IVF policy and global/local politics: The making of multiple-embryo transfer regulation in Taiwan

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A B S T R A C T

This paper analyzes the regulatory trajectory of multiple-embryo transfer in in-vitro fertilization (IVF) in Taiwan. Taking a latecomer to policy-making as the case, it argues the importance of conceptualizing the global/local dynamics in policy-making for assisted reproductive technology (ART). The conceptual framework is built upon recent literature on standardization, science policy, and global assemblage. I propose three interrelated features that reveal the "global in the local": (1) the power relationships among stakeholders, (2) the selected global form that involved actors drew upon, and (3) the re-contextualized assemblage made of local networks. Data included archives, interviews, and participant observation. In different historical periods the specific stakeholders selected different preferred global forms for Taiwan, such as Britain’s code of ethics in the 1990s, the American guideline in the early 2000s, and the European trend in the mid-2000s. The global is heterogeneous. The failure to transfer the British regulation, the revision of the American guideline by adding one more embryo than it specified, and the gap between the cited European trend and the "no more than four" in Taiwan's 2007 Human Reproduction Law all show that the local network further transforms the selected global form, confining it to rhetoric only or tailoring it to local needs. Overall, Taiwanese practitioners successfully maintained their medical autonomy to build a ‘flexible standardization’. Multiple pregnancy remains the most common health risk of IVF in Taiwan.

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Introduction

The international medical community has heatedly debated how to regulate the number of embryos transferred in in-vitro fertilization (IVF). Soon after the first so-called test-tube baby, “Louise Brown,” was born in the UK in 1978, the health risks of multiple-embryo transfer for mothers and babies became a concern (Kerin et al., 1983; Muasher, Wilkes, Garcia, Rosenwaks, & Jones, 1984; Wood et al., 1981). In the early years, physicians tended to transfer multiple embryos to enhance the implantation rate (Edward & Steptoe, 1983; Speirs, Lopata, Gronow, Kellow, & Johnston, 1983). This led to an increased incidence of multiple pregnancy, which resulted in increased maternal, neonatal, and pediatric complications (Bronson, 1997; Templeton & Morris, 1998; Wagner & St. Clair, 1989). Several formal regulations began to be implemented. Germany stipulated as early as 1990 that the number of embryos transferred be less than three (Federal Law Gazette, 1990). By 1998, at least nine countries had legislated limitations on the number of embryos transferred (Jones & Cohen, 1999).

Medical professionals and some evidence-based medicine datasets established guidelines to try to achieve a balance between the success rate of IVF and its health risks (Pandian, Templeton, Serour, & Bhattacharya, 2005). Yet the widely discussed controversy has not led to a global standardization. Current policies range from the Nordic countries' move toward elective single-embryo transfer (eSET) to the American Society for Reproductive Medicine (ASRM) guideline, which allows five embryos for women over 40 years old. Great diversity exists.

This controversy has gained little attention from social scientists. When scholars examine assisted reproductive technologies (ART) policy, they focus on aspects of access, kinship, funding, and the market. This rich literature analyzes important issues such as lesbian donor conception, insurance coverage for IVF, gestational surrogacy, and commodification of oocytes, but almost no studies to date have focused on the issue of multiple-embryo transfer. An academic division of labor exists: social studies on ART policy-making concentrate on the social organization of ART use, whereas the medical community debates the details of clinical procedures, such as number of embryos transferred in IVF.

Using Taiwan’s multiple-embryo transfer regulation as a case study, this paper hopes to bridge this division and contribute to
social studies of ART policy-making both empirically and theoretically. The first goal is to incorporate the available conceptual tools from the social studies on ART into the multiple-embryo transfer issue. Previous literature has shown that ART regulations are enormously diverse, comprising a sort of “legal mosaicism” (Pennings, 2009), because they are formed in specific cultural, social, and political contexts. For example, scholars have examined how pronatalism in Israel (Birenbaum-Carmeli, 2004; Kahn, 2000), religion in the Muslim world (Inhorn, 2006), and political culture in Britain, Germany, and the US (Jasanoff, 2005) have shaped ART governance. Drawing on this well-established analytical angle, I show that deciding on the number of embryos to transfer during IVF needs to be understood through the contextually specific regulatory regime, despite the fact that this often involves scientific calculation of risk and benefits via complicated modeling and statistics.

