

CONNECTING WORLDS:
HOW DO PROFESSIONALS MAKE SENSE OF AN INSTITUTIONAL
CHANGE AND HOW DO THEY INSTITUTIONALISE NEW KNOWLEDGE?¹

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Abstract

The aim of this paper is to answer the question as to how a practice spreads and how technological change can be understood using a practice-based approach rather than a technology-based one. By means of the case study of assisted reproduction we have sought to contribute to two debates ongoing in the organization studies community: the diffusion of an innovation and the institutionalization process, both traditionally conceptualized in terms of the S-shaped curve model. Contrasting with these model is our conceptualization of innovation and institutionalization process in terms of distributed agency and institutional work.

Key words: practice, institutional work, knowledge

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Introduction

Decisions on questions such as when life begins and ends are delicate ethical matters for any state which must deliberate on laws concerning abortion, euthanasia, and research on stem cells. Such decisions mobilize very different knowledge bases: from ethical judgment, which regards biopolitics, to medical scientific knowledge and that of other professions conducting research in the life sciences. The institutional field that sustains medical practices around issues so crucial for individual freedom and collective ethics is an interesting case with which to understand how new practices are institutionalized and how previous ones are de-institutionalized. Given the rapidity of innovation in scientific and technological knowledge, and the constant legislation on these matters, institutional work can be analysed in its production (as institutions are created and stabilized) and in its reproduction cycle (what the stabilized institutions ‘do’).

In this article we shall treat medically assisted reproduction as a practice field subject to strong institutional pressures (a recent Italian law limits medical practices) which normalize the technological practices of the professions involved in the process, and on which there is extensive cultural debate on how to redefine the institutions regulating knowledge within that field of practices. To give a concrete example of how this field of practices is in search of a definition that stabilizes it, one may consider how ‘medically assisted reproduction’ is defined. If it is a response to infertility problems, it is medical knowledge which is mobilized because infertility is defined as an illness, and couples which request medically assisted reproduction are exercising their right to health. Vice versa, if it is defined as a technology to support reproduction, other institutional instances come into play and pose the ethical question of whether there exists a right to have children, and whether this right can be guaranteed by the state for all citizens. Ethics and the politics encounter each other on the cultural plane and on that of mobilization of legitimation claims (Suchman, 1995; Suddaby and Greenwood, 2005) in support of more or less conservative positions (especially in a strongly Catholic country like Italy).

By means of longitudinal search in the field, we have analysed how enactment of a law restricting medical practices has exerted coercive power (and an isomorphism) on organizations and professions, and how, because of the institutionalization of a restrictive conception of medically assisted reproduction, change has taken place in the technological practices of professionals.

While rational interpretative models explain the occurrence of a technological change on the basis of the presumed technical superiority of the innovation and support the S-shaped curve of innovation diffusion (Powell and DiMaggio, 1991; Rogers, 1995; Strang and Tuma, 1993), a reading of technological change based on practice theory highlights the institutional dimension which stabilizes a new technological practice within a field of practices, doing so through institutional work simultaneously oriented to change and to stabilization.

The article is organized as follows. It first conducts a practice-based reading of institutional work in order to outline the theoretical-interpretative framework of the empirical research. It then describes the research context in order to illustrate

and subsequently discuss the institutional mechanisms that explain how a technological change is stabilized in the practices of medically assisted reproduction.

1. Practice theories and institutional work

Organization studies are currently witnessing the rediscovery of the sociological concept of social practice and a flourishing of practice-based studies (Corradi, Gherardi and Verzelloni, 2008). Nevertheless, a single practice theory has not yet been developed, and the conception of what constitutes a ‘practice’ varies according to the researcher’s position in regard to activity theory, ethnomethodology, actor-network theory or workplace studies. In this article we adopt a conception of ‘practice’ based on the definition given to the term by Rouse (2002: 161), who stresses that practices become institutionalized and habitual, and therefore argues that practices should be analysed, not simply as regularities or commonalities among the activities of social groups, but rather as being characterized in terms of the normative accountability of various performances.

While the first definition leads to the domestication of practice-based studies, in that practices become equated with activities and their productive endeavour, the second definition, to which this article intends to contribute, makes it possible to signify both our production of the world and the result of the production process. Practices are not only recurrent patterns of action (level of production) but also recurrent patterns of *socially* sustained action (production and reproduction). What people produce in their situated practices is not only work but also the (re)production of society. In this sense practice, is an analytical concept that enables interpretation of how people achieve active being-in-the-world. A practice is not recognizable outside its intersubjectively created meaning, and what enables the competent reproduction of a practice over and over again and its refinement while being practised (or its abandonment) is the constant negotiation of what is thought to be a correct or incorrect way of practising within the community of its practitioners, and within the larger society and its institutions. A practice is such when it is recognized as a habitual and institutionalized way of doing something. That is to say, it is sustained by a normative network of actors and inter-organizational connections through which that practice become normatively supported and sanctioned.

The interest for a sociology of practice is also evident in the concept of ‘institutional work’ which has recently renovated institutional studies (Lawrence and Suddaby, 2006). These two authors define institutional work as intelligent, situated institutional action, and ‘a practice perspective highlights the creative and knowledgeable work of actors which may or may not achieve its desired ends and which interacts with existing social and technological structures in unintended and unexpected ways’ (Lawrence and Suddaby, 2006: 219). On this definition of the practice perspective, it is important to bear in mind that the (intentional) actions of actors may also have unintended and unexpected effects. In our view, however, in the institutional studies surveyed by Lawrence and Suddaby the volitional dimension which privileges the intentional action of actors does not fit well with a

