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How The Face Became And Organ:
Regulating The Body In/And Experimental Biomedicine

In late September 2014, a face transplant operation was performed at the Cleveland Clinic in the US state of Ohio. While a number of face transplants have been performed in the world, including in the states, this is the only one that has taken place since changes were made to US federal health law mid last year. These changes moved the operation under the jurisdiction of the two agencies responsible for governing organ transplantation in the USA, the United Network for Organ Sharing, and the Organ Procurement and Transplantation Network. They modifications in medical law did this by introducing into the world a new kind of thing: the VCA organ. **The term refers to Vascularized Composite Allografts, complete sections of tissue that are procured for transplantation.** The most common VCA procedures are face transplantation and hand transplantation. My research on the field examines how the former has introduced new institutional understandings and epistemic practices into politics and biomedicine.

Reporting on the Cleveland operation, a writer at *The Daily Mail* described the latest procedure as follows:

Doctors transplanted about two-thirds of the scalp, the forehead, upper and lower eyelids, eye sockets, nose, upper cheeks, upper jaw, upper teeth, salivary glands and nerves, muscles and skin.¹

¹ <http://www.dailymail.co.uk/news/article-2839470/Cleveland-Clinic-does-2nd-face-transplant.html#ixzz3KGLYajz60>

Significant to the operation is not only the new ways in which the face is increasingly medicalized and politicized; the very meaning, boundaries, contours and limits of the face are changing in the process. What the face is, exactly, and how it should be governed as a transplantable therapeutic object, are both at stake in this realm of experimental biomedicine.

Today I am going to talk about the coproduction of regulatory infrastructures and onto-epistemic infrastructures in US face transplantation. By examining how modes of political experimentation shape and are shaped by biomedical experimentation, I draw attention to how the ontological status of the face (it's materiality) is mediated by its politico-epistemic status (as a regulatory object). Following the likes of Annemarie Mol (2002) and Karen Barad (2007), I point to the intimate relation between knowing (*episteme*) and being (*ontos*) in the biomedical science, to show how standardization in face transplantation is altering and underlies attempts to secure its medical and political stability. I am especially interested in how the boundaries between policy and practice breakdown *as* the doing of medicine, the making of knowledge, and the governing of experimental therapeutics bleed into and inform each other.

In the case at hand, this is happening as regulators join with clinical and bureaucratic experts (1) to standardize what is the face in & for transplantation, (2) to implement procedures for measuring surgical outcomes, and (3) to design new software for calculating "equitable" access to the operation. I suggest that what we see here can usefully be regarded as a sociotechnical experiment in which regulators have produced a new kind of regulatory object, the VCA organ, in order to nationalize the procedure and make it a politically and medically legitimate enterprise. The current

policy language surrounding VCA transplantation is only temporary, as is the definition of a VCA organ itself: once initial data collection has taken place, the authorities overseeing the procedure plan to submit outcomes for public comment. Changes to the definition of a VCA, and thus what counts as a face in this realm of biomedicine, could be remade in the future depending on factors ranging from public concerns to the success of current transplant protocols and the development of new biomedical technologies. In the meantime, however, the ethics of the state and of experimental biomedicine are coproducing the future of the field.

Weaving together analytical tools for investigating scientific practice with theoretical forays into the emergence and solidification of social and political orders, the notion of “coproduction seeks to illustrate the particular ways in which ordering the natural world requires not just scientific ideas and practices, but also laws, norms of ethical practice and credible governing arrangements”

(Reardon 2001: 358; Jasanoff 2004). I continue to find this concept useful in my analysis because it draws attention to the entanglement of medico-scientific and social orders. Using it alongside Foucault’s notion of assemblage, it helps us to see the mutations in ontological categories, institutional practices, and material infrastructures that accompany the emergence of novel biomedical technologies. Assemblages are “a distinctive type of *experimental* matrix of heterogeneous elements, techniques, and concepts” (Rabinow 2003: 56). The face transplant assemblage, as it currently exists in the USA, is inherently experimental: it unites computer algorithms with politically infused understandings of biomedicine; it couples the making of knowledge with the regulation of clinical practice; and it governs in and by producing nascent artefacts and novel ontologies.