Taiwan, with its extreme practice in multiple-embryo transfer, is an important example. In 1998, the average number of embryos transferred there was 4.07—the highest average in the world, followed by the US and South Korea (International Working Group for Registers on Assisted Reproduction, 2002). In 2007, Taiwan’s Human Reproduction Law limited the number of embryos transferred to less than five. According to the latest survey by the International Federation of Fertility Societies (IFFS), among the 43 countries that regulate the number of embryos transferred either by statute or guideline (Jones et al., 2010), Taiwan’s policy of “four or fewer” is one of most lenient. Explaining Taiwan’s regulatory formation, this paper provides the first social analysis of multiple-embryo transfer policy-making in ART policy literature.

More importantly, this paper develops a conceptual framework for analyzing the aspect of the “global” in ART regulatory formation. While the transnational move of ART use has gained much attention in research (Inhorn, 2003; Inhorn & van Balen, 2002; Inhorn & Birenbaum-Carmeli, 2008; Storrow, 2005), the global travel of ART regulation remains to be explored. Most research discusses ART regulation within the boundaries of a given nation-state. Some pioneering work has investigated how religions as regional factors affect the IVF governance of individual countries unevenly (Inhorn, 2006; Roberts, 2006). However, few studies have systematically examined the role that the “global” or “transnational” plays in ART policy-making. Rules and standards diffuse at different paces and in different formats. For latecomers like Taiwan, growing exposure to foreign policy often becomes reference points, constraints, or resources in generating local clinical standards in ART. Examining this trajectory can reveal the specificity of interaction between the global and the local—an emerging research agenda of ART to which this paper aims to contribute.

Global/local politics of medico-scientific regulation

Several recent intellectual inquiries beyond social studies of ART offer useful insights into the global/local politics of medico-scientific regulation. First, the burgeoning literature on standardization provides an important framework (Clarke & Fujimura, 1992; Timmermans & Berg, 2003; Timmermans & Epstein, 2010). Deciding the number of embryos to transfer is what Timmermans and Berg (2003: 5) categorize as “procedural standards.” This new scholarship emphasizes how standardization is a complicated social act, although often involving the best available scientific evidence and shared scientific findings. To examine the process of building standards, the primary approach is to identify the involved actors, trace the process of inclusion and exclusion, and analyze the interaction among stakeholders. Various studies map how medical professions, governments, scientists, courts, health-insurance companies, and activists take action in building clinical standards, and how their interests and identities influence their arguments, policy preferences, and interpretations of evidence (Castel, 2009; Epstein, 2007; Jorland, Opinel, & Weisz, 2005; Timmermans & Epstein, 2010). A few studies have begun to include the transnational network in the analysis of standardization, pointing out the negotiation between global and local (Dunn, 2005; Geltzer, 2009).

Some science policy scholars further advocate examining the regulatory regime of science and medicine “within a network of global dynamics, rather than regarding them as the products of discrete national histories and debates” (Gottweis, Salter, & Waldby, 2009: 3). This is particularly salient vis-à-vis recent research on human embryonic stem cells, a case in which the global regulatory forces seem stronger than ever (Gottweis et al., 2009; Salter & Salter, 2007). On the one hand, a newly formed global regime of regulation can become prominent in shaping local policy. For example, policy-makers at the national level may refer to the international agreement on bioethics as the guiding principle in local political deliberations. On the other hand, the striking regulatory variations among nations show that national policy-making must be located within a nation’s specific local cultural, social, and political contexts. Scholars have proposed investigating the particularities of a given political system that shapes its regulations, the discursive memory in each society that connects new science with earlier debates, and the trust-building strategies employed during the political persuasion (Gottweis & Prainsack, 2006; Gottweis et al., 2009; Jasanoff, 2005; Prainsack, 2006). Rather than assume an encompassing global force or a pre-existing local path, such an approach investigates the dynamic interactions among international, regional, and local politics.

The research done outside Europe and North America reveals the importance of global—local relationships in analyzing technoscientific governance. How non-Western countries or latecomers interact with existing regulatory practices from pioneering countries or from international organizations is an obvious phenomenon and a “must examine” theme. For example, Greenhalgh (2008) found that China borrowed a particular version of Western population sciences in the 1970s and implemented its one-child policy with specific methods of state planning and party mobilization. And Chen (2009) illustrated how Taiwan implemented the HIV/AIDS harm-reduction policy twenty years after its initiators, and took advantage of being a latecomer to assemble several different methods of policy implementation and create a unique one, by mobilizing various personal international social networks. This scantly but inspiring scholarship presents a contingent and unstable relationship between the global world of scientific governance and other actors, be they the Polish meatpacking industry negotiating with the International Organization for Standardization (ISO: Dunn, 2005); Taiwanese delegates presenting bridging methods in clinical trials during global pharmaceutical regulation (Kuo, 2009); or post-Soviet Russia’s negotiations with the Western origin of evidence-based medicine to redefine its professional position (Geltzer, 2009). The concept of “global assemblage” may best describe the multiple determinations and heterogeneous engineering during recent medico-scientific policy-making (Collier & Ong, 2005; also see Gottweis, 2008).

