EUROPEAN SCIENCE FOUNDATION
SETTING SCIENCE AGENDAS FOR EUROPE

**Exploratory Workshops Scheme**

Standing Committee for the European Medical Research Councils (EMRC)

## SCIENTIFIC REPORT

### ESF Exploratory Workshop on

# From Standards To Concerted Programs Of Collective Action The Standardization Process Of Medical Practices

**Paris, France, 5-8 December 2007**


**Convened by:**

**Virginie Tournay**

PACTE department (Politiques Publiques, Action Politique, Territoires), Grenoble Universities

*In association with*

MEOS (Groupe d'Etudes sur le Médicament), University of Montréal.

GEPECS (Groupe d'étude pour l'Europe de la culture et de la solidarité), René Descartes University


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*Co-sponsored by :*

# 1. Contents




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## 2. Executive Summary

The ESF Exploratory Workshop “From Standards to Concerted Programs Of Collective Action. The Standardization Process Of Medical Practices” was held at the René Descartes University (Paris, France) from 6 to 8 december 2007. The workshop took place conveniently in the city centre of Paris, so activities, meals outside of the workshop could easily be done. All participants initially expected were attending the workshop. The general atmosphere was very friendly. The meeting itself opened on Thursday 6 December in the morning with a welcome speeche by the convenor, Virginie Tournay, introducing the role and aims of the ESF, addressing the set of issues surrounding the collective production of medical evidence with a pragmatic approach, and summing up the questions, in particular the ingredients (including policy instruments) participating in the social shaping of medical innovations and related industrial activities. The main asset of a pragmatic approach is that it does not explain the production of medical objectivity as a direct consequence of an intrinsic performativity to social objects. Even though most participants are working on medical objects, the convenor has included some people working on other objects that have points of comparison. This was true of Fabrizio Cantelli, who less than a month ago organized an international workshop in Brussels on the pragmatic approach to public action around the materiality of public policy. The very interesting work by Ragna Zeiss on the establishment and implementation of quality standards in the English water industry allow us to compare the production of objectivity in various fields. This is also the case of Pascale Trompette’s work on standards and the funeral business. Some people who work in the interface between the day-to-day work in laboratories and the production of a legal framework were equally included: that is to say, persons representative of state health agencies: Brigitte Panterne of the Laboratories and Controls Department of the French Health Product Safety Agency and Marie-Odile Ott of the Biomedicine Agency who works on the statutory frame of embryonic stem cells. 3 participants were adding to the expected list: 2 representatives of state health agencies. One participant: Arco Timmermans had to cancel at short notice, so Marta Kiejczyk, a scientist from the department of Timmermans’s one in Netherlands, came into the workshop and present “Positioning women in human embryonic stem cells research”. Notwithstanding, Arco Timmermans will be included in every step of future activities that comes out of the workshop.

The workshop aim was to develop a historical and process-based perspective of the construction of medical evidence. It explores the whole progress from an innovation statement to the production of new normative spaces and the recurrent management of individuals and objects. We hypothesize that an integrated pragmatic sociology can offer

new insights. The framework of pragmatic sociology implies that agreement among the individuals is not based exclusively on discussion. In confirming or refuting a given interpretation of the reality, the very nature of the devices and structures surrounding the actors plays a crucial role because it integrates and materializes specific references to certain demonstrations, and not to others. Bearing in mind this ontological interdependence between heterogeneous entities in mind, the objective of the encounter is to bring closer the reduction of risks, the construction of proofs and our concerns around harmonization of medical practices which depend on heterogeneous material cultures and administrative points of reference. So, we were explored an integrated pragmatic theory bringing together the construction of social mobilizations and the making of medical history. In other words, the question was to understand how a type of medical objectivity is maintained durably in time rather than to study its extension in space. In order to study the implementation of concerted medical practices and to understand how the construction of medical evidence pragmatically occurred, we choose two kinds of medical fields. Practically speaking, the workshop was organized around four main panels (two panels per day).