practice theory. In fact, if we recall the distinction drawn by Ira Cohen (1996) between theories of action and theories of practice, we may say that whilst the former theories privilege the intentionality of actors, from which derives meaningful action (in the tradition of Weber and Parsons), the latter locate the source of significant patterns in how conduct is enacted, performed or produced (in the tradition of Schutz, Dewey, Mead, Garfinkel and Giddens). Hence theories of practice assume an ecological model in which agency is distributed between humans and non-humans and in which the relationality between the social world and materiality can be subjected to inquiry. Whilst theories of action start from individuals and from their intentionality in pursuing courses of action, theories of practice view actions as ‘taking place’ or ‘happening’, as being performed through a network of connections-in-action, as life-world and dwelling. This conception of practice as epistemology is well represented in actor-network theory (Gherardi and Nicolini, 2005), and it entails analysis of the institutional work associated with institutionalization rather than institutions as reified social structures (Tolbert and Zucker, 1996). From an actor-network perspective the stable elements of institutions are a relational effect (Law, 1992) stemming from a field of associations between human and non-human elements, and institutional work may be seen as a process of aligning or of heterogeneous engineering of materials, or a bricolage where creativity and improvisation are resources at hand to reconfigure courses of action and institutions.

We therefore propose a normative conception of practice and an ecological model of analysis, inspired by actor-network theory, in order to interpret the institutional work that leads to enactment of a law regulating medically assisted reproduction, to the stabilization of the practice of the latter, and to the de-institutionalization of the previous practice. To this end, we shall consider institutional work not as a linear process (creating, maintaining and disrupting institutions) but as a cyclical one in which actors engage in institutional work in order to produce institutions and institutions which – once stabilized – reproduce themselves. In this way we will analyse at the same time the institutional work performed by actors and the institutional work performed by the circuit of reproduction of practices. Bourdieu (1972) speaks of ‘circuits of reproduction’, i.e. the reciprocal, cyclical relationships through which practice creates and recreates the objectified social structures and the conditions in which it occurs. At this analytical level the researcher asks: what is it that doing the practice does? And it is the level at which ethical questions can be asked and at which the emancipatory or exploitative effects of a social practice may be questioned.

2. Research design

The research began with analysis of the public debate prior to enactment of law 40 of 19 February 2004, and it continued until the referendum on abrogating the law held on 12-13 June 2005. It was then resumed in 2007 when the new set of practices could be considered stabilized, and when the first empirical evidence – including the data published by the Ministry of Health in its annual reports on implementation of law 40 – on how the technological practice used for assisted reproduction had changed since the law came into force.

A first step of the research consisted mainly of analysis of press reports and public documents, as well as 25 interviews with key informants. Then, in order to analyse the medical practices of the professionals and to document ongoing changes, three ethnographic studies were conducted at the main types of assisted reproduction centre: a public clinic, a private one, and a network of associated clinics. The fieldwork lasted for three years, during which analysis was made of the practices of the two professional communities most closely involved in assisted reproduction, and description was made of how practical knowledge and tacit coordination were learned by the clinical teams (Perrotta, 2008a, 2008b, 2008c).

The analysis of the institutional work which mobilized legitimation resources in negotiations on the new practice is now described, with particular emphasis on the mechanisms that stabilized the new practice (redefining interpretive categories, mobilizing technology, standard creating), and then the de-institutionalization process enacted to destabilize the previous practice. However, before illustrating the institutional work done by the actors in the field and the institutional work done by the new institution, is necessary to illustrate what the medical practice was before law 40 and by what mechanisms the law exerts coercive power on the medical professions of gynaecologists and biologist, and on the organizations in the field.

3. Assisted reproduction before law 40/2004

In this section we describe the activities that constituted the practice of assisted reproduction prior to law 40, in order to show how the law intervened to modify it, and how and with what resources the professionals resisted the law and translated it into a new practice.

Assisted reproduction consists of successive phases in which the patients, and above all the women, undergo various kinds of clinical examinations and treatments. Table 1 illustrates the practice prior to law 40 step by step.

Step 1: producing oocytes

The first phase of the process begins when a couple is deemed suitable for treatment and the female partner is subjected to pharmacological stimulation of the ovaries in order to induce the simultaneous maturation of several follicles and to obtain the largest possible number of oocytes. In this phase, the bodies of the patients are disciplined by pharmacological intervention and constant medical control. Their natural biological rhythms are adjusted to those of the treating organizations by means of body medicalization practices which make it possible to organize the work and to plan the harvesting of the oocytes.

Step 2: harvesting the oocytes

The second phase is that of harvesting the oocytes. This is done in the operating theatre with local anaesthesia and deep sedation. The content of all the follicles (which are usually numerous owing to the ovarian stimulation) is aspirated, and the liquid extracted is examined in the laboratory for the presence of the oocytes.

During the oocyte harvesting, or immediately afterwards, the male partner is asked to produce a specimen of seminal liquid, which after suitable preparation is used to inseminate the oocytes.

Step 3: fertilizing the oocytes

When the oocytes arrive in the laboratory they are treated by means of two different techniques: IVF (In Vitro Fertilization), the most frequently used technique, first introduced in 1978, in which oocytes and spermatozoa are put in a test-tube together with a specimen of the seminal liquid for 'natural' fertilization to take place; ICSI (Intracytoplasmic Sperm Injection), is a more recent technique introduced in 1991, with which the biologist injects a single spermatozoon into the oocyte using a micromanipulator needle. When the oocyte has been fertilized and placed in a culture (i.e. an environment for its incubation), there begins the process that may produce an embryo and which is, as we shall see, crucial for answering the question of when life begins.

Step 4: producing the embryos

During the first 16 hours after contact between the oocyte and the spermatozoa, the oocyte's features remain unchanged; 16 to 24 hours later, however, the oocyte displays two distinct pronuclei (ootids or pre-zygotes). Then after 24 to 36 hours it becomes a cell with a diploid nucleus (46 chromosomes) originating from the fusion of the female gamete with the male one (zygote). Finally, after 36 hours, the cell division occurs (blastocyst or embryo).