Built upon the above inspiring literature, I propose here an analytical framework to reveal the “global in the local” in ART policy-making. It is composed of three interrelated aspects. The first is to identify the key stakeholders in the process of creating regulation. Who at different historical periods are included or excluded to make this clinical standard? What is the context that shapes the power dynamics among the involved stakeholders? Second is the selected global form that the involved parties draw upon in policy-making. What kind of available regulatory models are chosen as
the useful reference? What is the contact zone (Anderson, 2002)? What rationale is mobilized to justify the specific international model, and how is it linked (or de-linked) with local narratives (Gottweis et al., 2009)? This leads to the third aspect: the encountering local network. What are the local networks for executing (or not executing) the selected global form? What is the decision-making structure and the power relationships among stakeholders in the space of political deliberation (Jasanoff, 2005)? Examining these three aspects helps us understand the re-contextualized policy assemblage (Collier & Ong, 2005). The theoretical contribution of this paper consists of this framework for analyzing the regulation process within the local—global dynamics of ART policy-making. This framework will then allow us to examine the case of Taiwan.

Data and method

The research design was born of a broad project on IVF (Wu, 2011). I conducted three waves of research on IVF development in Taiwan, in 1999—2001, 2006—2008, and 2010—2011. I first learned how embryo transfer proceeded in the earliest fieldwork of one IVF center in Taipei, and through interviews with IVF personnel from different centers. My understanding of multiple-embryo transfer politics grew with this IVF project. However, focus on the multiple-embryo transfer controversy in Taiwan began in 2006, and intensified between 2010 and 2011.

The data for the following analysis included archives, participant observations, and in-depth interviews. Combining through archival data and fieldwork, I adopted multi-sited ethnography to trace various stakeholders' standardizing and regulating activities (Marcus, 1995; Rapp, 1999), including relevant actors' opinions of media releases, public education, arguments and testimony during public hearings, discussion during regulatory meetings, negotiating processes with other actors, and proposed solutions. Since regulating activities occur at different sites, I followed these activities through different methods. Archival data used to follow these activities included newspaper databanks, newsletters of related organizations, conference discussions, academic research, and governmental documents. One important part of this research was to search for “the global.” This part of the data included searching major medical journals via keywords such as “multiple-embryo transfer,” reading publications from ART organizations such as IFFS, and examining national and regional ART policy reports.

I interviewed 23 relevant actors about their practices of multiple-embryo transfer and participation in policy-making. Historical archival research helped me identify the important actors in standard-building processes who either voiced their opinions on this issue or participated in regulating activities. I then tried to reach as many of them as possible through purposive sampling and snowball sampling. The interviewees included three government officials, fourteen IVF specialists and technicians, two NGO activists, one legislator, one journalist, and two scholars of bioethics. Four of them served on the governmental advisory committee, and three were Taiwanese Society for Reproductive Medicine (TSRM) presidents. I also attended conferences, annual meetings, and continuing education programs held by TSRM to learn how the medical community discussed this controversial issue.

Most research institutions in Taiwan, including the institution with which I am affiliated, did not have Institution Review Boards (IRB) for social science studies when I conducted this research project; hence I utilized the protocol of the Common Rule of the U.S. Office for Human Research Protections in the Department of Health and Human Services as a model of international research ethics. Because the project involved interviews, the participants’ identities were anonymously coded, and the data analyzed did not involve information that could place participants at risk of any criminal or civil liability or damage their financial standing, employability, or reputation, but fell within the category that is exempted from IRB review according to the Common Rule (45 CFR 46.101(b)(2) exemption from 45 CFR part 46 requirements). Despite this exemption, I obtained written consents and informed all participants of the purpose and procedures of the research, their right to withdraw from the interview, and the techniques of maintaining confidentiality.

These in-depth semi-structural interviews lasted between 30 min and 2 h, with average of 1 h. All interviews were recorded and fully transcribed, except four that were summarized with detailed notes and verbatim quotations. Interviews focused on their regulatory participation experiences, including their understanding of the multiple-embryo transfer controversy, regulatory activities, encounters with other stakeholders, and their use and understanding of international models.

Archival data, interview transcripts, and field notes were read and coded to identify the major themes. The main analytic focus was to explore global—local dynamics in ART policy-making in the historical change. I first identified the stakeholders in regulating multiple-embryo transfer in different historical periods, found the global form that these actors drew upon, and analyzed the local network that worked with the global form, in order to understand the resulting regulation outcomes.