Entitled “Treating the institutionalisation of medical claims and the consolidation of medical entities symmetrically”, the first day was focused on the implementation of embryonic stem cell research field. It brings together the biological drug products, the drug testing (Session one: Defining Standards of Human Embryonic Stem Cells) and the storage of biological elements issues (Session two: Biobanking – Toward Concerted Programs of Collective Action). Bio-banks and National, international administrative agencies faced products of inestimable value that are in variable, "donor-dependent" quantities, are produced in an irregular manner that depended on the state of the patient, and presented biological samples lacking uniform properties (as would be found in a traditional pharmacopoeia case). Consequently, standardization of controls on biological products encountered a necessarily irregular collection of human cell samples. Samples contained in each batch were dissimilar and therefore did not obey the rules used in traditional statistical analyses of drugs. Faced with these difficulties, the first day examined the standardization process of contemporary non-systematic laboratory manipulations of human cells and their clinical uses. The aim was to understand how frequently these practices are subject to a progressive series of administrative rules that are undergoing a process of standardization. In summary, the first day was focused on the consolidation of medical entities in areas dominated by uncertainties and expectation statements (such as standards of human embryonic stem cells, cell therapy products and biobanking activities). At the end of the day, Fabrizio Cantelli was discussed the need of a critical sociology of 'science pragmatics' in public policy analysis. On the first evening, we had prolonging the lively discussions in a famous Italian restaurant “The Monteverdi”, located in the city centre of Paris.

Entitled “The production of Medical Good Manufactured Products and the Writing of Individualities”, the second day was related to medical practices which recognize the importance of the bio-psycho-social uniqueness of each individual. The second day has examined the production of objectivity in areas defined by a strong presence of personal factors such as measuring health-related quality of life, the production of natural health products, caring for the deceased (Session Three: The collective materiality of Individual Subjectivities), and diagnosis and treatment of mental diseases (Session For: Which Standards for Manufacturing the Cerebral Subject?). More specifically, this day was focus on practices (Palliative Care, mental diseases and Naturopathic Medicine) that resist to the growing evidence-based-medicine movement and protest for a standardization of the clinical view (through best practices guidelines for instance). Participants of the second day proposed to follow the circulation of different paradigms (quality of life, oriental medicine) that can be applied in order to coordinate their own practices. These innovations represent attempts that are progressively being connected, in some context, to the palliative-care treatment or to the diagnosis of the naturopathic practitioner. All of these areas are characterized by competition, by a struggle between different forms of evidence-based-medicine. At the end of the day, based on all your work, an integrated pragmatic theory that combines the production of medical objectivity and the making of medical history was explored.

The discussions that followed each of the sessions were prolonged during all meals and buffets taken together during the workshop. These definitely contributed to creating an atmosphere of mutual trust leading to fruitful exchanges that are a first step to have lasting effects on all participants’ future research and scientific commitments. All participants enjoyed these two days in practices as well as Parisian hospitality. The convenor warmly thanks everybody for their participation, both for the quality and interest of the talks given.

## 3. Scientific Content of the Event

For a more detailed description of the presentations, please consult the abstracts of the programme.
All papers relate to a collective work of qualification in an environment characterised by the heterogeneity of the epistemic and material cultures involved. As we have seen, this qualification bears upon:

- either entities themselves such as human embryonic stem cells, embryos in research, cybrids, cell therapy products, natural health products.

- either measurement tools and indicators such as databases of biological samples, the health related quality of life, the neuroimaging.
- either the production line of entities such as work chain around the dead, notably “the standardized dead care”; the process of clinical investigation, the introduction of quality of life issues into the discourse on medications.

These programs makes appears new stakeholders: women’s participation is a key in constituting the meaning of egg cells and embryos. More generally, the emergency of institutional activities reframes debates around new issues. Some concerted works such as the setting of standards for sharing data facilitate the harmonization of heterogeneous local environment. It’s the case of collaborative studies for bacteriological control of cell therapy products or for the establishment of shared-databases from biobanking initiatives. All these concerted programs of standardization gradually renewed the articulation between the medical field considered and the social network in a large sense, including people, things and discourses. This is what we have seen the first day.