Step 5: transfer of the embryos

Around 48-72 hours after the oocyte harvesting, some of embryos obtained are transferred to the uterus (to avoid the risk of multiple pregnancies), while any surplus ones are cryoconserved for re-use in subsequent cycles (so that the patient does not have to undergo further cycles of ovarian stimulation and oocyte harvesting).

Step 6: unfreezing and/or disposal of surplus embryos

The embryos produced which are not transferred to the uterus are cryoconserved to be unfrozen and re-used for the subsequent cycles. When patients instead no longer wish to procreate, the embryos are donated to research on stem cells, to other couples, or disposed of.

This description of the assisted reproduction process depicts the everyday practice of reproduction centres in many countries – and of those in Italy until February 2004. The meaning of the practice substantially centred on assisted reproduction as a medical technology to increase the likelihood of fertilization (Chelo, 1992). After enactment of Law 40/2004, the outcome of intense political debate on the value of human life and on the embryo's equivalence to a person, the conception of assisted reproduction and work practices at the Italian centres underwent major changes, as we shall see in the next section.

4. The trajectory of the law and its institutionalization effect

Law 40/2004 was the result of institutional work by numerous political and social actors which mobilized to intervene in the previous practice, and which deployed resources to support diverse proposals for change. The first resource deployed was

the public and scientific debate which sought human, institutional and organizational allies, as well as ‘scientific evidence’ in support of contrasting ideological positions.

The debate on the ethical and moral aspects of assisted reproduction was extremely heated, with radically opposed ethical, moral and religious stances being taken up. On the one hand, the Catholic front – highly influential in the Italian debate – proposed that restrictions should be imposed on therapeutic treatments by virtue of the moral argument that an embryo is not only a life-form but also a person. On the other hand, there were those who argued (and were accused of scientism) that it was necessary to go beyond biological limits to adjust reproductive capacity to the life-choices typical of contemporary society.⁴

The most striking example of this latter perspective is provided by the ‘pioneering’ work of Severino Antinori, a controversial obstetrician and gynaecologist, who in 1989 had also begun to experiment with the *in vitro* fertilization of women with non-precocious menopause. In 1994, in fact, with Antinori’s help, a 63-year-old woman was impregnated and became the oldest child-bearer in the world. The media sensation caused by Antinori’s achievements, together with futuristic visions of human cloning, were cited in the public debate as examples of a “test-tube Wild West”. In this cultural climate, problematization (Callon, 1986) began of what is meant by ‘assisted reproduction’. Allies were enlisted in support of diverse ethical positions, and resources were mobilized to support the legitimacy of conflicting arguments. Thus produced was the cultural and political context in which the state could intervene to regulate what had previously been within the jurisdiction of the professions.

Law bill 40/2004 – the most restrictive in Europe on assisted reproduction – was put forward as necessary to remedy the lack of specific legislation on the matter, and to counter the risk that ‘improper’ use might be made of these technologies. However, this official justification for the legislative initiative ignored the accords previously reached by the institutional actors active in the institutional field of assisted reproduction.

In fact, as early as 1985 a ministerial circular (no. 55/1985) had forbidden assisted reproduction treatment at public centres for single persons, unmarried couples, and homosexual couples, heterologous fertilization, and the creation of embryos for therapeutic purposes or for research,. Instead, in the case of private centres, given the absence of specific legislation, in 1992 the CECOS Italia association (www.cecos.it) had drawn up a self-regulatory code which guaranteed the right of infertile couples to have children but also protected the future rights of neonates. According to this code (art. 1), artificial reproduction techniques could be used on heterosexual, married, or stably cohabiting couples of fertile age (the maximum age for the woman was 51). Some reservations were expressed concerning the use of spermatozoa and oocytes obtained from donors external to the couple, and the use of cryoconserved sperm was expressly prohibited after the partner’s death. The maximum number of transferable embryos was four (art. 13), the

⁴ In fact, higher female education levels, together with a huge increase in labour-market entry by women and a lack of care services, have led to a drastic reduction in Italy’s birth-rate and to postponement of pregnancy almost to the age of 40.

cryoconservation of embryos was allowed, and the manipulation of embryos was permitted for diagnostic and therapeutic purposes.

Moreover, the Code of Medical Ethics (*Codice di Deontologia Medica*, the final version of which was approved by the Italian general medical council in July 1995) had prohibited all medical practitioners working in the public and private sectors from using four specific fertilization techniques (art. 41): surrogate motherhood of any kind; insemination of homosexual couples and singles; insemination after the partner's death; and the insemination of women in non-precocious menopause.

Finally, an ordinance issued by the then Minister of Health in 1997 "prohibited the publicizing and sale of human gametes and embryos". This demonstrates that the practice of this institutional field was negotiated among the state, professionals belonging to different associations, and public and private organizations; and therefore that an agreed regulatory system was already in force. In the terms of DiMaggio and Powell (1983), coercive isomorphism was at work among all the actors in the field even before the law, but this limited the jurisdiction of the professionals and their associations and had the unexpected effect of producing a change in technological practices.

Law 40/2004 not only forbade surrogate motherhood of any kind, the insemination of homosexual couples and singles, insemination after the partner's death and of women in non-precocious menopause; it also prohibited heterologous fertilization (i.e. with gametes from donors external to the couple), the production of more than three embryos per cycle, the cryoconservation of embryos, and the performance of pre-implant diagnosis. And it ordered that all the embryos produced must be transferred to the uterus even if they were potentially malformed. It therefore changed steps 3 and 4 of the previous practice.

The law, in support of its coercive effect, stated that breaches of its provisions were to be punished with imprisonment for up to 6 years and a fine of up to € 150,000 for operators, as well as immediate closure of the centre.