“First” discourse and IVF

In 1985, Taiwan’s first test-tube baby, “Baby Boy Chang,” was born in the Taipei Veterans General Hospital. The event remained headline news in all the major newspapers for an entire week. Since the 1970s, gaining international visibility through “Asia First” medical achievement had gradually become of Taiwan’s national “sociotechnical imaginaries” (Jasanoff & Kim, 2009: 120). IVF thus became a new way to demonstrate national power by achieving medical miracles in the early 1980s. The timetable for Taiwan to achieve a “test-tube baby” became more and more urgent after successful cases in Singapore and Japan. Newspaper editors advocated developing IVF to “elevate Taiwan’s status in the world” and warned against Taiwan being seen to “lag behind” (Li, 1982). This “medical achievement for national development” imaginary therefore prompted IVF investment in Taiwan.

“First” discourse also helped transform IVF from a potentially controversial technoscience into a glorious innovation in Taiwan. Like many third-world countries, Taiwan had started its population control policy in the mid-1960s, so in the early 1980s, promoting ART could still be viewed as against the national interest. When the dean of Taipei Veterans Hospital promoted IVF as the organization’s ambition, he skipped the issue of population policy and used the rhetoric of “pursuing something first in Taiwan” (Chang & Ng, 1999). “Something First” became a useful strategy for IVF promoters to use to mobilize expensive hospital resources, from recruiting experts who had trained abroad to gaining access to capital-intensive lab operations (Doctor L interview 2011).

However, soon after the excitement of “Baby Boy Chang,” several tragic cases revealed the risks of multiple pregnancy. In the initial stage, doctors in Taiwan, like their international counterparts, tended to transfer more embryos to increase the implantation rate. More and more twins, triplets, and quadruplets were born, facing serious health problems. In 1988, quadruplets were born at Chang-Geng University Hospital; three of them weighed less than 1500 grams each, and two relied on medical technology to breathe (Anonymous, 1988). Dr. Soong responded to the quadruplet controversy in a newspaper:
Multiplets are the new problem that new reproductive technology brings. Due to the immaturity of current technology, the only way to increase the success rate is to implant more embryos. (Soong, 1988)

Yet the risk of having twins, triplets, or quadruplets was far outweighed by the need to counter the relatively poor results of IVF. Although these tragic events were reported in the media, they stirred only a little discussion. Other proudly announced cases dominated newspaper headlines on IVF: “Taiwan’s First IVF Twins, Taiwan’s First Gift Baby, Taiwan’s First IVF Quadruplet,” and even “World’s First IVF Case Combining the Method of Zona Cutting and Cryo-Preservation” (Chang et al., 1991). This “First” discourse thus minimized the controversial aspects of multiple births during this period of “catch-up.”

The British model as a rhetorical tool

Multiple pregnancy became more and more common in Taiwan as the egg retrieval technique was stabilized, the fertilization rate increased, and the number of embryos available to transfer increased. According to the first national statistics report in Taiwan, between 1985 and 1993, 51% of IVF cycles were implanted with four or more embryos, which led to one in every four live births being multiplets (Yuan, 1995). IVF specialists in Taiwan started to offer some techniques to manage the risk of multiple pregnancy, including “fetal reduction” and “frozen embryos,” but did not solve the problem of multiple pregnancy. Freezing embryos took time for IVF centers to learn and stabilize. Fetal reduction has its own risk of miscarriage. The need for legal regulation of the number of embryos transferred began to be voiced.

The British model emerged as an example for Taiwan to follow. Britain’s 1990 Human Fertilization and Embryology Act (HFEA) was one of the earliest formal regulations of ART in the world. The first edition of its Code of Practice limited the number of embryos transferred to three or less. Although Germany and some Australian provinces also had statutory regulations, it was the British model that was most often raised in Taiwan as the policy option, in part because it was the model most widely reported in the English medical journals and mass media (Journalist W Interview 2011). Some newspaper reports in Taiwan exemplified the British regulation as an ideal from the advanced countries (Chang, 1994; Yuan, 1995). The very existence of statutory regulation on embryo transfer, at least in Britain, inspired some Taiwanese IVF experts to support regulation. For example, Dr. Tzu-Yao Lee, a pioneering infertility specialist at National Taiwan University (NTU) Hospital, criticized the high incidence of multiple births and asked for standardization (Lee, 1995).