These concerted programmes of standardization are a way to drastically reframe disciplinary outlines and to establish uniformed categories of medical products. But this collective work of standardization and qualification is equally a way to redistribute the repartition of uncertainty by introducing new knowledge competitors. This could be seen with the genealogy of a translation: that of rhetorical goal of medicine: a “better quality of life” into measurement tools. If the QOL instruments are used in evaluative studies to determine which therapies, which medication, which technology works, this new criterion of medical evidence is not without criticism by end of life caregivers. This new quantification parameter is counterbalanced by the general idea of “holistic caring” and other ways of produce medical evidence as we have seen in the socio-history of the naturopathic field. So, the wide circulation of the concept of *quality of life* and the attendant controversies can be used as a good model for investigating the origins of the knowledge standardization process in palliative care. Quality of life constitutes a good indicator, simultaneously an instrument for measuring end of life and an object for claims by activists. This circulation enables the coordination of medical practices without the actors needing to reach a consensus on how the practices are carried out. In summary, medical practices are built and coordinated through the same process of circulation leading to the transformation of the dynamic of a collective production of evidence. “Standard of standard”, the QOL is called “operator of standardization” by the convenor. The production and management of evidence, is therefore above all a dynamic of circulation, commencing with the operator of standardization and leading toward the production of standards. This is what we have seen the second day

Such an undertaking would consist of examining data collection and the concrete description of entities and procedures through which the operator of standardization becomes apparent and can be described, and then of observing how it circulates.

## 4. Assessment of the results, contribution to the future direction of the field

The aim of this workshop – like the project which will emerge from it – is to develop a historical and process-based perspective of the construction of medical evidence with a pragmatic approach. The topic was discussed from the various perspectives of the medical areas presented by the participants. A network of researchers from 10 countries was created, bringing together academics (of various fields: medical anthropology, political science, Science and Technologie Studies) and representatives of state health agencies. In spite of the very different contexts in which participants are working, discussing these issues would give insights to policy makers as well as to practitioners. So, we have commonly decided:

- To structure the results of the discussion in a set of publications.
- To disseminate the detailed workshop report to most representative of state agencies.
- To explore the possibility of future meetings in which the implications of these results could be develop further, according to various medical fields and, in a comparative way. full consideration was given to other ESF instruments with the idea of setting-up a programme proposal.

All participants are very grateful to the ESF for having funded this workshop which will hopefully be the first step in a long-term research cooperation dealing with the standardization process of medical practices under the scope of a pragmatic approach of policy making.

# 5. Final Programme

## Thursday 6 December 2007

**Day 1: Treating the institutionalisation of medical claims and the consolidation of medical entities symmetrically**

09:30-10:00 Welcome by **Virginie Tournay**, UMR – PACTE (Politiques publiques, Action politique, Territoires), Grenoble

10:00-10:30 Introduction of the Workshop: Opening paper
**Andrew Webster**, University of York

*Standards, standardisation, and safety: from uncertainty to pragmatics*

*Drawing on a recently completed research project that has examined the role of standardisation in the field of embryonic stem cells, this paper discusses the ways in which the search for standards and the ensuing standardising process closes down contingency. The International Stem Cell Initiative is used to illustrate this process. Standardisation is examined in terms of its pragmatic character as enabling of scientific work and its subsequent scale up via automation, but also in terms of the implications this has for the long term safety of the field when translated into clinical practice. The paper closes with an analysis of the inevitable distribution of uncertainty across a much wider range of social actors, and the need for a critical sociology of 'science pragmatics'.*

### Session One: Defining standards of Human embryonic Stem cells

***Chair and discussant*: Nik Brown**, University of York
***Discussant*: Françoise Baylis**, Dalhousie University and Brocher Foundation