By equating the embryo with a person, Law 40 made its rights prevail over those of the mother. It was widely discussed and criticised in regard to both its ethical and clinical aspects. Scientific procedures were paralysed, while the clandestine market and the search for assisted reproduction in other more permissive countries were stimulated (Benagiano and Gianaroli, 2004). There developed around these criticisms a broad political movement which mobilized public opinion for some months (open letters written by Italian and international scientists against the restrictions imposed by the law, petitions, newspaper articles, etc.) and led to a referendum to abrogate the law⁵ – which was not successful, however, because the quorum was not reached.

Coercive isomorphism results from both formal and informal pressures exerted on organizations. Such pressures may be felt as force, as persuasion, or as

⁵ The four referendum questions concerned abrogation of the provision on: a) the restrictions set on clinical and experimental research on embryos; b) the obligation to fertilize a maximum of three oocytes, to implant all the embryos produced without eliminating any of them, and the prohibition on freezing embryos; c) the article granting an embryo in the initial stage the same rights as a neonate; d) the prohibition of heterologous fertilization.

invitations to join in collusion (DiMaggio and Powell, 1983: 150). Among the coercive pressures at work in this institutional field were those emanating from government mandate, resource interdependence, state-sponsored legitimacy, and more overt or subtle political processes.

5. The stabilization of a new practice

The restrictions introduced by Law 40/2004 were incorporated into the complex texture of the work practices of assisted reproduction centres, and they led to stabilization of a new practice through three different mechanisms – *definitional work*, *mobilizing technology*, and *creating a practice standard* – which are now described.

5.1 Definitional work

The first reaction of the operators at the reproduction centres to the prohibition on freezing surplus embryos was to redefine the categories of their practice. They questioned the notion of ‘embryo’: when can a fertilized oocyte be considered an ‘embryo’ and therefore as constituting life and a person?

The prohibition on cryoconserving embryos meant that patients had to undergo ovarian stimulation for every cycle of treatment. To avoid this restriction, in the first months after enactment of the law some scientists, drawing on their professional authority, proposed an intrinsic distinction between embryo and pre-embryo. Mobilizing their professional authority, they thus proposed not a legal, but a medical interpretation of the law which enabled them to circumvent its provisions. In order to legitimate the freezing of the pre-embryo or the selection of potential embryos, the professionals cited the practice of professional communities in countries like Germany and Switzerland. They therefore allied themselves with professional authority on the one hand, and with semantic ambiguity on the other.

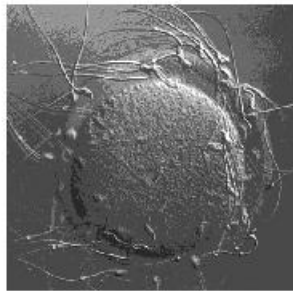
In fact, the term ‘embryo’, though widely used within and without the scientific community, is not the correct one in the language of biology, which calls the fertilized oocyte divided into several cells as a ‘blastocyst’. The biological nomenclature, however, is often set aside in reproduction centres, where the technical language of biology is little used. It is replaced with a simpler and more comprehensible language in order to communicate with personnel external to the laboratory (doctors, nurses, anaesthetists, and so on) and with patients. Often used, therefore, is the generic expression ‘fertilized oocyte’, and especially ‘embryo’ as a commonplace term.

However, the use of ‘embryo’ in the legislative sphere in particular has assumed fundamental significance in the bioethical debate on the question of when life begins. In fact, depending on the point of view, the various stages of embryo development can be used to ‘establish’ when life begins, at least in public debate. The main positions on the beginning of life can be summarized thus:

- the moment when the oocyte and the spermatozoon come into contact;
- the disappearance of the two pronuclei in the zygote, which indicates that fusion between the male and female elements has taken place.



Oocyte



Oocyte and sperms



Fertilized oocyte



Two cells embryos

The position implicitly expressed in law 40/2004 adopted the first interpretation. It therefore viewed the contact between the gametes as the beginning of an unstoppable process that would lead to the birth of a child. The interpretation proposed by many scientists was instead that the embryo should be seen as a zygote, and therefore as a cell with a single nucleus (of 46 chromosomes) in which the fusion between the male and female gamete had already taken place. This interpretation therefore left leeway for negotiation and the redefinition of categories through creation of the so-called ‘pre-embryo’ (or ‘pre-zygote’) – that is, an oocyte fertilized less than 36 hours previously. The practical calculation of the 36 hours pertained to laboratory organization, and therefore to medical jurisdiction and the opacity of the times of practice.

The creation of the pre-embryo – symbolic in nature and linguistically justified in opposition to the law – had high material significance for work practices, because the distinctive feature of the pre-embryo was that it was not subject to the same restrictions imposed by the law on embryos. In other words, it was not technically forbidden to freeze pre-embryos. The professions thus asserted their jurisdiction and opposed the coercive pressures applied by the state.

However, the attempt to negotiate by redefining categories was subsequently blocked by ministerial circulars and guidelines establishing that, although Italian law made reference only to ‘embryo’, the restrictions also applied to the pre-embryo, since it had clearly been the intention of the legislators to protect potential ‘life’ from its beginning: namely the moment of encounter between oocyte and spermatozoon.⁶

In this negotiation on the ‘constitutive rules’ (Scott, 2001) it is apparent that these latter were intended to prohibit and to constrain institutional action, but they were

⁶ Interestingly, the same argument was put forward by the Pontificia Accademia per la Vita in a statement on the sale of the so-called “day-after pill” published in the *Osservatore Romano* on 1 January 2000: “Whilst for the purposes of scientific description it may be useful to distinguish, using conventional terms (fertilized ovum, embryo, foetus, etc.), different stages in a single growth process, it can be never permissible to decide arbitrarily that a human being has greater or lesser value (with a consequent fluctuation in the duty of protection) according to the stage of development that s/he has reached”.

also “directed toward establishing the parameters of future or potential institutional structures and practices” (Lawrence and Suddaby, 2006: 222).