Governmental regulation of IVF in Taiwan did start early, but none of the early official rules addressed the issue of multiple-embryo transfer. The first regulation was established in Taiwan in 1986, one year after the birth of “Baby Boy Chang.” Called “Ethical Guidelines for Practicing ARTs,” it specified that ART be made available to infertile married couples and be operated by qualified medical personnel, and prohibited the commodification of sperm and eggs. To offer advice on IVF practices, an advisory committee was established composed of eleven members, six of whom were doctors. In 1994, “Regulations Governing ARTs” provided more detailed measures but included no regulation on number of embryos. An accreditation system was established in 1995 to certify IVF centers through governmental evaluation of lab standards. Cryopreservation—the preservation of eggs, sperms, and embryos by freezing techniques—only counted 3 points in a total possible score of 125, and number of embryos transferred was not even among the evaluation criteria.

This early absence of multiple-embryo transfer regulation in Taiwan shows that the British model served as a rhetorical tool but hardly as a model to actually follow. Taiwan lacked most of the policy elements that had forced the British government to regulate. No religious groups or anti-abortion groups in Taiwan voiced their concern over the status of embryos (cf. Franklin, 1997; Inhorn, 2003). The specialty of bioethics was not formed in Taiwan until the twenty-first century (cf. Jasanoff, 2005). Legal experts and social scientists were involved with ART, but they tended to focus on the “social” aspects, leaving the “technical” ones to the medical experts. Most importantly, the government left the territory of clinical procedure to medical professionals. When responding to the media’s questions about potential regulation like the British model, governmental officials emphasized the “fast-changing” character of ART, and regarded formal regulation as inflexible to this innovative technology (Chang, 1994). An official I interviewed promoted the self-regulation model:

The number of embryos transferred is related to doctors’ clinical judgment. Cases are diverse and each judgment differs. Law, such as limiting with a specific number, is rigid; once it is stipulated, if we want to make changes, it has to undergo a lot of procedures. It is better to leave the judgment to doctors themselves. (Official M Interview 2011)

Overall, in the 1990s, no stakeholders in Taiwan exerted pressure to regulate the number of embryos transferred.

The medical community in Taiwan preferred no regulation on clinical procedures. Leading IVF experts did voice concerns about multiple pregnancy, but favored the technical solutions of perfecting the skills of cryopreservation or improving the quality selection of embryos. They also stressed the limitations of regulation, stating that it could not prevent multiple pregnancy caused by ovulation-induction drugs (Chang, 1994). Their policy suggestions avoided the imposed standardization of clinical procedures found in the British model. The decision-making structure in Taiwan in this period also strengthened medical professionals’ autonomy in IVF. The advisory committee in Taiwan, as well as the officials in charge, were all under the Department of Health, in contrast to Britain, where the HFEA committee was an independent organization. The HFEA required diverse expertise and laypeople (Johnson, 1998), whereas in Taiwan medical professionals dominated the committee. Therefore, Taiwan lacked a regulatory regime via which the British model could be executed.

The “American model plus one”

The first international statistics on IVF found that Taiwan had implanted the highest number of embryos in the world (International Working Group for Registers on Assisted Reproduction, 2002). This 1998 report showed that the average number of embryos transferred there was 4.07, and that 66% of IVF cycles involved four or more embryos. However, this worldwide distinction was not reported in the Taiwanese media and did not trigger public debate. Instead, the Premature Baby Foundation of Taiwan (PBFT) emerged as a new actor to throw light on the controversial aspects of multiple-embryo transfer.

PBFT found that the increasing numbers of premature babies in Taiwan came from twins and triplets following IVF treatment. The proportion of IVF babies who were twins, triplets, or other multiplets increased from 30% in 1992 to 55% in 1996—twice that of the US. In 1998 in Taiwan, 43.2% of live births through IVF were of infants weighing less than 2500 g, classified as premature babies (ROC Department of Health, 2000). Parents of premature babies caused by multiple-embryo transfer expressed their suffering to PBFT. PBFT began to respond to the media reports on the
increasing births of multiplets, overtly criticizing some IVF practices in Taiwan.

To address the increasing concern, the Taiwanese Society for Reproductive Medicine (TSRM) took two initial steps: education and informed consent. Seminars and continuing education classes were held to recommend that doctors implant an appropriate number of embryos. This included a 2002 seminar that the PBFT director co-chaired with TSRM President Kuo-Kuang Lee. TSRM also offered new information about the increasing risk of multiplet and premature babies on the official informed consent form for ART. In addition, President Lee recommended that TSRM members consider the guidelines of the American Society for Reproductive Medicine (ASRM).