The first face transplant surgery was performed in Amiens, France, on 25 November 2005. Leading up to the operation the field was characterized by debate over the ethics of the procedure, and quarries over its ability to work. A number of known and unknown factors related to human biological and psychosocial processes were front and center of this debate and related concerns. Foremost was the question of exposing patients to a potentially fatal, lifelong course of immunosuppressant drugs in order to improve their quality of life. Careful patient selection was presented as a panacea to the difficult epistemic and ethical issues that the procedure raised. The first such operation in the USA was performed approximately three years later. As mentioned above, the advent of face transplantation has not only altered how the face is done in biomedicine – the dissection, separation, removal and transplantation of its parts, whatever they may be – it has also altered the political status of the face as a regulatory object, that is, it is no longer regulated as tissue but as an organ.

The piece of law that governs organ transplantation in the USA is referred to in short as the OPTN Final Rule. The modifications to this law were made in late 2013 and required the national transplant agency to develop policies for VCA transplant before July 3. **Following amendments to the Final Rule, now “Organ means a human kidney, liver, heart, lung, pancreas, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract) or vascularized composite allograft.”**

The clinical protocols established and used by the 3 face-transplant centers in the US brought together longstanding organ transplant guidelines with specific measures developed to ensure the success of the operation. And while these teams had been

gaining “extra” consent from donor families for the use of tissue from the face, there was no national mandate for them to do. Moreover, the advent of face transplantation in the USA was accompanied by discussion within the Department of Health about the need to regulate the procedure at a Federal level. Importantly, the ethics of the operation are being refracted in the present, producing the potential for emergent fault lines as medical practitioners are forced to work within competing politico-moral frameworks and institutional agendas.

This resulted in the changes to the definition of an “organ” in US health policy that came into force mid last year, which sought to standardize clinical practice for VCA procedures, and that in doing so aimed to:

[E]nsure equitable access for those awaiting VCA transplantation, [as] there is a need to provide for consistency in allocation processes and reliable outcomes reporting on a nationwide basis. Appropriate Federal oversight of **a national allocation system** can increase safety of such transplants and provides *equitable* and *consistent* national access to such transplants while also conveying to the public that donation for such purpose will serve an essential medical need.

Contained within the above is an implicit understanding both of what VCA procedures and the US state are about: ensuring equitable, safe and essential biomedicine. In making the face an organ, the Federal government nationalized face transplantation in two interrelated ways: by standardizing disparate practices and by encoding them with values of what it stood for. From the get go normative sociopolitical concerns were embroiled in the shifting medico-political status of the face for transplantation.

A core task of the committee that was formed to implement the updated law was to standardize protocols and practices in face transplant in the field *and* to harmonize these protocols with existing organ transplant guidelines. The result was a potentially troubling blurring of different ethico-moral regimes. **According to numerous commentators, “The goal of deceased donor organ allocation policy in the US has been to balance utility and equity in the distribution of deceased donor organs. The policy has changed incrementally over time in efforts to optimize allocation to meet these often competing goals”** (Smith et al (2012: 3192). During the meetings of the committee, the members were faced with the following question: “When multiple recipients are waiting and clinically eligible, what dictates priority?” These concerns manifest in computer algorithms, as IT experts were tasked with modifying existing mechanisms for calculating where patients should sit on the organ transplant waiting lists in order to account for the technical particularities of face transplantation. This means that the ethical panacea of patient selection that made (politically) possible the operation in its earliest stages is being refracted as equity is entered into the equation. In doing so, it provides a political imperative to search for donors for those patients that the algorithm ranks at the top and arguably seeks to modify how the medical community views the bodies of brain-dead donors with suitably matching faces.