In this institutional field, the attempt by the professions to overcome the restrictions imposed by the law through defining work failed because the coercive pressures of the state, allied with large part of public opinion and contrary political parties, were able to use force. The professions then resorted to another ally by mobilizing technology.

5.2 Mobilizing technology

One of the most striking effects of the new law was a change in technological practices. But this was also the mechanism that stabilized the new post-law 40 practice by anchoring it in the materiality of everyday routine and in the professionalism of the biologist. To understand how this happened, it is necessary to reconstruct the steps of the practice.

After the prohibition on embryo freezing, the only therapeutic option for limiting the cycles of ovarian stimulation dangerous to the woman’s health was freezing the oocytes. Even before the law, cryoconservation of oocytes (and of gametes in general) was an option available to couples. But above all it was a possible therapeutic option for patients who had to undergo therapies (e.g. chemotherapy) invalidating from the point of view of fertility.

However, until 1997 there were few reports of children born from cryoconserved oocytes. The post-unfreezing survival and fertilization rates long remained low, because the exposure of the cell egg to the cryoconserving agents and the variation of temperature to which they were subject could damage its cellular structure. According to the ministerial report for 2006,⁷ although the results showed some improvement, they were still poor if compared with the cryoconservation of embryos: 49.7% of oocytes survived unfreezing against 75.5% of embryos; pregnancy percentages of (calculated on the number of embryo transfers) were equal to 17% in embryo unfreezing cycles as opposed to the 12.6% of oocyte unfreezing. Finally, the spontaneous abortions occurring in oocyte unfreezing cycles amounted to 31.3% compared with 18.1% for cycles with embryo unfreezing.

Because the technique was still underdeveloped, few centres acquired the equipment necessary for the cryoconservation of oocytes. According to the same ministry report, in 2006, in 80 centres out of 184 (43.5% of the total) there had been no oocyte freezing, while in another 40 centres (21.7%) oocyte freezing had been performed in no more than 10 cycles, and only in 20 centres (10.9%) had the ceiling 50 oocyte freezings been exceeded. At centres where this technique was not used, surplus oocytes (i.e. all those produced in excess of the three that could be inseminated according to the law) were discarded: in particular, during 2006 38.8% of harvested oocytes were inseminated, 12.9% were cryoconserved, and 48.3% were discarded.

⁷ *Relazione del Ministero della Salute al Parlamento Italiano sullo stato di attuazione della legge contenente norme in materia di procreazione medicalmente assistita (Legge 19 Febbraio 2004, n. 40, articolo 15) – Anno 2007 – issued by the Ministry of Health on 30 April 2008.*

Considering that a woman (above all if young) stimulated with hormones can produce more than 20 oocytes per cycle (with an average of 6.8 gathered for each harvesting effected in 2006), the magnitude of the problem becomes evident, not only for the patients that must undergo further stimulation cycles but also for the operators at the reproduction centres.

In fact, one of the questions which arose after the law was how to select the three oocytes to inseminate: that is, how to choose those with the greatest likelihood of fertilization.

Of the oocytes produced by the patients, selection was usually made of the most mature ones, and therefore at the ideal stage for fertilization. Although there is no formalized knowledge on the morphological characteristics indicating the greater or lesser likelihood of fertilization, various centres developed selection strategies often linked with the sensory knowledge (Strati, 1999) of the operators, who developed criteria based aesthetic categories which enabled them to choose the 'best' three oocytes. For example, one of the biologists interviewed during the empirical research described the characteristics to evaluate when selecting oocytes thus:

“you look at the cumulus oophorus cells, which must be arranged in a radial pattern: in English it's called 'the spread', I mean, it's spread out like when you take an egg and drop it in a frying pan.

The oocyte's appearance must be clear, mature, and this gives the image of the so-called 'sunburst', therefore of a radiated column.

The cumulus is expanded, the cells are clear and well-defined”.

This is therefore a case of an innovative practice and the production of practical knowledge in action. Defining these morphological characteristics and not others as central to identifying good-quality oocytes and the correct degree of maturation is, in fact, an example of learning-by-doing, in this case developed as a refinement of previous knowledge.

But the prohibition on inseminating more than three oocytes interweaves with the choice of the type of technique to use. While with IVF, in fact, the oocyte is not treated, in the case of ICSI the oocyte is 'cleansed', and in this way it is possible to identify the maturation phase more exactly. Hence, in the case of IVF the biologists use the morphological appearance of the cells, their arrangement, and their colour to obtain information on their state of maturation, but they do not have certainties. In the case of ICSI, the cleansing of the oocyte instead enables them to be more certain about an oocyte's state of maturation, and therefore select the best oocytes.

The fact that it is necessary to cleanse the oocyte from surrounding cells in order to perform an ICSI, and that this gives greater certainty about that oocyte's degree of maturation, means that the law allies itself with this technique and becomes another contextual reason for preferring it to the IVF in an increasing number of cases.⁸

The marked increase in the use of the ICSI technique has been highlighted by both ministerial reports and by data in the medical literature. The 2007 Ministry

⁸ For details on the technological change from IVF to ICSI see Perrotta 2008a.

Report⁹ expressly acknowledges that the percentage of use of the ICSI technique probably reflects application of law 40: “The law forbids the freezing of embryos and requires the transfer of all the embryos produced, defining a maximum number of three transferable embryos. These restrictions entail the impossibility of fertilizing more than three oocytes so as not to produce more than three embryos. To be expected in this context is the greater use of the ICSI technique to increase the likelihood that oocytes will be fertilized” (p. 67).

