programme, and discounted packages for community service providers and those making under \$55,000 a year. The International Council on Infertility Information Dissemination, Inc. (INCIID) runs a limited scholarship fund, with practitioners at given clinics donating treatment to successful applicants; the latter have to apply and have to be deemed worthy and needy (<http://inciid.org/scholarship-faq>). The other kind of low-cost programme involves providing a less medically intensive treatment protocol. Several clinics around the nation offer micro-IVF, or mini-IVF, which includes lower doses of fertility drugs and less monitoring and lab manipulation, but is usually only available to younger patients with no male factor contributing to the infertility.

In general, public funding is meagre. Public programmes such as the federal health insurance system, Medicare, which provides basic healthcare to those living with disabilities (and those over 65, who are not at issue here), covers childbirth and pregnancy but not IVF. State-specific health insurance systems offer emergency and other basic care to low-income individuals, and typically cover some fertility services, especially if medical necessity can be shown, but do not cover IVF. The Affordable Care Act (ACA, the so-called 'Obamacare') does not have to offer IVF except in states where there was an IVF mandate in place before 2012, and where the state benchmark for determining Essential Health Benefits (EHB), such as a Health Maintenance Organization (HMO) plan, includes that mandate. The ACA covers IVF in six states: Connecticut, Hawaii, Illinois, Massachusetts, New Jersey and Rhode Island.

In states with insurance coverage for IVF, age limits vary from state to state. Insurance typically only covers IVF with couples' own gametes, often specifies heterosexual marriage or coupledness, and requires the woman to be under 40 to 45 years of age, depending on the state. While a male intended parent's age is not specified, sperm and egg donors and surrogates all also have to fall within strictly specified age limits, and must be free of certain diseases, tall (for sperm donors), thin (for egg donors) and appropriately motivated and compliant (for surrogates and donors). The proportion of public IVF among the whole is thus tiny; if state-mandated insurance is taken into account, it rises significantly, but still only covers a small proportion of total numbers of assisted reproductive technology cycles.

In summary, the history of US IVF would be incomplete without emphasizing the role that having to pay for IVF has played both in selecting for some kinds of patients over others and in shaping IVF as a medical market. As noted in the section above on the origins of US IVF, IVF in the USA took off using fertility drugs rather than natural cycles, and

has never been an obvious fit for low-stimulation micro-IVF. Nonetheless, in a nation without universal healthcare, and in which medical approaches to involuntary childlessness are not widely covered by health insurance, there is a large unmet need for IVF among those who do not have the ability to pay. It is customary to think of micro-IVF as most appropriate for low-resource countries, and yet its expansion would be invaluable in the USA in improving access and inclusion and reducing eugenic market trends.

Regulation

There are three main kinds of federal regulation of the practice of IVF. First, laboratories are regulated under the *Clinical Laboratory Improvement Act (CLIA) of 1988*; second, the drugs and devices used in IVF are regulated by the Federal Food and Drug Administration (FDA), and finally, the *Fertility Clinic Success Rate and Certification Act* discussed above is implemented by the CDC in conjunction with its partners. In addition, when patients are part of research protocols for drugs or devices, they are covered by federal human subjects' protection. In addition to the Dickey-Wicker Amendment appropriations bill rider that prohibits the Department of Health and Human Services from using federal funds to create or destroy embryos purely for research purposes, many individual states also prohibit embryo destruction and research and set restrictions on IVF.

As mentioned in the section on data collection above, IVF and assisted reproductive technology are also self-regulated through continuous action by and on behalf of patient advocacy organizations such as RESOLVE and professional organizations led by the ASRM. Scholars have explored the consumer subjectivity, self-regulatory rational and market dynamics of the self-regulation of US IVF (Becker, 2000; Spar, 2006; Thompson, 2005). Often working together, patient and professional organizations address ethical, technical and regulatory issues by committee, at annual meetings, in informational booklets and guidelines, in data reporting standards and through the media. This kind of voluntary self-regulation produced by interested parties cannot directly represent the needs and rights of the general public, but perhaps because prospective patients rely on success rates when choosing clinics, compliance with proactive reporting is the overwhelming norm.

Because of the low levels of public funding for assisted reproductive technology and healthcare in general, low levels of federal oversight, regulatory and insurance differences among the states, and abortion and embryo politics in the USA, assisted reproductive technology is widely seen as under-regulated in the USA. This stands in contrast to some European countries, such as the UK, where IVF is sometimes portrayed as over-regulated. The absence of comprehensive federal regulation has had the effect of keeping assisted reproductive technology more accessible to non-low income LGBT and single individuals than is the case in many nations that regulate assisted reproductive technology more systematically. It has also kept many assisted reproductive technology procedures legal in the USA that have been banned elsewhere, such as commercial surrogacy and compensated egg donation. This inclusivity of different family forms and permissiveness of reproductive markets attracts not only US

users but also reproductive tourists from abroad. In general, the USA sends its own reproductive travellers abroad to seek advantageous pricing, and receives reproductive travellers seeking procedures that are illegal or otherwise unavailable in their own countries. The rise of reproductive travel both in and out of the USA speaks of the need for supra-national, cross-border oversight that is sensitive enough to harmonize with very different national settings and IVF regulatory regimes.