By the late 1990s, the ASRM guidelines were the most lenient of all the regulations around the world that limited the number of embryos transferred. Increasingly heated discussions had taken place in leading medical journals (e.g., Ozturk & Templeton, 2002; Templeton & Morris, 1998), and some articles had provocative titles, such as “Who’s afraid of single embryo transfer?” (Coetsier & Dhont, 1998). The UK had already limited the number of embryos implanted to three per cycle, and in 1998 the British Fertility Society further recommended that “it should be the usual practice to transfer a maximum of two embryos” (Murdoch, 1998: 2669). ASRM offered a more lenient guideline in 1998, and a revised one in 1999, specifying that if the maternal age is over 40, a maximum of five embryos could be transferred; if aged 35–40, a maximum of four embryos; and if less than 35 years old, it should be two to three (Stern et al., 2007).

Why did the ASRM guidelines appeal to TSRM? Compared to statutory regulation, a voluntary guideline has the advantage of retaining medical autonomy while demonstrating professional responsibility. Other medical societies, such as the British Fertility Society, also offered guidelines, but TSRM preferred the American ones. Doctors interviewed offered the following rationales. First of all, the US is a superpower in terms of technological innovation. Following the American guideline thus cannot be wrong.” Second, the American guideline adds a variable—the mother’s age. Doctors believed that this would increase their autonomy to make clinical decisions. Third, by the mid-2000s, the US guideline was very similar to what most Taiwanese doctors practiced, so most did not have to change their clinical behavior to follow it. Fourth, among all the countries with regulation and guidelines, “Taiwan is most similar to the US” (Doctor N Interview 2011).

Here “similarity” refers to the two countries’ lack of health-insurance coverage for IVF and their offers of IVF treatment on the free market. One opinion leader explained:

Taiwan is much like the US. We are very similar. Both do not offer health-insurance coverage for IVF. Consumers can choose IVF in the market. Those European countries offered health-insurance coverage, so they could afford to limit the number to one or two. We should pick a country that is similar to us to follow. (Dr. N interview 2011)

Taiwan and the US may not be that similar. Some US states, such as Illinois, require mandated insurance coverage for IVF (Reynolds, Schieve, Jeng, & Peterson, 2003). Taiwan and the US also differ in terms of geographical space and degrees of competitiveness—factors that affect clinical decisions on the number of embryos transferred, but ones that are seldom highlighted by policy-makers.

It was Taiwanese doctors’ affinity for the American model, rather than the similarity of the two IVF systems, that guided TSRM to ASRM. The familiarity of Taiwanese IVF experts with the American situation started from their early training in IVF. Most pioneering Taiwanese IVF specialists learned IVF in the hospital labs at the University of Southern California or University of Rochester (Doctor L Interview 2011). In the initial period, some Taiwanese-Americans helped several Taiwanese hospitals build up IVF centers, strengthening the link between Taiwan and the US. Taiwanese doctors also learned IVF skills from the UK, Australia, France, Japan, and Singapore, and attended conferences held by the IFFS and European Society of Human Reproduction and Embryology. Still, they most regularly attended the annual meeting of ASRM, selected a US university lab in which to learn new skills during their sabbatical years, and reported on their American experiences in the TSRM newsletter or national newspapers. Taiwan’s affinity for the American IVF model reflects its continuing dependence on the US since the Cold War period in terms of knowledge acquisition. This affinity extends to policy borrowing in the regulation of embryo transfer.

TSRM announced its own voluntary guidelines in 2005: two or three embryos for women 35 years old or younger; three or four for women 35–40 years of age; and for women 40 years old or more, doctors could implant five or more embryos. The guideline followed the recommendations of the revised 2004 ASRM guideline, but overall with one more embryo for each age group (see Table 1). Several doctors termed it the “American model plus one.” One doctor who became involved with the guidelines explained the result:

The overall pregnancy rate in Taiwan looked good, but it was uneven: some centers were good, and some were bad. It is also at the expense of implanting multiple embryos. Our one- or two-embryo implantation rate was still low. Some members still lacked the skill to get a good pregnancy rate with few embryos. If we gave a strict guideline, we were afraid that it would work against some members’ interest. We would be badly complained about. (Doctor L interview 2011)

Dr. L pointed out the emerging enterprise culture at that time. IVF has moved from a technical competition for “First” status in the 1980s to market rivalry for good business in the 2000s. The number of government-accredited IVF centers rose from 25 in 1997 to 65 in 2001. IVF centers expanded from the medical centers in metropol-itan Taipei to private clinics in other parts of Taiwan. For newcomers particularly, the risk of IVF failure remained a major concern.