Studies on data for individual centres likewise confirm the greater frequency of ICSI compared with the period prior to the law. They also explain its use as deriving from the possibility to identify the three best oocytes to inseminate (Ragni et al., 2005). Indeed, they advocate its use in all cases as a ‘remedy’ for the restrictions imposed by the law (Levi Setti et al., 2005), although international studies have stressed that ICSI has no advantages with respect to IVF – in terms of clinical results – for couples whose infertility is not due to the male factor (Van Steirteghem and Collins, 2003).

In fact, ICSI was introduced in assisted reproduction laboratories in 1991 as a solution for serious problems of male infertility and as a possible alternative to the donation of external gametes to the couple. By using a single spermatozoon, ICSI enabled fertilization of an oocyte even in severe cases of azoospermia, that is, an absence of sperm in the semen, because it could be aspirated directly from the epididymus or testicle.

Over the years, however, ICSI was employed in an increasingly large number of cases, and today the percentage use of ICSI largely outstrips that of IVF (respectively 76.5% and 23.5% in 2006). Although the change from IVF to ICSI was already in progress (ICSI was already being used in 65% of cases in 2003), Law 40 changed technological practices especially in terms of the normative accountability of various performances. In fact, the law’s provision that only three embryos can be produced, and therefore that only three oocytes can be fertilized, has produced not only a shift in recurrent patterns of action (between 2003 and 2006 the use of ICSI rose from 65% of cases to 76.5%), but especially in the recurrent patterns of socially sustained action. In fact, professionals reacted to the law by changing their practices of accountability for the choice of technique. As one of the biologists interviewed explained:

“The law prohibits the production of more than three embryos, but you can’t do all this work and risk not getting even one. If you take three oocytes and do IVF, it may happen that none of them is fertilized, especially if the woman is of a certain age. From this point of view, ICSI gives a lot more certainty”.

An accountability based on the greater reliability of this technique with respect to the restrictions imposed by the law therefore explains why, according to the data in the ministerial report for 2006, not only has there been a further percentage increase in the use of ICSI but 42 centres out of 184 (22.8%) have decided to use

⁹ *Relazione del Ministero della Salute al Parlamento Italiano sullo stato di attuazione della legge contenente norme in materia di procreazione medicalmente assistita (Legge 19 Febbraio 2004, n. 40, articolo 15) – Anno 2006 – issued by the Ministry of Health on 28 June 2007.*

solely the ICSI technique, even though some studies have shown that the indiscriminate use of this technique has a serious impact on the work schedules of laboratories and on medical resources (Devroey and Van Steirteghem, 2004).

As evinced by the excerpt from the interview with the biologist, the restrictions imposed by the law have not only favoured the new technique with respect to the old one but they have created a practice standard.

5.3 Creating a practice standard

Institutional work, inasmuch as it defines work, is stabilized when collective and individual actors are able to embed the negotiation within standard practices (Lawrence, 1999; Brunsson and Jacobsson, 2000). What is often observed in industrial work occurs in this field as well: the maximum amount becomes the minimum standard (Roy, 1969).

When the Law 40/2004 came into force, it forbade the production of more than three embryos, but it did not forbid to produce fewer than three. In their everyday work, however, all laboratories opt for insemination of all three oocytes allowed by the law (if they have been produced), thereby constructing a new standard. In the words of the director of one of the centres studied:

“The law says a maximum of three; it doesn’t tell you to produce three of them, but a maximum of three. But those who do this work know full well that after you’ve done a cycle of ovulation stimulation to produce two embryos, if those two embryos aren’t inseminated, you’ve done everything for nothing”.

Inseminating two oocytes (or even only one) may in fact mean not having a single embryo to transfer. Whilst prior to the law, the ethical code and various codes of private associations like the CECOS established four as the maximum number of transferable embryos, this was considered a valid option only in extreme cases. The tendency was to produce the largest possible number of embryos in the first cycle, freeze them, and transfer only one or two of them at a time. If three embryos were transferred instead of two, there was an increased likelihood that one of them would implant itself and lead to pregnancy. But it also had to be borne in mind that transferring three instead of two embryos leads to higher percentages of gemellary pregnancy, which in some cases might be dangerous to the health of the patient and jeopardize the lives of the unborn children.

The introduction of the law raised the average number of embryos implanted for every cycle and consequently increased the number of gemellary pregnancies – as shown by the figures reported by the *Relazione del Ministero della Salute* for 2006: overall, 50.9% of transfers were performed with three embryos, 30.4% with two, and 18.7% with only one.

6. The de-institutionalization of the old practice

Institutional work in which all actors are engaged does not consist solely in the creation of a new institution and its maintenance, but also and simultaneously in the de-institutionalization of the negotiated order which previously regulated relations and sustained isomorphic practices (Oliver, 1992). In this institutional

field, in fact, it was not sufficient to let the old practices fall into disuse, so that abstaining from them or doing them differently produced their de-institutionalization. On the contrary, it was necessary to take action to resolve an ethically controversial issue. What was to be done with the embryos produced before the law and which every centre had kept in storage? How could the principle of equating the embryo with a person, and therefore guaranteeing it the same rights, be applied retrospectively to the already-existing embryos?

In Italy, in fact, there are today around 31,000 cryoconserved embryos stored in what are often called “orphan embryo banks”. Some of these embryos will be used by the aspiring parents in further attempts to obtain a pregnancy. But what will happen to those belonging to couples who have already had children and do not want any more? Or in cases where the couple does not intend to procreate further for some reason (separation, adoption, age)? In this case, the law states that the embryos produced and frozen before its enactment must be kept in their actual state at the expense of the couple, or they must be abandoned.¹⁰ Couples are therefore required to pay for the maintenance of their own embryos (the costs relative to the cryoconservation of embryos vary from centre to centre, but they range between 500 and 1000 euros a year), or they must sign an abandonment form with which they lose all rights over the embryos. Instructions have not yet been issued on what is to be done with abandoned embryos, which are currently awaiting conservation in a national biobank. What is certain is that other options – such as donation to other couples or for research purposes, or disposal, which represented 77% of choices (see step 6) before enactment of the law (Cattoli et al, 2005) – are now illegal.