With the increasing use of bone and skeletal components in the operation, the importance of finding a donor with a similar appearance is further increasing. At the same time, the extensive use of subcutaneous tissue by face transplant surgeons forced the committee members to ask what exactly is a VCA in face transplantation: “Is the recovery of extra vessels/tissue/nerves for the purpose of an enhanced outcome allowed?”

Answering this question required engaging with the interpretive flexibility of the changes to organ transplant law, which defined a VCA as:

- 1 That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
- 2 Containing multiple tissue types;
- 3 **Recovered from a human donor as an anatomical/structural unit;**
- 4 **Transplanted into a human recipient as an anatomical/structural unit;**
- 5 Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement);
- 6 For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);
- 7 Not combined with another article such as a device;
- 8 Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and
- 9 Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient

The changes to national transplant law and the redefinition of an organ to include VCAs mean that the face for transplantation now has a rather peculiar ontological status in the present. It is never just a face and never fully an organ; it is only an organ

once it is removed from the donor and transplanted to the recipient, at which point it straightaway becomes a face. As a vascularized composite allograft the face extends past the immediate area of the face to include veins, nerves and extra soft and hard tissue – bone, scalp, muscle, cartilage, etcetera – that aids operative outcomes.

Following Mol's (2002) account of how medicine enacts its objects, we may say that the ontological status of the face in this form of medicine is thus both fluid and fractured: what is the face, its materiality, is open change vis-à-vis its new political status and the necessities of clinical practice.

Unlike solid organs – kidneys, hearts and livers – the face is not considered an organ until it is harvested and transplanted for therapeutic purposes. There are a number of clinical practices that are necessary for this to take place: how the face is enacted, how it exists in networks of clinical practice is mediated by its new classificatory status. A number of practices must be put in place for this to be possible. Alongside new procedures for informed consent and allocation, how the face is treated in the clinical space has also been standardized. It must be labelled in a new way, travel accompanied by paperwork, not be combined with “another article or device”, and used solely for replacing a person's body part. (If the procedure does not conform with the last two criteria, it would likely fall under the regulatory authority of the FDA.) What the face is, how it is understood and constituted and the clinical arena, has thus been altered through the implementation of new regulatory policy.

There is an interesting tension at play here. The expansion of US transplantation policy to include face and other VCA organ transplantation aims to “facilitate the collection of data for studying outcomes and best practices” by standardizing clinical practice and record keeping. An increasing number of studies have shown that “the

promulgation and enforcement of standards is a central type of social regulation” (Timmermans and Epstein 2010). Here, standardization allows for the mobilization and centralization of a legible body of data, and the production of a unified medical field: US face transplantation. However, in treating the face as a *unit* current policy obscures the fluid and fractured remaking of not only the transplanted biological object/s but also of the an experimental field in the making.

As a story of coproduction, how the face becoming an organ thus points us toward the tensions and contradictions that are often obscured in experimental techno-medicine. . It is here we see how the friction inherent in the ordering of the world that produces sociotechnical change. **The anthropologist Anna Tsing (2005; 2012) theorizes friction** in her study of global connections. She writes that: “friction draws attention to the unpredictable heterogeneity of worlds coming into being” and that “Scientific research questions ... emerge in the friction of regional and national histories even where scientists are in constant international communication” (2012: 1-2). In this reading, “friction” is a productive and energizing force. It results in the reworking of established relationships and knowledge, and the emergence of new networks of practice. In making the face an organ, standardization emerged as a mode of producing legible and viable politico-scientific knowledge. The labor involved in standardization, and the forms it took, emerged through the frictions produced by the discrepancies between political virtues and medico-scientific morality.

The coproduction of science and social order is not a clean process; rather, it is riddled by competing agendas, ethical sensibilities, and moral frameworks - between the need to accommodate clinical protocols for patient selection within federal mandates to insure equity in transplantation, for example. Neither is it coproduction

ever complete. As the boundaries between policy and practice bleed into each other, this produces the potential for fault lines, requiring the experimental iterative reworking of standards and policy in order to stabilize the relationship between science and the state.