10:30-10:50 **Stellan Welin and Anders Persson**, Linköping University
*Early confusion on human embryonic stem cell standards*

*Soon after the derivation of the first human embryonic stem cell lines in 1998, the issue of such stem cells became politically sensitive. In the policy decision in August 2001 President Bush announced that only research on already existing human embryonic stem cell lines could be federally funded. In a world-wide survey the NIH found 64 such lines, among them 25 from Sweden. Soon the number of pre-August 2001 human embryonic stem cell dwindled. Some of this had to do with conflicting ideas of what constituted a human embryonic stem cell line.*

10:50-11:10 **Marta Kirejczyk**, University of Twente
*Positioning women in human embryonic stem cells research*

*The national regimes regulating human embryonic stem cell research display a large diversity, ranging form restrictive ones, prohibiting any research on embryos to very liberal, endorsing creation of embryos for the derivation of stem cells. The common feature of these regulations is the centrality of discourse on the moral permissibility of using embryos in research. But no embryo research can proceed without the material availability of donated embryos and egg cells. In this sense the development of stem cell science is highly dependent on women's willingness to cooperate. In my presentation I will explore how women and their interests were/are positioned in the regulatory debates on embryo research in the Netherlands and in the UK.*

11:10-11:30 **Françoise Baylis**, Dalhousie University and Brocher Foundation
*Plenty cheap: Animal eggs for hESC research*

*In recent years there have been a number of efforts to show how it might be possible to derive hESC lines without killing human embryos – thus avoiding the debate about the moral status of the developing human. Alternative approaches to hESC derivation include: single-blastomere biopsy; altered nuclear transfer; parthenogenesis; somatic cell differentiation; and somatic cell nuclear transfer. At the present time, many stem cell scientists are particularly enthusiastic about the option of somatic cell nuclear transfer – i.e., creating cloned human embryos for stem cell research. These researchers, undaunted by the scientific and ethical challenges they face, have nonetheless been stymied by a rather significant practical problem: large numbers of human eggs are required for cloning research and women are not lining up to provide stem cell researchers with their eggs. To overcome the shortage of human eggs, scientists propose using human DNA and enucleated nonhuman (rabbit or cow) eggs to create cytoplasmic hybrid embryos from which humanesque stem cell lines could be derived. Some see this interspecies research as an interim measure until the efficiency of human cloning is increased; others are less clear on this point.*

11:30-11:50 **Marie-Odile Ott**, *Partnership Development Representative, Généthon*
*The French framework of human embryonic stem cells and embryo research: a restrictive law with a flexible probatory period allowing research projects under tight control. How scientists and regulations do manage to evolve together?*

*The French laws of bioethics have been revised in 2004 after ten years' debate. We will see what framework is now in place not only in the case of (supernumerary) human embryo research but also how basic research with other human body part is regulated. We will then focus on the experience of the first years of research with human embryonic stem cells and embryo per se research and examine how research projects' design can be influenced by the definitions and constraints of the law. The bioethics law has been made and written to ensure protection of the human embryo. This process is quite new, and scientists and regulators have to work "together", especially about issues not*

*foreseen by the law. The French example will then be compared with the situation of neighbor countries.*

11:50-12:30 **Comments** by **Nik Brown** and **Françoise Baylis**
**General discussion**

12.30-14.00 *Buffet lunch*

14:15-14:30 Presentation of the European Science Foundation (ESF)
**Bob Pinedo** (Standing Committee for the European Medical Research Councils)

## Session Two: Biobanking: Toward concerted programs of collective action

***Chair and discussant*:** **Ragna Zeiss**, Maastricht University
***Discussant*:** **Nik Brown**, University of York

14:30-15:00 **Béatrice Panterne**, Afssaps/DLC
*External Quality control of cell therapy products. Towards recommendations and monographs*