What is considered incest?

US views on incest in the context of IVF can be seen in the ASRM Ethics Committee 2012 paper on the subject, *Using Family Members as Gamete Donors or Surrogates* (ASRM, 2012). In this document, no national, community, ethno-racial, sexual orientation-based or third/fourth/fifth-party restrictions in relation to the marital bond are raised. The only kinship relationships considered are mother/father/child/sister/brother/uncle and aunt. The authors separate out genetic and social relationships, and don't consider pregnancy without genetic relationship to be relevant to true incest. They summarize what they consider to be incest in a table, under the headings sperm donation, ovum donation, traditional surrogacy and gestational surrogacy (p. 798–799).

The Committee notes many concerns with intra-familial third-party assisted reproductive technology procedures that they do not define as incest. Thus, they point to the potential for coercion, especially in daughter-to-mother egg donation or surrogacy, and son-to-father sperm donation; age-related risk of increased mutation rates in gametes in father-to-son or mother-to-daughter donation; the risk of undue obligation resulting from mother-for-daughter surrogacy, and the wider effects on familial relationships, such as a sister-to-sister donation meaning that the social aunt is the genetic mother. Incest *per se* is discussed in two kinds of cases. The first are those cases where there is actual 'consanguineous relationship', which they define by the combination of a father's or brother's or son's sperm with his daughter's or sister's or mother's egg, respectively (whether or not the offspring is gestated in the sister's or daughter's or mother's womb). The Committee advises that this kind of incest 'should be prohibited'. Second are the cases where the procedure 'may create the impression of incest', such as when a woman uses donor eggs from a non-relative and donor sperm from her brother to initiate her pregnancy; in this case, that she is carrying her brother's genetic child can give the impression of incest, even though her own eggs were not used. The authors do not conclude that these second kind of cases should necessarily be prohibited, because they consider them to be based on the impression rather than reality of what they consider a consanguineous relationship.

The definition of incest that emerges is thus a genetic one involving a child conceived with the gametes of a sibling–sibling or parent–child pair. From this, it can be inferred that in mainstream US biomedical society, incest is defined narrowly compared with other parts of the world, and is restricted to one or two generations, requires direct or shared biological descent, and is indifferent to the marital status and collective identities of parties to the procedure.

Furthermore, US IVF spokespeople believe actual incest, as opposed to the impression thereof, occurs only when genetic, rather than gestational, ties are too close. This is a national biology that IVF itself has had a hand in creating, through making it possible to separate gestation and gamete provision.

Conclusion

IVF emerged in the USA in a political context marked by three major factors: low levels of federal regulation and a patchwork of regulations for reproductive technologies state by state; the absence of a universal healthcare system; and a politically partisan abortion debate that restricted federal funding for research. These factors together pushed most IVF into the fee-for-service healthcare sector. As a result, market dynamics took hold in US IVF, increasing the products on offer in a manner freer of common restrictions on price, family form or treatable diagnoses than in many other countries. Commercial surrogacy, gamete donation and genetic screening all flourished in the more permissive states, in a modified market form. Over time, new kinds of patient-purchasers such as single and asexual men and women, LGBT men and women, and overseas reproductive tourists joined the original US-based heterosexual infertile treatment population. The sector also became populated with new service providers such as career surrogates and donors, psychologists and IVF finance specialists.

The market growth of IVF in the USA was marked as much by exclusion as by its inclusivity. The market proliferation of IVF led to the circulation and monetization of eggs and embryos in ways that quickly developed price stratification according to hierarchies based on highly desirable traits in contemporary US culture, such as academic and artistic achievement, height in men, and thinness and attractiveness in women. Consumers expected to be able to shop for the procedures and donor traits they desired, and did so in ways consistent with ableist, classist, sexist and racially supremacist ideas of what kinds of children would be most desirable. US IVF, then, has a history marked by this particular mix of inclusiveness and exclusiveness stemming from the factors that contributed to its low levels of federal regulation. Its increasingly strong data collection efforts, and the salience of professional organization and patient–consumer advocacy collaborations with government agencies, have begun to bridge the gap between consumer markets and public health concerns. It remains to be seen whether US IVF can keep some of the progressive aspects of its history alive, such as its openness to changing family norms, while improving access, minimizing health disparities, monitoring public health effects, and acting where exploitation of third parties or excessive selection of gametes and embryos is evident.

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