Although expressions like ‘orphan embryos’, ‘abandoned embryos’ and ‘adoption of embryos’ recall the principle of the law which equates them to persons, this definition is in fact problematic and morally controversial.

7. What the new institution ‘does’

We have thus far analysed the institutional work whereby actors – state, professions and political groups – discuss and negotiate their respective jurisdictions on a practice. This has enabled us to describe the distributed agency that presides over the legitimation and stabilization of a practice. We now consider the circuits of a practice’s reproduction, and we consider the effects that this produces in being practised. We shall mention three two phenomena in particular: the ‘double bind’ created in the production of knowledge, the change of technological practice, and the marginalization of the patients.

One of the unexpected effects of de-institutionalization work in the case examined here is the double bind that Law 40/2004 has created in the production of scientific knowledge. This concerns the ambiguity of banning research on embryos by virtue of their alleged sacredness. The prohibition on embryo research envisaged by Law 40 is not a legal preclusion of research on embryonic cell lines

¹⁰ *Decreto del Ministero della Salute Norme in materia di procreazione medicalmente assistita*, issued on 4 August 2004 and published in the *Gazzetta Ufficiale* no. 2000 of 26 August 2004. The Decree identified two different types of cryoconserved embryos: those awaiting future implant, and those whose abandonment has been ascertained (art. 1).

created in other countries – also because EU legislation stipulates the free circulation of goods and therefore makes it impossible to prohibit the importing of stem cells.

Again we have an instance of negotiation among the actors in the institutional field and defining work aimed both at prohibition and at establishing parameters for future practice. In fact, this initially translated into a veto on the disbursement of EU financings for research on embryo stem cells. Later, since May 2006, an attempt to reconcile financial support for research - which does not involve the destruction of embryos - with incentives for advanced research on the possibility of research on surplus embryos. In 2004, in fact, the decree implementing Law 40/2004 allocated funds to research intended to improve embryo and gamete cryopreservation techniques. But it did not specify how research could improve the cryopreservation of embryos and gametes without using them, and therefore without destroying them. Moreover, knowledge on cryoconservation techniques is meagre and poorly institutionalized, so that there is no precise information on the maximum duration of embryo resistance to cryopreservation. In other words, because these embryos are kept alive by means of cryoconservation, there are no data on its long-term effects.

A second effect relates to technological change. The law seems to have initiated a definitive change from IVF to ICSI, increasing the risk of failure and the responsibilities of the professionals working in the sector. It should be pointed out, in fact, that the success rate (in terms of pregnancies achieved) of assisted reproduction varies from 10% to 20%. This means that the operators at these centres are subject to severe stress due to a lack of positive results which often leads to burnout (Agnello, 2005). If added to these are the restrictions imposed by law, and therefore the fact that the female partner must undergo ovarian stimulation for each single treatment cycle, one understands how the laboratory biologists feel overloaded with responsibilities.

On the other hand, the law has fostered the shift from one technology to another by activating negotiation on what is thought to be a correct or incorrect way to practise within the community of practitioners.

The shift from one technique to the other, in fact, cannot be explained by the principles of efficiency and effectiveness proposed by the S-shaped curve model, because the new technique does not produce better results in terms of pregnancies (the ministerial data for 2006 show that the percentages of pregnancy per oocytes harvested was 21.4% with IVF and 21.1% with ICSI). Hence, it is no longer economic for the reproduction centres (neither in terms of costs of the materials used nor in those of execution time), and nor for the patients, because the price of ICSI treatment is higher than IVF.¹¹

¹¹ The increase in cost is particularly marked for patients attending private centres. The average price paid for an IVF by patients is around € 3,000, while for ICSI it increases by around € 1,000 on average. Instead, at private centres contracted to the National Health System, which offer treatments at lower prices on the basis of regional contracts, and at public centres, where charges are made for individual examinations and treatments, the price difference between the two techniques is less important for patients.

The fact that in ICSI the 'natural' process of sperm selection is 'overridden' by the biologist has raised numerous doubts concerning the harmful effects on neonates, given that spermatozoa and ova not suitable for fertilization are subjected to a forced process, and that the technique is accompanied by an increase in malformed embryos (Wennerholm et al. 2000; Oehninger, 2001; Ludwig and Katalinic 2002; Belva et al. 2007). The concerns regarding ICSI results relate to certain of its technical aspects: the invasiveness of the injection procedure; the subjectivity of the criterion on which the sperm to inject is selected; the fact that a small quantity of the culture medium is injected into the oocyte during the micro-injection (Van Steirteghem et al., 2002).

At present, the data on the negative effects of ICSI and comparisons between ICSI and IVF are somewhat contradictory. To summarize, the medical literature on the presumed harmful effects of ICSI has produced rather controversial data which have not dispelled the doubts concerning the higher risks of malformations in children conceived by means of this technique and do not allow explanation of why it has become so widespread in recent years, increasingly replacing IVF.

Over the years, ethical questions concerning the selection of oocytes and spermatozoa not suitable for fertilization, the fact that the ICSI technique does not produce a larger number of pregnancies, and the fear of malformations, have restricted the definitive shift from IVF to ICSI (given that, for these various reasons, the use of this technique when not strictly necessary, i.e. in cases of severe male sterility, is viewed by many practitioners as contrary to professional ethics), so that the two techniques now co-exist.