Table 1

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<th>ASRM embryo transfer guidelines</th>
<th>TSRM embryo transfer guidelines</th>
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<tr>
<td><strong>Publication date</strong></td>
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ASRM – American Society for Reproductive Medicine; TSRM – Taiwanese Society for Reproductive Medicine.
Considering the need of some IVF centers to raise their success rate through higher numbers of embryos transferred, TSRM further expanded the lenient American guideline when forming a standard.

**Standardization by statute: interpreting the global trend**

When the Taiwanese Department of Health first drafted the Human Reproduction Law, regulation of the number of embryos transferred was not included, nor was it contained in two later drafts provided by legislators. It was the legislator Shu-Ying Huang, a feminist activist, who in 2006 proposed adding a regulation that would limit the number of embryos to “no more than four.” Her written proposal emphasized the risks of the fetal reduction technique to women’s health, and listed the regulations from Belgium, China, Germany, Japan, Sweden, and Switzerland. All these countries have legislated three or even fewer embryos for transfer during IVF. Legislator Huang and her women’s health movement team took advantage of global communication technology to collect international data. They stressed during the congressional meetings that the Nordic countries, Belgium, and the Netherlands have moved to single-embryo implantation. Then she presented the local statistics: the pregnancy rate for implanting three embryos was 22% in 2002, the rate for four was 35%, and the rate dropped to 15% when five were transferred (see Graph 1). Legislator Huang proposed “no more than four” as a balance between protecting maternal and infant health and maximizing the local success rate of IVF.

Despite the fact that the global trend in IVF was to limit the number of embryos to three or fewer, local practice in terms of pregnancy rate was presented as the most important criterion when considering the extent of limitation. “No more than four” was a compromise for Legislator Huang, considering the dilemma she faced in attempting to protect women’s health. That dilemma was to calculate the health risk caused by fetal reduction and repeated IVF. After she learned of the local low success rate using just one or two embryos, she could not just copy the European trend without considering the local situation. Gauging the multiple risks women might face, Legislator Huang chose to limit the number of embryos transferred based on the performance of local practice. Lack of health-insurance was another local practice taken into consideration in the legislature. Asked about the possibility of using single-embryo transfer, Dr. Szu-Yuen Chen, the invited expert for legislation, responded:

The above-mentioned countries that require one embryo at one time have health-insurance coverage, so they can absorb the burden of failure. However, most of the countries in the world do not offer health-insurance coverage.

Dr. Chen linked the single-embryo transfer to insurance coverage to explain why it wasn’t feasible to implant just one embryo at a time in Taiwan. However, what Dr. Chen described was more the Belgian model, or the case in some Nordic countries, than an accurate global picture. This is a widely discussed practice in international medical journals. Half of IFFS-reporting countries offer at least partial insurance coverage (Jones & Cohen, 2007). Some countries (such as Israel and France) offer generous coverage without official regulation of the number of embryos transferred, while others do not have any national insurance coverage (such as Switzerland and Canada) but require three or fewer embryos transferred. Although the association between regulation of the number of embryos and third-party payment is complicated, a particular image of the global trend was given to justify the permissive regulations in the local proposal before the Taiwanese legislature.

“No more than four” did not encounter any objection in the arena of legislation and soon became part of the drafted Human Reproduction Law. As I investigated this story, I found that the powerful statistics that Legislator Huang relied on were inaccurate, due to badly presented governmental data. The Y-axis on Graph 1 was mistakenly labeled “Percentage of live births” by the Bureau of Health Promotion; it should be “Percentage of total live births,” and it would be better presented as a pie-chart, since all the percentages would then add up into 100% (ROC Department of Health, 2005). If we look at the success rate for each number of embryos transferred—the statistics Legislator Huang would have liked to quote—we find that in 2003 the live birth rate was actually highest when six embryos were transferred (see Graph 2), which was also listed on the annual government report of ART practices.

None of the legislators, governmental officials, or IVF experts pointed out Legislator Huang’s inadvertent use of misleading governmental data. This may be because “no more than four” happened to be the best compromise among various stakeholders. For Legislator Huang, a legal enforcement was imposed on doctors. For doctors, “four or fewer” meant a flexible standardization. After all, in 2007, the year the legislation passed, only 13.1% of IVF cycles in Taiwan were implantations of five or more embryos (ROC Department of Health, 2008). Therefore, despite the fact that “no more than four” came from a misrepresentation of data, it paradoxically fulfilled the diverse interests of stakeholders, and resulted in a consensus on statutory regulation.