*The French Health Products Safety Agency was created in 1998 within a national context of strengthened health monitoring and control. The Afssaps evaluates the security, the efficacy and the quality of health products. The law 96-452 of May, 28th 1996 and the law 98-535 of July 1st 1998, published in the "Public Health Regulation" have established rules for the use of cell therapy products. The Laboratories and Controls Department (DLC) is in charge of external quality control of cell therapy products. Considering hematopoietic cells are the main cellular products used in routine, their control was first developed based on a investigation for practices, a pilot study, a feasibility study with all the French production sites and on collaborative studies for the bacteriological control. At that time, external quality control takes place 2 to 3 times a year. As a result, this control has increased technical standardization, has checked the quality of products and will allow to compare performances between various French producers. At least, this work allowed us to propose recommendations at the European Pharmacopoeia to promote standardized methods to guarantee the cellular product quality. These recommendations are now validated as monograph.*

15:00-15:30 **Aaro Tupasela**, University of Helsinki
*Database federation and biobanking: setting standards for global computing*

*Recently a great deal of attention has been given to national or regional biobanking initiatives. The goal of many such initiatives is to study disease and thus provide the basis for developing treatments and medicines. At the same time, however, local biobanking initiatives are increasingly being embedded into a global network of biobanks and the data that can be derived from them. Database federation is the process by which data from different research projects can be brough together to form larger data sets for statistical analysis. In order to do this, however, a great deal of standardization needs to take place between the various actors. In this presentation, I will look at*

*some examples where database federation has been used to accomplish such tasks. From this I will derive some conclusions as to the direction and form that current and future biobanking initiatives will take in terms of practices in the biomedical sciences.*

15:30-16:15 **Comments** by **Ragna Zeiss** and **Nik Brown**
**General discussion**

16:15-16:45 *Coffee break*

16:45-17:15 **Fabrizio Cantelli**, FNRS/Université libre de Bruxelles
*Summary of the international workshop: « Les approches pragmatiques de l'action publique: pragmatic approaches of public action », Bruxelles, November 15-16, 2007*
*To be or not to be a pragmatist? For a new public policy analysis*

17:15-17:30 **Comments** by **Virginie Tournay**

19:30 *Conference dinner – Monteverdi restaurant*

## Friday 7 December 2007

**Day 2: The production of Medical Good Manufactured Products and the writing of individualities**

### Session Three: The collective materiality of individual subjectivities

***Chair and discussant*: Rachel Prentice**, Cornell University
***Discussant*: Fabrizio Cantelli**, FNRS/Université libre de Bruxelles

10:00-10:30 **David Armstrong**, King's College London School of Medicine
*The struggle to measure patients' health related quality of life: 1970-2007*

*This paper describes the process through which a rhetorical goal of medicine (better quality of life) was transformed into a number of measurement tools over the last three decades. It also explores how the proliferation of such instruments (over a thousand to date) occurred and how some came to dominate the measurement process while others remained marginal.*

10:30-11:00 **Anne-Hélène Genné**, Quebec Representative of the Canadian Association of Naturopathic Doctors
*Standardizing Natural Health Products: the Canadian Breakthrough Approach*

*In the last decade the field of natural health products has become one of the hottest, fast-growing makets. Health Canada has been working for the past twelve years on unique and breakthrough guidelines to the standardization of natural health products. Recently, the Canadian Association of Naturopathic Doctors has put together an Affiliate Program which includes additional criterias. Together these programs show how the*

*standardization of natural health products goes well beyond the classic scientific approach to include environmental and holistic principles.*

11:00-11:30 **Pascale Trompette**, CNRS, UMR PACTE, Grenoble
*The standardization of the supply chain from dying to disposal: interprofessional coordination in the area of the dead care*,