The restrictions introduced by the law have instead become a node around which the use of ICSI in all cases is not only sanctioned normatively and professionally but also through which that practice becomes normatively supported. Interestingly, although the reasons for preferring the new technique to the old one are sustained by practical examples and accountability practices, they are always expressed in terms of continuity, not of opposition. The 'shortcomings' or the hypothetical inadequacy of IVF is never mentioned; on the contrary ICSI is discursively constructed as IVF's technical evolution.

A final effect considered here is the political one concerning the marginalization of women and couples as decision-making subjects. For example, when it is decided which technology to use, only rarely is the couple directly involved as a decision-making subject. It is often kept in the dark and is informed about the choice as a decision taken on the basis of professional authority. The restrictions introduced by the law, in fact, prevent the couple's self-determination and free choice in regard to its reproductive life, producing a discrimination between those that can afford treatment in foreign countries and those who cannot. Precluding treatment in Italy for singles, non-heterosexual couples or sterile partners (all those unable to produce gametes are excluded from treatment because heterologous fertilization is forbidden) has generated a reproductive tourism to countries with more liberal regimes such as Spain. The effects of domination thus produced have been mostly ignored, or they have been voiced only by a feminist position which has gone largely unheeded.

8. Discussion and conclusions

By means of this case study we have sought to contribute to two debates ongoing in the organization studies community. On the one hand, we have sought to answer the question as to how a practice spreads, and on the other how technological change can be understood using a practice-based approach rather than a technology-based one.

The concept of the diffusion of an innovation or a technology has been abundantly criticised in literature (Godin, 2006), with a preference expressed for concepts such as translation (Latour, 1987; Czarniawska and Sevón, 1996) or editing (Sahlin-Andersson, 1996), which highlight how the object to translate or to edit is constructed during the process itself, and by the human and non-human actors present and active within the action net. The institutionalization process has traditionally been conceptualized in terms of the S-shaped curve model: objects are first recognized, then accepted by a few actors, and then widely diffused and accepted within a field (Meyer and Rowan, 1977; Leblebici et al., 1991; Lawrence et al., 2001). Contrasting with this model is conceptualization of the institutionalization process in terms of institutional work and distributed agency. For this reason, we have proposed a methodological and interpretative framework which, on the one hand, considers institutional work as the outcome of negotiation by the actors in the field on both the change and stabilization of a practice, and on the other as the effect of the institutionalization of the practice in its circuits of reproduction. In our empirical analysis we have therefore adopted an ecological model in which the source of significant patterns within a practice is located in how conduct is enacted or performed within the practice-net and the relationality between the social world and materiality is subjected to inquiry. Institutionalization is therefore the effect of a distributed agency which seeks to stabilize a practice by mobilizing resources of power, strength, coercion, authority, legitimation and jurisdiction over knowledge.

In the case of an institutional field like assisted reproduction in Italy, where the practice and its relative jurisdiction used to be in the hands of the professions, a state law has intervened to regulate the practice differently, thereby opening negotiation on jurisdiction over it. We may draw on the empirical analysis to describe the stabilization of the new practice in terms of the following three mechanisms: by limitation, by rhetorical closure, and by anchorage in materiality (of language, technology, and standards of the practice).

Firstly, the stabilization of the new practice is the effect of the law, which intervenes by *limitation*. The coercive power of a collective actor produces a coercive isomorphism effect on the actions of the other individual, collective, and organizational actors. The constitutive rules of the new practice in the field analysed are of both a prohibitive and rhetorical nature. The closure of the debate on what constitutes the object of the practice (assisted reproduction) is symbolic in nature (Pinch and Bijker 1987), and it concludes at the moment when the embryo is granted the status of a 'person' and its rights prevail over those of the parents. The stabilization of the new practice therefore also comes about through *rhetorical closure*.

When one moves from the level of political mobilization to that of the performance of regulated activities, the stabilization of the new practice comes about *by anchorage* in the materiality of workplaces, in the practice's operational categories, in technologies, and in standards. We have described in this regard how anchorage in materiality is the effect of three kinds of institutional work: defining work, mobilizing technology, and creating a practice standard.

We have finally proposed that the institutionalization process should be viewed not just as a linear process of creating/maintaining a new practice but also as the institutional work necessary to de-institutionalize the old practice and thereby create new practices and new semantic objects (the orphan embryos). A cyclical description of the institutionalization process is not complete if consideration is not made of the effects also produced by the circuit by which the institution thus stabilized is reproduced. In this regard, we have described the two main effects of the institutional work of the institution: the double bind created in the relationship between a new practice and the practices interrelated with it, and because of which new knowledge is necessary to improve the new practice but cannot be produced without discontinuing the new practice. Finally, and more relevantly to our purposes here, is the technological change induced by the changed social and cultural circumstances.

How a new technological practice takes over from a previous one cannot be explained on the basis of the rational explanation model (the survival of the most efficient); it is better explained on the basis of a neo-institutional model in which isomorphism in a practice is the effect of coercive institutional pressures, normative institutional pressures due to cultural expectations, and mimetic institutional practices that conform with what the other organizations in the field do and how the professional cultures make sense of them. We have seen how the new technological practice is sustained on the symbolic plane on which professional jurisdiction (biologists versus gynaecologists), values, and identity anchor practice (doing) to being, and therefore the need to cope with the uncertainty of outcomes and the desire to be in control of them make a technology to be preferred despite its unclear technical superiority.

Finally, we must not forget two further factors that more covertly produce technological change. On the one hand, the latter is rhetorically sustained in that, as we have seen, there is a grey zone in practice where saying and doing are loosely coupled, so that hypocrisy keeps practices rhetorically sustained because they sustain a moral order in which the embryo is a person. On the other hand, there is an aesthetic dimension to the new technology (not investigated in this article) which also sustains it on the basis of the pleasure deriving from greater manipulation and sense of complexity. We therefore conclude by saying that the technological change is incorporated into everyday practice as an element in a practice net sustained by moral, aesthetic and political judgements.

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