The heterogeneous “global” encountering the changing “local”

Table 2 summarizes the regulatory trajectory of multiple-embryo transfer in Taiwan, within the analytical framework of global/local dynamics. In different historical periods the specific stakeholders selected different preferred global forms, such as

**Graph 1.** Governmental statistics cited by legislator Huang.

**Graph 2.** Percent (%) of live births by number of embryos transferred in 2003.
Britain’s code of ethics in the 1990s, the American guideline in the early 2000s, and the European trend in the mid–2000s. The “global” is heterogeneous. The configuration of these selected global forms depended on the encountering local network. The British model could serve at most as a rhetorical tool for early dissenters because strong pressure had not yet emerged in Taiwan as it had in Britain to limit the number of embryos transferred; moreover, the Taiwanese decision-making structure in IVF regulation favored doctors’ autonomy on clinical procedures. When pressure did increase in Taiwan, the American voluntary guideline became a useful policy template for TSRM to use to balance between the need for self-regulation and market competition. When Taiwanese legislators included number of embryos transferred in the 2007 Human Reproduction Law, the international trends acted as only to justify legal enforcement, while local statistics became the crucial criterion for specifying “no more than four.” The failure to seriously consider adopting the British regulation, the revision of the American guideline by adding one, and the gap between “no more than four” and the cited European trend all show that Taiwan required a local network as a re-contextualized assemblage in order to execute (or not execute) the introduced global model.

Overall, Taiwanese IVF practitioners successfully maintained their medical autonomy within the process of regulation of ART. No regulation on number of embryos transferred existed until 2005. IVF doctors had little need to change their clinical procedures in the face of either the TSRM guideline or “no more than four” legal enforcement. They managed to build a flexible standardization. Although some literature argues that “loose standards with great adaptability may work better than rigidly defined standards” (Timmermans & Epstein, 2010: 81), the result in this case is that the number of multiple births has not changed much since the stipulation of “no more than four.” In 2008, among 2265 live births following IVF, 34.4% were twins and 1.1% were triplets (ROC Department of Health, 2010), only slightly lower than the previous years. Multiple pregnancy remains the most common health risk of IVF in Taiwan.

Conclusion

This paper is the first attempt within the social sciences on ART to analyze the formation of multiple-embryo transfer regulations. Taking Taiwan as a case study, it demonstrates how specific sociocultural-political contexts shape the ways to standardize a clinical procedure. The medical world has debated the controversy of multiple-embryo transfer for more than thirty years, and the dispute continues even today. The international medical community has conducted surveys to understand the varieties of practice, worked on the technical (and sometimes economic) model to find solutions, and published reflective commentaries in medical journals to call for reform. Social scientists have much to contribute to a better understanding of this controversy, including systematically probing the shaping of regulation, just as they have done on other emotional and conflict-filled ART issues.

Exploring a latecomer’s regulatory path, this paper further argues the importance of conceptualizing the global/local dynamics in ART policy-making. The conceptual framework it proposes is built upon recent literature on standardization, science policy, and global assemblage. This framework suggests that we analyze the power relationships among stakeholders and the dynamics between selected global form and the encountering local network in order to understand the re-contextualized assemblage. This approach has guided this paper’s inquiry into the making of multiple-embryo regulation in Taiwan, and illuminates the specificity of interaction between global and local. The global in this case is neither an advanced ideal to copy nor an encompassing force to follow. Due to easy visibility or favored affinity, various stakeholders presented diverse global forms at different stages. The local network further transforms the selected global form, confining it to rhetoric only or tailoring it to local needs. The analytical framework presented here may be most revealing for latecomers, who often turn to international regulatory models for inspiration. Yet it might be useful when analyzing forerunners as well. For example, Franklin (1997: 86–87) argues that the British Parliament limited the use of commercial surrogacy in the 1980s in part because the general public resisted the “Americanisation” of Britain under Thatcher. More cases need to be investigated to enrich our understanding of the role that the global has played in ART policymaking.

The most recent action on multiple-embryo transfer regulation in Taiwan is worth a final note. At the annual meeting of TSRM in 2010, Dr. Kuo-Kuang Lee, the former TSRM president, gave a keynote speech on higher-order multiple pregnancy since the 2007 regulation. He did not talk much about the global trend but focused on a sophisticated analysis of local data and evaluation quite unseen in past debates. Dr. Lee then offered the guideline of the hospital he works at in order to propose a gradual move toward elective single-embryo transfer (eSET) for women under 35 years old. This is the most demanding proposal in Taiwan to date. Although its implementation remains to be seen, the effort to go beyond the permissive 2007 statute and work on a strictly voluntary guideline may provide a new contextualized assemblage for this controversial procedural standard. As doctors in Taiwan begin to produce their own statistics, their resulting deep reflexivity about the local practice of multiple-embryo transfer may paradoxically move Taiwan closer to the global trend.

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