*This paper focuses on the working chain around the corpse and its regulation. The governance of the funeral activity is here related to the negotiation between the funeral corporations, the health professions and the State. The paper will explore the historic turning point of the development of embalming, and more fundamentally, the rising of dead care in funeral services (funeral home, display, embalmment), which stretch the bounds between the medical world and the funeral world. The analysis combines different points of view on this transition: the central role of industrial actors to carry socio-technical innovation in burial and, furthermore, the standardization of the care process of the deceased; the intensification of the public action as vector of rules in the normalization of processes and equipments (tools, devices, spaces) ; the rising power of the professional group of embalmers and funeral directors in constructing their hegemony on the funeral activity. Then, we see the central stake constituted by "dead care" as a socio-technical innovation: on one hand in the construction of boundaries between public sector and private sector, on the over hand in the expression of occupational competition between health professions and undertakers.*

11:30-12:15 **Comments** by **Rachel Prentice** and **Fabrizio Cantelli**
**General discussion**

12:15-14:00 *Lunch: Restaurant "La Citrouille"*

## Session Four: Which standards for manufacturing the Cerebral Subject?

***Chair and discussant*: Annette Leibing**, University of Montreal
***Discussant*: Rachel Prentice**, Cornell University

14:00-14:30 **Marion Droz Mendelzweig**, Haute Ecole de la Santé La Source, Lausanne.
*Manufacturing the Alzheimer Patient: bridging the gap between symptomatology and diagnosis*

*Several cognitive dysfunctions use to play the alarm role in AD symptomatology. However, the same symptoms are also expressed in other dementia disorders. They come into being identification specifically for AD through a matching with different diagnostic instruments. This paper looks into the performative dynamic resulting from the encounter between patients with cognitive concerns and professionals working in a memory clinic and intends to find out how does this activity contributes to the standardization of the disease outlines and of the way to care for.*

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| 14:30-15:00 | **Annette Leibing**, University of Montreal<br>*Doubtful prescriptions: The disambiguation of Alzheimer medications*<br>*Disambiguation relates to a clarification process that transforms ambiguity and uncertainty into certainty. It is a concept that helps to better understand the multiple strands of the becoming of certainty – an important part of standardisation. This paper takes as a starting point the current debate about Alzheimer medications, consisting of two groups of medications: nootropics and psychiatric drugs. However, the effectiveness of both groups has been questioned since their inception. How do doctors prescribe this kind of medication within a context of uncertainty and on which authoritative knowledge do they rely in order to be able to prescribe? Relying on interviews with health professionals, participant observation in a psychogeriatric unit, and document analysis, this paper analyzes the different strands of argumentation which, together, might explain a certain therapeutic optimism. This paper finishes by exploring the role (un)certainty plays in standardisation practices.* |
| 15:00-15:30 | **Fernando Vidal**, Max Planck Institute for the History of Science<br>*Neuroethics and the Cerebral Subject*<br>*The paper will explore the view, extremely influential in contemporary society, that having the same brain is to be the same person, and that the brain is the only part of the body that we need in order for each of us to be ourselves, examine the position of neuroethics (a rapidly growing academic field concerned with the ethical, social and legal implications of neuroscience) relative to such view, and discuss the potential policy consequences of such position.* |
| 15:30-16:15 | **Comments** by **Annette Leibing** and **Rachel Prentice**<br>**General discussion** |
| 16:15-16.45 | *Coffee break* |
| 16.45-17.00 | **Concluding remarks and possible Future Developments of this exploratory research, Virginie Tournay**<br>*Treating the Sociology of Knowledge and the Writing of History Symmetrically: A pragmatic approach toward standardization* |

*Free: Shopping, visits, rest …*

## Saturday 8 December 2007

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|---|---|
| Morning | *Breakfast and departure* |

# 6. List of Participants

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# 7. Statistical Information on participants

Gender Distribution

- 23 participants

13 Females / 10 men

Repartition by Country of work

| | |
|---|---|
| BELGIUM | 1 |
| CANADA | 3 |
| FINLAND | 1 |
| FRANCE | 7 |
| GERMANY | 1 |
| NETHERLANDS | 3 |
| SWEDEN | 2 |
| SWITZERLAND | 2 |
| UNITED KINGDOM | 3 |
| UNITED STATES | 1 |

We find 24 different countries of work for 23 participants because one participant works in two places (Canada and Switzerland).